CLINICAL EVALUVATION AND THERAPEUTIC MANAGEMENT OF BAALAVATHAM (PARESIS) BY MAHA ANALURUVA CHOORANAM (INTERNAL) ALONG WITH CHENNAGARAPATTAI ENNAI (EXTERNAL) IN CHILDREN



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Submitted by

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2019-2022

DECLARATION BY THE CANDIDATE

I hereby declare thet this dissertation work entitled "Clinical Evaluation and

Therapeutic Management of Baalavatham (Paresis) by Maha Analuruva

Chooranam (Internal) along With Chennagarapattai Ennai (External) in

Children" is a bonafide and genuine research work carried out by me under the

guidance of Dr. P. ARUL MOZHI, Associate professor, Department of

Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai - 47 and the

dissertation has not formed the basis for the award of any Degree, Diploma,

Fellowship or another similar title previously.

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BONAFIDE CERTIFICATE

This is to certify that this dissertation work on "Clinical Evaluation and

Therapeutic Management of Baalavatham (Paresis) by Maha Analuruva

Chooranam (Internal) along With Chennagarapattai Ennai (External) in

Children" has been carried out by Dr. K.KAVITHALAYA (Reg. No:321914203)

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laid by The Tamilnadu Dr.M.G.R. Medical University, Chennai for the final M.D

(Siddha), Branch IV - KUZHANDHAI MARUTHUVAM. This dissertation Work

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1. INTRODUCTION

Siddha is one of the ancients medical system in India considered as the mother medicine of ancient Tamils in South India. The word Siddha means established truth. The Siddha system is a treasure house of secret science, embodying the results of the orient pursuit thereof by the ancient Siddhars. Siddha has also been defined to refer to one who has attained a siddhi ^[2]. The name Siddha medicine owes its origin to medicinal ideas and practices of a class of Tamil sages called the Siddhas "perfected" or "holy immortals" that were, and are still, believed to have super human powers. They had firm faith in the "deathless" physical body being in tune with the spiritual immortal "soul". Significantly, one of the definitions of Siddha medicine is conquest of death: "that which ensures preventive ^[2] against mortality".

In this world and universe around it are made up by the five basic elements, namely Earth, Water, Fire, Air and Space, which are called the fundamental Elements. The living creatures and the non-living things are made up of these five elements. They are the primordial elements Boodham (Five elements). These are Munn (solid), Neer (fluid), Thee (radiance), Vayu (gas) and Aakasam (ether). These five elements (Bhutas) are present in every substance, but in different proportions. The physical constituents which are identical to the various types of tissues are called as UdalThathus (Body Constituents). They are also constituted by the seven elements namely Saram (Primary Nourishing Fluid), Senneer (Blood), Oon (Muscle), Kozhuppu (Fat), Enbu (Bone) and Moolai (Bone Marrow). The human body b formed by these 96 thathuvam (basic factors). These factors include physical, psychological, intellectual aspect of every human [3].

Siddha system of medicine [4] was based on the theory of tridoshas. The physiological function in the body is mediated by three substances, which are made up of the five elements and are involved in all functions of the body, physical, emotional and mental. They are Vatham, Pitham and Kabam.

In each and every cell of the body these three doshas coexist and function harmoniously. The tissues are called dhatus. When the normal equilibrium of three humors (vatham, pitham and kapham) is disturbed, disease is caused. The factors which affect this equilibrium are environment, climatic conditions, diet, physical activities and stress [4].

Under normal conditions, the ratio between these three humors (vatham, pitham and kapham) is 1:1/2:1/4, respectively ^[27]. According to the Siddha medicine system diet and life style play a major role not only in health but also in curing diseases. The siddhar's are persons who Practiced Meditations, pranayamas and other Yogic practices. In Siddha system the diseases are classified according to Mukkutram theory and diseases are 4448 in numbers. The Vaatham diseases are 80, Pitham diseases 40 and Kabam 20 in number ^[2].

In human beings the life stages are classified as Pre natal, Newborn, infants, toddler, preschool and adolescent, Early adult hood, Midlife, Mature adult, Late adult hood and Death. In between these stages of the life the human body will be affected by disease [17]. According to the siddha system the pediatric life stages are classified into 10 stages. They are Kaapuparuvam (0-3Months), Sengeerai (3-5 months) Thaalaatu (5-7months), Sappani (7-9months), Mutham (9-11months), varugai (11-13months), and Ambulli (13-15months) these 7 stages are common for male and female child. After this period siruparai (15-17months), sitril (17-19Months), siruther (19-21months) are mentioned for male children and kazhangu (15-17months), ammanai (17-19Months), oosal (19-21months) are mentioned for female children [29].

Paresis [8] is a condition in which muscular weakness by impaired movement. It may be also referred to as mild paralysis or partial paralysis. The most common symptoms are, difficult to lift the arm or leg, hand or shoulder movement, decreased sensation in the affected area, a tingling or pins and needles feeling, muscle stiffness. The global burden disease estimates the number of children aged 0-14 years experiencing moderate or severe disability.

In India, 1.67% of the 0-19 population has the disability ^[26]. Other estimates say that India has 12 million children living with disabilities.

"Baalavatham" which is mainly interfering with the principal function of locomotion in human being. In this disease commonly Nervous system is being involved and in later stages it makes discomfort, weakness, and inability to the individual. This disease is also mentioned in siddha pediatric text books ^[20]. The sage Agasthiyar has classified BaalaVaatham into 8 types in his book of — Agasthiyar Kummi. In our siddha paediatric text, the definition for BaalaVaatham has been given as:

வாலையென்ற குழந்தைக்கு வாதம் வந்தால் வசம்கெட்டு கைகாலும் விளங்கிடாது கோலமென்ற சக்தியது குறைந்து காணும் குலைந்து விழும் நரம்பெல்லாம் தளர்ந்து நிற்கும் காலமென்ற கால் கரமும் யிட்டா போலாம் கண்டத்தில் விசை தளரும் கழுத்து கோணும் சீலமிக நடக்க ஒட்டா சீதம் தோன்றும் தேகத்தில் குளிர்ச்சையுண்டாம் விறைக்கும் தானே

In the pediatric text book of Mathalai Noi thokuthi part III, the symptoms of BaalaVaatham is explained as inability/difficulty to use the limb, loss of power and tone, weakness, inability to move the affected limb, deviation, loss of energy, weakness, chills, spasticity of the affected part [8].Siddha classic texts described the Balavatham is a condition in children with symptoms such as weakness and difficulty in walking.

At Present, Supportive therapies for training the children with paresis like occupational therapy, physiotherapy, therapy, conventional therapy, neurophysiological approaches, modified constraint induced therapy (MCIT), functional electrical stimulation to use improve range of motion, mental practise useful to helping walk are being used^[24]. Certain medication like Anti-spastic drugs also used in severe condition.

But, it's quite challenges to manage the children with paresis existing therapy. Certain medications like, stretching medical therapies like long term, short term various technique and effect is undocumented. Anti spastic drugs (benzodiazepines, baclofen, alpha2 adrenergic agonists ^[5] to cause the adverse effects and other complications. Because a number of major physical problems facing the children with paresis in their life, they cannot fulfil the expectation in the society.

As we strive to develop an effective management, the childhood conditions vary dramatically in their severity and impact on the quality of life of the child and family. In present scenario there is no health care profession has convincingly assumed the responsibility of thehealth for children with paresis. Although drug therapy may not completely correct the complications associated with childhood disability, evidence does show that it helps manage problems. Hence, its essential need to find out traditional theapy for the children with paresis.

In NIS many more Paresis children are reporting to our KuzhanthaiMaruthuvam Department. In the Siddha system of medicine, herbs, minerals, metals and salts are have been used for preparing the medicine. In this context, the need exists to evaluate many Siddha drugs and therapies in contemporary use, which also includes Mind–body interventions, Biological based therapies such as formulations and diets, Manipulative methods such as Thokkanam. Thus the aim and objectives of the present study was to test the efficacy of the Siddha medicines / methodologies in Paresis children.

The purpose of this study is to develop recommendations on best practices related primarily to the evaluate Siddha methodologies and Medicines. Different treatment modalities can improve the quality of life of children and these can include internal medication and External therapies like Thokkanam (Massage). Because children with paresis have multiple symptoms for which no curative treatment exists, their families seek therapies from many sources.

Some look for cures, while others seek therapies that will improve the way of their children day to day activities. In this regard, we had decided to take up a combination of Siddha formulation and therapy for the study. The drugs chosen for the study included *Mahanaluruva Chooranam* as internal medicine and *Chennagarapattai Ennai* was external medicine (Thokkanam) in the treatment of baalavatham. Most of the ingredients in the experimental formulation have neuroprotective activity and balance the equilibrium of mukutram. And, Thokkanam plays a vital role in the management of vathadiseases; it's stimulating the blood circulation release the muscle tension. So by rejuvenating the depleted vaayus through thokkanam it is easier to treat and prevent the disability [25].

The Internal drug *Maha analuruva Chooranam* is an herbal preparation mentioned in the text book of – Agathiyar vaithiya vallathi 600. Most of the raw drugs in *Chennagarapattai ennai* which is used for external application have Anti- Vaatha, Tonic, Stimulant, Anti-Oxidant, Neuro-protective [105], property mentioned in the text book of —Mathali Noi Thoguthi-III.Thokkanam is works to stimulation of blood circulation and the nervous system in the body cures disease pertaining to the muscles tendon, ligaments, bones and nervous and internal organs. In this study, apart from internal and external medicines, the effect of thokkanam is also being assessed.

2. AIM & OBJECTIVES

AIM:

Clinical evaluation and therapeutic management of Baalavatham [Paresis] by *Maha Analuruva Choornam* (internal) along with *Chennagarapattai Ennai* (external) in children.

Primary Objective:

- To evaluate the effectiveness of experimental formulations maha analuruva choornam for the management of baalavatham in children.
- To analyze the spasticity, intensity of muscle tone, muscle strength, gait index, and range of motion in the treated children.

Secondary Objective

- To study the disease baalavatham on the basis of mukutram, envagaithervu, udalthathukkal, neerkuri and neikuri and to calibrate the Resemblance and the Equivalence of Baala vatham with Paresis.
- To establish the standardized treatment methodolgy for Baala Vatham with the siddha medicine.
- To make a clinical observation about the disease in relation of age, sex, Socioeconomic status, natal history, miletones.
- To evaluate the Bio-chemical, Phytochemical, physicochemical properties of the trial drug Maha analuruva chooranam.

3. REVIEW OF LITERATURE

A. SIDDHA ASPECT

In Siddha system of medicine, the diseases are classified into 4448 types according to our ancient Siddha literatures, based on vatha, pitha, kaba theory. Vatha diseases get a major role among that by such classification there are 80 types of vatha diseases. Baalavatham is one of them. It is due to derangement in vatham.

Baalavatham is characterized by partial weakness of one or both upper and lower limbs, impaired movements, difficult to use the upper and lower limb such as difficult to lift the arm or leg, hand or shoulder movement, tingling sensation, muscle stiffness, difficult to stand, walking due to deranged Vatham.

குழந்தைகளுக்கு உண்டாகும் வாதநோய்களைப் பாலர் வாத நோய் எனக்குநிப்பிடுவர். வாதகுற்றம் கன் அளவில் மிகுந்து, உடல் நோதல்,குத்தல்,தொழில் குன்றிச்செயல் இழத்தல் போன்ற நோய் குறிகளை உண்டாக்கக்கூடியதும ,உடல் செயல் இழப்போடு, மூடம், அறிவின்மை,உளக்கேடு முதலியவற்றியும் உண்டாக்கக்கூடியதாகும். இவ்வாறு குழந்தைகளுக்கு உண்டாகும் வாதநோய்கள் நாற்பது வகையாகும்.

அவையாவன:

குழந்தைகளின் இடுப்பிற்க்குமேல் - 27 குழந்தைகளின் இடுப்பிற்க்குகீழ - 8 உடல் முழுவதும் பரவிப் பாதிக்ககூடியவை - 5

இடுப்பிற்குமேல் ஏற்படும் வாதநோய்கள்:⁽³²⁾

- 1. கெம்பீரவாதம்
- 2. முகவாதம்
- 3. நேத்திரவாதம்
- 4. கர்ணிகவாதம்
- 5. அமிர்தவாதம்
- 6. சுண்டு வாதம்
- 7. நாக்குவாதம்
- 8. கண்ட வாதம்

- 9. கருள் வாதம்
- 10. திவளைவாதம்
- 11. விரல் வாதம்
- 12. அனுதம்ப வாதம்
- 13. கன்னவாதம்
- 14. அலகுவாதம்
- 15. விரை வாதம்
- 16. அபானவாதம்
- 17. குடல் வாதம்
- 18. கும்ப வாதம்
- 19. பொருத்துளைவுவாதம்
- 20. உதரவாதம்
- 21. தாகவாதம்
- 22. சன்னிவாதம்
- 23. வாதத்தில் வாதம்
- 24. பித்தவாதம்
- 25. சலேற்பனவாதம்
- 26. நீர் வாதம்
- 27. விறைக்கும் வாதம்.

இடுப்பிற்குகீழ் ஏற்படும் வாதநோய்கள்:

- 1. கணைவாதம்
- 2. பாரவாதம்
- 3. சக்கரவாதம்
- 4. உள்ளடிவாதம்
- 5. காந்தல் வாதம்
- 6. முட்டு வாதம்
- 7. சூலைவாதம்
- 8. இடுப்புவாதம்

உடல் முழுவதும் பரவிப் பாதிக்கக்கூடிய வாதநோய்கள் (சர்வாங்கவாதம)

- 1. உருத்திராங்கன்வாதம்
- 2. பக்க வாதம்
- 3. பாலவாதம்

- 4. மயில் வாதம்
- 5. ஆந்திரவாதம்.

இவ்வாறு வகைப்படுத்துப்பட்டுள்ள பாலர் வாதநோய்கள், இடுப்புக்குமேல் ஏற்படுவனவற்றில் பன்னிரண்டுவகைகளும், இடுப்புக்குகீழ் ஏற்படுவனற்றில் மூன்று வகைகளும்,சர்வாங்க வாதநோய்களில் நான்கு வகைகளும் அசாத்திய நோய்க்குறிகளைஉடையனவாகும்.

தீரா பாலர் வாதநோய்களின் பெயர்கள்:

இடுப்புக்குமேல் ஏற்படும் வாதநோய்களில், பின் வருவன அசாத்தியமாமவை இவை தீராதவையாகும்.

- 1. கெம்பீரவாதம்
- 2. திவளைவாதம்
- 3. அமிர்தவாதம்
- 4. அனுதம்ப வாதம்
- 5. அபான வாதம்
- 6. குடல் வாதம்
- 7. கும்ப வாதம்
- 8. கருள் வாதம்
- 9. சன்னிவாதம்

இடுப்புக்குகீழ் ஏற்படும் வாதநோய்களில்:

- 1. இடுப்புவாதம்,
- 2. புாலவாதம்
- 3. சக்கரவாதம் ஆகியன தீராதவை.

சா்வாங்க வாதநோய்களில் பின் வருவன தீரா நோய்க்குறிகளை உடையதாகும்.

- 1. உருத்திராங்கன் வாதம்,
- 2. மயில் வாதம்,
- 3. பக்கவாதம்,
- 4. ஆந்திரவாதம்.

தீரும் பாலர் வாதநோய்களின் பெயர்கள்:

பாலா் வாதநோய்களில் தீரும் சாத்தியக் கூறுகளை உடைய வாதநோய்களின் பெயா்கள்.

தீரும் வாதநோய்கள்:

இடுப்பிற்குமேல் வரும் பாலர் வாதநோய்கள்.

- 1. முகவாதம்
- 2. நேத்திரவாதம்
- 3. கர்ணிகவாதம்
- 4. சுண்டு வாதம்
- 5. நாக்குவாதம்
- 6. கண்ட வாதம்
- 7. விரல் வாதம
- 8. கன்னவாதம்
- 9. அலகுவாதம்
- 10. விரை வாதம்
- 11. பொருத்துளைவுவாதம்
- 12. உதரவாதம்
- 13. வாதத்தில் வாதம்
- 14. பித்தவாதம்
- 15. சிலேத்துமவாதம்
- 16. நீர் வாதம்
- 17. நாகவாதம்
- 18. விறைக்கும் வாதம்.

இடுப்பிற்குகீழ் ஏற்படும் பாலர் வாதநோய்கள்.

- 1. குணை வாதம்,
- 2. முட்டு வாதம்,
- 3. காந்தல் வாதம்,
- 4. உள்ளடிவாதம்,
- 5. சூலை வாதம்,

ஷபாலர் வாத நோய் பரவும் காலம்:

சுற்றுப்புறச் சூல்நிலையில், குளிர்ச்சி அதிகம் உள்ளகாலங்களில் பாலர் வாதநோய்கள் பரவக் கூடும். கார், கூதிர், முன்பனி, பின்பளிக் காலங்களில் குளிர்ச்சி அதிகரித்து அக்காலங்களில் பாலர் வாதநோய்கள் அதிகரிக்கும்.

பாலர் வாதநோயோடு சர்ந்து காணப்படும் நோய்கள்:

- 1. சுரம்,
- 2. சூலை,
- 3. மேகம்,
- 4. காசம்,
- 5. இளைப்பு,
- 6. சன்னி,
- 7. அபஸ்மாரம்,
- 8. பித்தசோகை,
- 9. வன்னி,
- 10. அமிர்தநோய்,
- 11. உள்ளுரோகம்.

நோய் வரும் வழி:

முற்பிறவியல் செய்த பாவங்களாலும் பலவிதமான நஞ்சுகள் பண்டங்கள், சிலவகையான பழங்கள் ஆகியவற்றை உண்பதாலும் நோய் ஏற்படக்கூடும். எண்ணெய், புளி,மோர்,பால் ஆகியவற்றை அதிகமாகப் பயன்படுத்தியதாலும் நஞ்சுத்தன்மையடைந்த நிலையிலான தாய்ப்பாலைக் குடித்த்தினாலும், ஆண்பெண் சேர்க்கையின் போது உண்டாகும் பொருட்டு நோய் ஏற்படுகிறது.

பாலவாதம்

வாலையென்ற குழந்தைக்கு வாதம் வந்தால் வசம் கெட்டு கைாலும் விளங்கிடாது

கோலமென்ற சக்தியது குறைந்து காணும்

குழைந்துவிழும் நரம்பெல்லாம் தளர்ந்துநிற்கும்

பாலமெண்றகால் சுரமும் யிட்டாபோலாம்

கண்டததில் விசைதளரும் கழுத்துகோணும்

சீலமிகு நடக்கஒட்டாசீதம் தோன்றும்

தேகத்தில் குளிர்ச்சையுண்டாம் விறைக்கும் தானே.

-மதலைநோய் தொகுதி 111

பாலவாத உந்பத்த ிவிவரம்

சொல்லிய பாலவாதம் தொடர்ந்திடும் விபரங்கேளு மெல்லிய கருவில் வந்துமேவியதிசைவாயுவுள் நல்லியலில்லாமலத் தாண் நாதமுஞ சேருமாகில் தல்லியகுணமும் விட்டுதறைந்திடும் நரம்புதானே.

-பாலவாத நிதானம்

குழந்தைகளுக்குபாலவாதம் ஏற்படும் காரணத்தைக் கருவானது உற்பத்திஆகும் போது சுரோணிதத்துடன் பத்துவகையான வாயுக்களும் சேர்ந்து குணங்களுக்கு ஏற்ப நரம்புகளுக்கு ஏற்ப பற்றும்.

> தந்தையும் தாயும் கூடி தழுவியேபுணர்ந்தநாளில் வந்துமுன் செய்த் தோஷமருவியேகர்ப்பக் கூட்டில் விந்தியாகிசரத்தினூடேவேங்குழுலோடம் போலே அந்தநாள் உறுப்பைத்தொட்டுஅடர்ந்திடும் என்றுஎண்ணலாமே.

-பாலவாத நிதானம்

மேலும் தாய், தந்தையாகள் உடலுறவுகொள்ளும் போது கருவில் இணையும் ஆத்மா, முன் சென்மத்தில் செய்த கருமங்களின் பலாபலன்களின்படி, காப்பத்திலேயே நோய் அதன் உறுப்புகளின் குடிகொள்ளும்.

> ஆடர்திடும் சடத்திலேதான் அக்கினிகணக்கில் நின்று துடர்ந்துதான குறைந்தும் மீறிசுகமுற்று குளிர்ச்சையாகில் உடனந்த கர்ப்பந்தனில் உருவியேய மர்ந்தநோக்கம் நடந்துமே நாற்பத்து நால்மாதம் வருஷத்தின் மேலே.

-பாலவாத நிதானம்

உடலில் சூடானது பரவிதொடர்ந்து நின்று கூடியும் குறைந்தும் சிலவேளைகளில் கறைந்தும் இருக்கும். இந்நிலை காப்பப்பையிலிருக்கும் குழந்தையை பாதிக்கும். குழந்தை பிறந்த நாற்பத்திநான்கு மாதங்களுக்குப் பிறகு வாதநோயாக மாறும். மேல் தாவியதுஎன்றுமிகுந்திடுத் மூன்றுஐந்தும் குலமாமதனின் மேலும் கண்டிடுமீராற் மட்டும் சீலமாய் வந்துவாதம் சிசுக்களுக்குதுடருமென்று சாலவேமுனிவனிதானும் பாலற் கென்றே.

- பாலவாத நிதானம்

மேலும் மூன்று, ஐந்து, பன்னிரெண்டு, வருடங்களில் வாதமானது குழந்தைகளை தொடரும் என்று வேதங்கள் ஓதும் முனிவர்கள் சொல்லியுள்ளனர்.

> என்றதோர் முன் சென்மத்தின் இசைந்துடன் இவர்கள் தானும் நின்றதோர் சீவசெந்துநிலை தளர்ந்திடுத் வாற் தன்னை கொன்றிடாது தைத்து கைகால்களைத் துலைத் திட்டபாவத்தாலும் அன்றுதான் பெரியோர் சாமிசக்திகள் வணங்காததாலும்.

- பாலவாத நிதானம்

முற்பிறவியில் உயிர் பிராணிகளை நிலைதளரும் வண்ணம் உதைத்து கை,கால்களை முறித்துவிட்ட பாவத்தாலும் ,பெரியவர்கள் இறைவன் இவர்களை வணங்காததாலும்.

> வணங்காத கோபத்தால் சாபத்தாலும் வல்வினையாம் தீவினைகள் அதிகரித்தாலும் இணங்காத கோபத்தால் அழுகையாலும் இரையதனால் மலசலத்தின் பெந்தத்தாலும் கணங்க கால்கைநரம்பிலாது ஊனத்தாலும் கணத்தபிலன் செய்ததாலும் வாதம் வந்து வணங்காதேயானுமே இது வாலைகளுக்கு.

> > - பாலவாத நிதானம்

கோபத்தாலும், சாபத்தாலும், தீவினையின் பலனாலும், அழுகையாலும், உண்ணும் உணவிலுள்ள குற்றத்தாலும், மலம், சிறுநீர், இவைகளை கட்டுவதாலும் கை,கால் நரம்புகளின் ஊனத்தாலும் ,உடலை இறுக்கிப் பிடித்தாலும், குழந்தைகளுக்கு வாதம் வந்து சேரும்.

கூறுவேன் இதில் எட்டுவகையின் பேரும்
குறிப்பாக சாத்தியமும் அசாத்தியந் தானும்
வேறுமே அவுஷதமும் கிறிகை யாவும்
விபரமதாய் திகழும் கழிப்பும் செய்ய
ஆறுமேவிசை தளர்ந்து நோவும் மாறி
அங்கமது நன்றாகி வளர்ந்துமேல் மேல்
தேறுமே உடல் பலத்து திடமாக
திருந்திடு வாரென்று முனிசொன்னமாமே.

-பாலவாத நிதானம்

குழந்தைகளுக்கு வரும் எட்டு வாதத்தின் பெயரும், சாத்திய அசாத்தியப் பிரிவுகளையும், மருந்து வகைகளையும் ,கிரிகை, கழிப்புமுறைகள் போன்றவற்றை செய்தால் வாதத்தின் விசை தளர்ந்து வேதனையும் நீங்கி உடல் திடமுடன் செம்மையாய் வளர்ந்துவருமென்று மாமுனி கூறிய அரும் கருத்தாகும்.

வாதம் எட்டுக்கும் பெயர்

ஆமென்ற சுரத்தின் வாதம் அக்கினி வாதத்தோடே ஓமென்ற மூலவாதம் உணக்கிய வாதந்தானும் தாமென்ற அதிசாரவாதம் தறுக்கும் மேல் மூச்சுவாதம் போமென்ற விரைவில் வாதம் பொருந்துலா தங்களென்றே.

-பாலவாத நிதானம்

சுரத்தின் வாதம், அக்கினிவாதம், உணக்கல் வாதம், அதிசாரவாதம், மேல் மூச்சுவாதம், விரைவாதம், பொருந்துவாதம் ஆகியவையே ஆகும்.

சாத்தியம் அசாத்தியம்

எட்டுவாதங்கள் தன்னிலஅசைவுறும் சாத்தியசாத்தியம் மட்டமாஞ் சுரத்தின் வாதமிசைந்த அக்கினியின் வாதம் விட்டறு மூலவாதம் விரையினில் வாதம் நாலும் டமாதீருஞ் சாத்தியம் தீராது உணக்கல் வாதமென்றே.

-பாலவாத நிதானம்

முன் சொன்ன எட்டுவகை வாதங்களின் சுர வாதம் ,அக்கினிவாதம் , மூலவாதம் ,விரைவாதம் ஆகிய நான்கு வித வாதங்கள் சாத்தியப்பிரிவைச் சார்ந்தது.

> வாதமே பொருந்துவாதம் வருகும் மேல் மூச்சுவாதம் சீதமே அதிசாரத்தின் செப்பியவாதம் நாலும் கோதற தீர்ந்திடாது கொடும் பிணிஅசாத்தியமாகும் தீதறப் பொதிகைவாழும் திருமுனிஅருளிச் செய்தார்.

-பாலவாத நிதானம்

உணக்கல்வாதம், பொருந்துவாதம்,மேல் மூச்சுவாதம், அதிசாரவாதம், ஆகிய நான்குவித வாதங்களும் அசாத்திய பிரிவைச் சார்ந்துத என்று பொதிகைமலையில் வாழும் அகத்தியமுனிவர் தீர்க்கமாய்.

சுரவாத குணம்

குத்திடும் அங்கமெல்லாம் கொடும் சுரம் கோபமாகி சுற்றிடுமுதிர்த்துன்னைசுழன்றுடேல் வாந்தியுண்டாம் இவற்றிவலம் லிடாது இடுப்பொருபக்கம் தன்னில் வற்றியபாலற்மெய்யில் வருமடசுரவாதந்தானே.

உடல்முழுவதும ்குத்தலும், சுரமும் ஏற்பட்டு, அதன் விளைவாக வாந்தியுண்டாகும், மலம் சரியாக வெளியாகாது, இடுப்பின் ஒருபக்கம் தேய்ந்து வரும் இதை சுரவாதம் என்பர்.

அக்கினிவாத குணம்

எரித்திடும் தேகமெல்லாம் இருமலும் செருமலுண்டாம் பெருந்திடும் சிரங்கும் உண்டாகும் பேய் முளிமுளிக்கும் பிள்ளை அரித்திடும் முடங்கும் கை கால் அன்னைபால் உண்ணமாட்டார் தெரிந்திடும் அரிப்புமுண்டாகும் சில்லெரிசத்தாமாமேஅரி.

ஏந்படும் உடல் முழுவதும் எரிச்சல் எழும், இருமல், செருமல் சிரங்கும் உண்டாகும். குழந்தை பேய்முழி போன்ற பயங்கரமான பார்வையைக் காட்டும். உடலில் அரிப்பு தோன்றும், கைகால்களை (முடமாக்கும், தாய்ப்பால் குடிக்கமாட்டது சில்லெரி வண்டின் சத்தம் போன்று தோன்றும், குரலானது இதுவேஅக்கினிவாத குணங்களாம்.

மூலவாதகுணம்

வருமடில் குழிலினாளோ மைந்தர்மேல் திமிற்புஉண்டாகும் பொருமலும் மலம் விடாது புக்கிடும் ஆகந்தன்னிலட செருமலும் வேர்வையாகி சேரவே குளுந்து காட்டும் விருவியே எட்டாம் நாளில் விட்டிட காலில் சேரும்.

மூலவாதம் ஏற்பட்டகுழந்தையின் உடலில் திமிர்ப்பு ஏற்படும். வயிற்றில் பொருமல் உண்டாக ிமலமானது வெளியேறாது. செருமலுடன் வியர்வை ஏற்பட்டு உடல் குளிர்ந்தும் காணப்படும். எட்டுநாள் சென்றபின்பு வாதமாமது காலில் வந்துச் சேரும்.

ஆனந்தவாதம் (விரைவாதம்)

வித்தொருபரலில் தோன்றிவீக்கமுங் குத்துண்டாகும் சுத்தியே குடல் வலித்து சுருட்டிமேலிழுத்து வாங்கும் தெற்றிடுமிரு பாலோயும் திரிந்திடாசைவு குன்றும் மத்தளம் போலேசத்தம் கதறிடும் பாலன் தானே. விரைவாதமென்று சொல்லப்படும் ஆனந்தவாதம் குழந்தைகளின் விரைபரவில் தோன்றி வீங்கி சுருட்டிமேலே குத்தலுண்டாக்கும். குடல் நொந்து இழுத்துவைக்கும். ஓய்ந்துபோகும். இரண்டு கால்களும் நடைதடுமாறி நடக்க இயலாது. அசைவு குறையும்.

உணக்கல் வாதம்

உரைத்திடுங் கையுங்காலும் உறுப்பெல்லாந் தளர்ந்துக் காட்டி நிரைப்பறுங் கழுத்துகோணும் நீர்மலம் செறுத்துக் கொள்ளும் துரைத்திடும் சீதம் வேர்வை துவள்முலை விருப்பமில்லை கரைத்திடும் பாவைபோலேஅடங்கலு முணக்கலாமே.

அணக்கல் வாதம் ஏற்பட்டால் உறுப்புகள் யாவும் கை,கால்,உடல் வெளியேறாது. தளர்ந்துகழுத்தும் கோணும். சிறுநீரும் சீதம் மலமும் வியாவைதோன்றும் பாவைபோன்று தாய் பால் உண்ணமாட்டாது. உடல் மெலிவுறும்.

பொருத்து வாதகுணம்

அவயவம் பொருத்துதோறும் அதனில் நீர் கட்டுண்டாகும் கவயவம் போலேநின்று காய்சலு மதிபமுண்டாம் இவயசமிகுதியாகம் இசவெல்லா மிளகிநிற்கும் உவயவம் கையுங்காலும் உறுப்பெல்லாம் தளர்ந்துபோமே.

பொருத்து வாதத்தின் நிமித்தமாக உடல் பொருத்துகளில் நீர்கட்டு உண்டாகி வீங்கி, வேதனையும், சுரமும் தோன்றும். பொருத்துகள் இளகி நிற்க்கும். கை,கால் மற்றுமுள்ள உடல் உறுப்புகள் களர்ந்து தோன்றும்.

மேல் மூச்சுவாதம்

வருந்தியே பாலற்மெய்யில் வசைகெடுங்கையுங் காலும் திரும்பிய அசவநாது தேகமுங் குளிர்றசை யாகும் விரும்பிய விதைளரும் விளைத்திடுங் கழுத்து கோணும் நிரம்பிய சக்திகுன்றும் நிலந்தளந்தூணிடாதே. குழந்தைக்குமேல் மூச்சுவாதம் ஏற்பட்டால் கை,கால் அசைக்க முடியாது. உடல் குளிர்ந்து காணப்படும். உடல் தளர்ந்து கழுத்தும் கோணும். குழந்தையின் சக்தி குறைந்து நிலத்தில் காலை ஊன்றாது.

ஆதிசாரவாத குணம்

வசங்கெட்டுங் கையுங்காலும் வளைந்துமே குளைடந்து போகும் கசங்கியே வயளுரிந்துகழிச்சலும் பொருமலாகி வீசம்பெர குளிர்ச்சையுண்டாம் விக்கலும் பனியும் காட்டும் மசங்கிய ஹபோதக் கேடாம் அதிசாரவாதமேன்னே.

-பாலவாதநிதானம்

அதிசாரவாதம் ஏந்பட்டால் கையும் காலும் வளைந்து குழைந்துவிடும். ഖധിന്റന്റിல് எரிவு உண்டாகி கழிச்சலும் பொருமலும் ஏற்படும் உடல் குளிாந்து காணப்படும். மயக்கமும் விக்கலும், தோன்றும். தோன்றும். மேலும் சுரமும் இத்தகைய குறிகுணங்களை கொண்ட பாலவாதம் என்னும் நோய்க்கு உள்மருந்தாக மகா வெளிமருந்தாக அனலுருவ மற்றும் தொக்கண **ഗ്ര**ത്വെപിல് சூரணம் சென்னகரபட்டை எண்ணெய் உபயோகப்படுத்தப்படுகிறது.

3.1. VATHAM:

Other names of vatham: Vaayu, Vali

Definition:

Vatham or Vaayu is not mere a wind, but also cause motion, energy and sensation of every cell in the body. Hence Vatham is one of the three humours (vatham, pitham, kabam) which are responsible for construction nature of works in the human body. In physiological conditions, the existence of three thadhus is in ratio of 1, 1/2, 1/4 respectively. This ratio is altered when there is disturbance of normal existing, thadhus by the environmental factors, diet, habits, etc., and vathakutram may be increased or decreased.

Physiology of Vatham:

The three basic factors Vatham, Pitham and Kabam working in physiological condition are called three thadhus and Uyirthadhus. These factors are working through an internal instrument called andhakaranam, which is composed of

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Manam, Puthi, Siddham and Agankaram. So, mind is the receptor of all sorts of impulses produced within the body.

Kundalini sakthi, an enormous power is kept in the mooladharam like a sleeping snake. It can be revitalized and fully utilized by yoga and meditation. When this aanmasakthi is stimulated by the external factors, the kundalini goes upwards like an angered snake and produces motor (seiunarvu) and sensory (meiunarvu) functions. This is otherwise called as Kanmaindhiriyam and Gnanaindhiriyam respectively. These are closely associated with nervous system of the body and this is discussed in Vingnanamayakosam in detail.

In human body, the locomotor activity functions through voluntary muscles and it is controlled by nervous system called kanmaindhiriyam. Likewise, the sensation and its activities are known as gnanaindhiriyam. These types of activities are governed by the Vatha humour among the three thadhus.

Relation with five elements:

Vatham - Kaatru + Aahaayam

Vatham has kaatru and aahayam as its elemental constituents. If kaatru and aahayam or any of is decreased or increased from the normal level, it will surely lead to pathological state of vatham.

Regarding diet, bitter, pungent and astringent tastes contain vali and bitter alone contains aahayam. So if these are consumed in large amounts this results in the vitiation of vatham and eventually vatha disease. The six tastes and their constituent's elements are as follows.

- 1. Sweet = Earth+ Water
- 2. Sour = Earth+ Fire
- 3. Salt = Water + Fire
- 4. Bitter = Air + Sky

- 5. Pungent = Air + Fire
- 6. Astringent = Earth + Air

Vatham = Air+ Sky, Pitham = Fire, Kabam= Water +Earth

Locations of Vatham:

Lies of Vatham: Below the umbilicus. Generally, Vatham lives in

- 1. Abanam
- 2. Edakali
- 3. Kaamakodi
- 4. Undhiyinkeezhmoolam
- 5. Muscles
- 6. Bones
- 7. Hair follicles
- 8. Nerves
- 9. Skin
- 10. Joints
- 11. Stools

Physiologically, Vatham which has no alteration lives in GI tract, bones, ear, thigh, hip and skin.

Properties of Vatham:

- 1. Giving briskness
- 2. Expiration and inspiration
- 3. Functioning the seven udal kattugal uniformly
- 4. Functioning the mind, thoughts and body.
- 5. Regulation of 14 physiological reflexes.
- 6. Protection and strengthening of the five sensory organs.

Charecteristics of Vatham:

- 1. Body ache
- 2. Pricking pain
- 3. Tearing pain
- 4. Mental distress
- 5. Movements
- 6. Pain in the joints
- 7. Traumatic pain
- 8. Dislocation of joints
- 9. Weakness of organs
- 10. Paralysis of the limbs
- 11. Polydypsia
- 12. Severe in calf and thigh muscles
- 13. Bony pricking pain
- 14. Anuria and constipation
- 15. Unable to do flexion and extension of the limbs
- 16. All tastes like astringent
- 17. Excess salivation

Natural qualities of Vatham:

- 1. Kadinam Roughness
- 2. Varatchi Dryness
- 3. Elesu Lighter
- 4. Kulirchi Coldness
- 5. Asaithal Unstableness
- 6. Anuthuvam Subtleness

Opposite qualities of Vatham:

- 1. Mirudhu Softness
- 2. Pasumai Unctous
- 3. Paluvu -Heaviness
- 4. Akkini Hot

5. Sthiram - Stableness

6. Katti - Solidity

The siddha classical texts divide the general principles of vatham into ten subsidiary forms that differ from one another by their localization in the body and by their particular functions.

They are,

1. Pranan (Uyirkaal)

It corresponds to the cardiac plexus and refers to the chest. It regulates the respiratory system and helps the digestive system. Its derangement cause respiratory disorders.

2. Abanan (Keezhnokku kaal)

It corresponds to the pelvic plexus and expels fecal matter and urine. It constricts the anal sphincter. It helps to digestive food all over the body. It is also responsible for the expulsion of sperm and menstrual flow. Its derangement leads to diseases of the bladder, rectum and reproductive system.

3. Viyanan (Paravukaal)

It corresponds to the vaso-ciliary at the root of the nose and base of the skull. It spreads over the body in all endings and causes constriction and relaxation of both voluntary and involuntary muscles. This is responsible for the movements of the body and sensory perceptions. It causes flow of fluids, flow of sweat, opening and closing of eyes etc., it is responsible for taking the absorbed essence of the food to the different parts of the body. The neurological problems of the body are basically because of the derangement of viyanan.

4. Udhanan (Melnokku kaal)

It corresponds to the pharyngeal in the throat region and regulates the higher function of brain like speech. Its derangement cause symptoms of upper gastro intestinal tract diseases, problems in speech etc, it is also responsible for the physiological reflex actions like vomiting, hiccup, cough, sneezing, etc.,

5. Samanan (Nadu kaal)

It corresponds to the solar plexus in the naval region and controls digestion. It acts as a neutralizing air for the upward and downward air (abana&udhana). Its derangement will cause gastrointestinal symptoms and neurological, respiratory symptoms as this vaayu are the neutralizing force for the other four vaayus.

6. Nagan

It is responsible for the intelligence of an individual. It causes opening and closing of eyelids. Its derangement causes impaired memory and lack of coherent.

7. Koorman

This cause yawning and closure of eyelids. This is responsible for vision; lachrymal secretion is also attributed to koorman. It gives energy to the body and helps in body building.

8. Kirugaran

This lies in the tongue, salivary glands, nasal secretion, hunger, concentration of the mind on one particular thing, sneezing, cough are all attributed to kirugaran.

9. Devadhathan

Laziness is attributed to this vaayu. The ocular movements, human passions like anger are attributed to this vaayu.

10. Thananjeyan

It produces swelling all over the body and leaves from the body by blowing of the cranium only on the third day after death. This vaayu is responsible for decay of the body after death.

Piniyari Muraimai:

Pini means the disease which affects the body and any interruption of the normal functions of any body part, organ or system. *Ari* means identify, Muraimai means Rules. *Piniyari muraimai* is the method of diagnosing the disease affecting the people.

It is based upon the following aspects:

- 1. Poriyalarithal
- 2. Pulanaalarithal
- 3. Vinaathal

The above principles correspond to the methodology of inspection, palpation and Interrogation of modern medicine.

Poriyalarithal and Pulanalarithal:

Gnanaindhiriyam:

Mei (skin) - Touch
 Vaai (mouth to tongue) - Taste
 Kan (eye) - Vision
 Mooku (nose) - Smell
 Sevi (ear) - Hearing

Kanmendhiriyam:

1. Kai (upperlimb) - Movements of upper limbs

2. Kaal (lower limbs) - Movements of the lower limbs

3. Vai (mouth) - Speaking

4. Eruvaai (anal orifice) - Defecation

5. Karuvaai (reproductive orifice) - Reproduction

Pori is considered as the five sense of perception namely Nose, Tongue, Eye, Skin and Ear. While Pulan are five object of senses. They are smell, Taste, Vision, Sensation and sound. Physician and pulan are used as the tools for examining the pori, pulan of the patient. Vinaathal is obtaining informations regarding the history of the disease, its clinical features etc., from the patient or his immediate relatives who are taking care of him.

Vinaathal:

It has a procedure for gathering information about the patients name, age, occupation, nativity, socio economic status, family history, dietary habits, allergic factors, period of suffering from the complaints, history of previous episodes, relevant history of habits and treatment etc., from the patient or from his immediate relatives, if the patient is not in a position to speak or if the patient is child.

Envagai Thervugal:

Eight different kinds of test to be applied or attended by a physician before arriving a correct diagnosis. Envagai thervugal is considered as physician's Instruments

- 1. Naadi (Pulse)
- 2. Sparisam (Palpation)
- 3. Naa (Tongue)
- 4. Niram (Color of the body)
- 5. Mozhi (Speech)
- 6. Vizhi (Eye)
- 7. Malam (Fecal)
- 8. Moothiram (Urine)

Therefore to arrive at the diagnosis for any disease, it is imperative to apply the Envagaithervugal. In Muthuvenilkaalam, the increased solar radiation increases the evaporation of the water content in the world. At the same time, the similar action on the body produces increased absorption of water from mucosa for digestion and develops the vitality of Vatha disease. So this disease occurs predominantly in muthuvenil kalam.

The prime method adopted to diagnose the disease is by mean of Envagai thervugal. The value of Envagai thervugal is very important for diagnosing purpose, which is the unique and special method describing in Siddha system of medicine. Hence the diagnosis is made by the following.

1. Naadi (pulse):

The study of naadi is the important factor in Envagai thervugal which gives almost the correct diagnosis, Naadi may be studied at 10 points which are Heel, Genital organ, Abdomen, Chest, Ear, Nose, Neck, Hand, Eyebrow and Vertex. But the study of naadi at hand is the best because the radial artery is located here superficially. The unique factor which pertaining the soul in the body is known Naadi. Naadi must be studied in right hand for men and left hand for women

The three Uyirthaadukkal are formed by combination of

Edakalai + Abanan => Vatham

Pinkalai + Piranan => Pitham

Suzhumunai + Samanan => Kabam

They can be felt one which below wrist on the radial side by means of Palpation with Tips of the index, middle and ring fingers corresponding of vatham, pitham, kabamrespectively, The three humours exists in the ratio of 1: ½: ¼ . Normally, Derangements of this ratio leads to various diseases.

In cases of Vatha diseases the following stages of Naadi are seen.

- 1. Exaggeration of Vatham
- 2. Vatha pitha thondhanaadi
- 3. Vatha kaba thondhanaadi
- 4. Kaba vatha thondhanaadi
- 5. Kaba pitha thondhanaadi

Naadi is the first and foremost diagnostic parameter of the Siddhars.

In Baalavatham the following types of Naadi can be commonly seen.

They are,

Vatha pitham

Vatha kabam

Pithavatham

Kaba vatham

2. Sparisam (Palpation):

By sparisam, the temperature of skin (hot and cold), smoothness or roughness, sweat, dryness, hard patches, swelling, growth, of abdominal organ, tenderness, nourishment can be felt. In *Baalavatham* warmth is felt over the affected joints. Stiffness present in both lower joint and upper joint.

3. Naa (Tongue):

By the examination of tongue, its color, coating, dryness, deviation, movements, Variation in taste and gums can be noted.

4. Niram (Colour):

By the examination of niram the type of dhegam (Body), cyanosis, redness, pallor and yellowish discoloration can be noted.

Vatha dhegi – Dark color

Pithadhegi – Yellow or Red color

Kaba dhegi – White or Yellow color

5. Mozhi (speech or voice):

In the examination of mozhi the pitch of voice (low or high) action of slurring and speech hallucination can be noted. In Baalavatham, there is difficulty in speech.

6. Vizhi (Eye):

By the examination of vizhi, pallor, redness, yellowishness, dryness, lacrimation, sharpness of vision must be noted.

7. Malam (Stools):

By the examination of malam, its nature, color, quantity, presence of blood or mucous can be noted.

8. Moothiram (Urine):

The examination of urine is classified in to two types Neerkuri and Neikuri

Neerkuri: It includes examination of color, odor, deposits, quantity and frothy nature. In Baalavatham, there would be normal straw yellow color of urine with decreased frequency of urine.

Neikuri: Prior to the day of urine examination for Neikuri and Neerkuri, the patient is advised to take the balanced diet and quantity of food must be proportionate into his appetite. He should have a good sleep. After waking up in the early morning urine collected in the glass container must be examined within 1

½ hours, a drops of gingili oil is added through the side of vitreous without any disturbing. The nature of neikuri should notice in direct sunlight.

If the drop of oil,

- 1. Lengthens like a snake –Vathaneer
- 2. Spreads like ring-Pithaneer
- 3. Appears like pearl–Kabaneer
- 4. Spreads like snake in ring, ring in pearl,
- 5. snake in pearl thondhaneer

Besides Envagaithervugal, a disease can also be diagnosed by means of other methods namely thinaigal, paruvakaalangal, uyirthaadhukkal, udal thaadhukkal, gnanaindhiryangal and kanmaindhiriyangal, hence through a knowledge about the disease can be studied out systematically and properly in Siddha system of medicine.

In Baalavatham, the pattern of Neikuri is often

"Aravena neendenagthey - Vaatham"

Mukkutram:

Vatham:

In Baalavatham,

- 1. Viyanan Affected (produces restricted joint movements)
- 2. Abanan Constipation
- 3. Samanan Affected (Due to derangement of other vaayus)
- 4. Udanan Difficulty in speech
- 5. Naagan poor intelligence

Pitham:

Pitham is located in urinary bladder, heart, head, umbilicus, pinkalai, piraanan, abdomen, stomach, sweat, blood, eye and skin. It is classified in to five types. They are,

- 1. Anar pitham it digests all inserted particles
- 2. Ranjagapitham it gives color to the blood
- 3. Saadhagapitham it is used to complete the work properly what he thinks in the mind
- 4. Alosagapitham it gives vision to the eyes

5. Pirasagapitham – it gives color to the skin.

In Baalavatham,

- 1. Saathagam Difficulty in walking.
- 2. Ranjagam Pallor
- 3. Anarpitham Loss of Appetite

Kabam:

Kabam is located is samanan, semen, fat, bone marrow, nose, chest, bones, brain, large intestine, stomach and pancreas. It is divided into five types they are

- 1. Avalambagam it controls the other four types of kabam
- 2. Kiledhagam it moistens the food
- 3. Podhagam it helps to know the taste
- 4. Tharpagam it gives cooling effect to the eye
- 5. Sandhigam it is gives lubricating effect to the joints.

In Balavatham,

- 1. Santhigam is affected because of restricted joint movements.
- 2. Kilesagam is affected difficult to moisten the food, poor appetite
- 3. Avalambagam is affected because of deranged other vaayus.

Udal Thaadhukkal:

- 1. Saaram it strengthens the body and mind
- 2. Seneer it gives power, knowledge and boldness to the mankind
- 3. Oon it gives a structure and shape to the body and is responsible for the movement of the body.
- 4. Kozhuppu it lubricates the joints and facilitates their functions
- 5. Enbu it protects the all internal organs and gives structure to the body
- 6. Moolai it is present in the bones and gives strength
- 7. Sukkilam or Suronidham mean for reproduction

In Baalavatham,

- 1. Saaram Affected (Tiredness)
- 2. Seneer Affected (Anemic)
- 3. Oon Affected (Weight loss)
- 4. Kozhupppu Affected (Weight loss)
- 5. Enbu Normal

- 6. Moolai Normal
- 7. Sukkilam / Suronitham Normal

Gnanaindhiriyangal:

The five gnanaindhiriyangal are:-

- 1. Mei feels all types of sensations
- 2. Vai for knowing taste
- 3. Kan meant for vision
- 4. Mookku for knowing the smell
- 5. Sevi

In Baalavatham "Mei" is affected. This is due to stiffness and deformities,

Kanmaindhiriyangal:

The five kanmaindhiriyangal are:

- 1. Kai majority of normal works are done by kai
- 2. Kaal for walking
- 3. Vaai for speaking
- 4. Eruvaai for defecation
- 5. Karuvaai for reproduction

In Baalavatham– Kai and Kaal are affected. This is due to stiffness and deformities. Eruvai affected constipation. Vai affected difficulty in speech.

Thinaigal:

- 1. Kurinji- Mountain and its surroundings, kabanoigal and liver diseases are common.
- 2. Mullai– Forest and its surroundings, pithanoigal, vathanoigal, liver diseases are Common.
- 3. Marudham– Field and its surroundings, safest place to maintain good health.
- 4. Neidhal— Sea and its surroundings, vatha diseases and liver enlargement are common.
- 5. Paalai –Desert and its surroundings, vatha, pitha, kabanoigal are common.

Study five lands are very much needed, as some diseases are common in the particular lands.

Paruvakaalangal:

A year is classified into six seasons, each constituting two months.

They are,

1. Kaar kaalam – Aavani and purattasi

2. Koodhirkaalam – Iyppasi and karthigai

3. Mupanikaalam – Maargazhi and Thai

4. Pinpanikaalam — Maasi and panguni

5. Elavenirkaalam – Chithirai and vaigaasi

6. Mudhuvenirkaalam – Aani and Aadi

Some of the diseases, during a particular season are commonly prevalent and study of it was also being much useful to diagnose. The final diagnosis is confirmed by summarizing all the clinical findings observed by the above methods.

Change in lifestyle, occupation, food and habits lead to development of this disease by causing derangement of macro elements in the body (panchaboothangal). Improper food habits alter the elemental composition directly while the other causes lead to derangement of these elements indirectly. When the elemental composition is altered uyirthaathukkal or the three humors which are made up of these elements naturally get deranged. This simultaneously leads to derangement of seven udal thaathukkal, which produces symptoms of Baalayatham.

Noi Kanippu Vivaadham (Differential Diagnosis):

There are certain other vatha diseases, which resemble the clinical symptoms As Baalavadham, but they differ in some ways. The careful and clear History taking an examination was revealing the correct diagnosis.

They are sirasthambavatham, thasai vatham.

Line of treatment:

In Siddha system, the treatment is based upon the Mukkutra theory. Treatment is not only for healing it helps to the prevention of disease and rejuvenation of Udal Kattugal. While treating a disease, it is essential to know the etiology, the nature of the patient, severity of the illness, the seasons and the time of occurrence.

Line of treatment is as follows:

- 1. Neekam (Treatment)
- 2. Niraivu (Restoration)
- 3. Kaappu (Prevention)

I. Neekkam (Management in Siddha):

The aim of treatment is based on,

- 1. To restore the three humors to normal equilibrium state.
- 2. To treat the patient with mahaanaluurvachooranam as internal medicin.
- 3. Agni (the digestive fire) is balanced
- 4. Udarthadhukkal (7 body tissues) are functioning normally.
- 5. To promote self healing and resistance to disease.
- 6. To prevent the other complications.

To bring the three Thodams to normal equilibrium state, first the deranged Vatham has to be brought to its normal state by giving purgation .As it is said that Viresanam.

II. Niraivu (Restoration):

Patients are advised to lead a healthy lifestyle changes promotes disease free life. The patients are well motivated. The nature and course of the disease is explained to them, Life-style modification advised.

Diet regimen

Intake of bitter, astringent and pungent taste in excess, consumption of cold foods, intake of millet etc., aggravate vatham.

முத்தோடங்களை மிகுதிபடுத்தும் சுவைகள்:

```
புளிதுவர் விஞ்சுங் கறியார் பூரிக்கும் வாதம்
ஒளியுவர் கைப்பேரில் பித் துச் சீறும் - கிளிமொழியே
கார்ப்பினிப்பு விஞ்சிற் கபம்விஞ்சுஞ் சட்டிரதச்
சேர்ப்புணர் நோயணுகாதே
```

முத்தோடங்களை சமன்படுத்தும் சுவைகள்

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வாத மேலிட்டால் மதுரம் புளியுப்பு
சேதமுறச் செய்யும் சிரயம் - ஓதக்கேள்
காரந் துவர் கசப்பு காட்டுஞ் சுவையெல்லாம்
சாரப் பரிகாரஞ் சாற்று
```

-கண்ணுசாமியம்

Children with paresis may have a harder time getting sufficient nutrients due to the physical difficulties of chewing and swallowing. The main goal in a diet is to provide high quality foods that are easy to eat or drink. Healthy, high calorie foods are especially important since it can be difficult for many children to physically eat enough to meet their nutrition requirements. Constipation and acid reflux are the most common physical symptoms. This is due to poor muscle tone that affects the ability to push stool through the colon and of the lower esophageal sphincter, which causes the stomach's contents towash back up into the esophagus causing acid reflux.

Limit processed foods with low nutritional value as much as possible and focus on calorie dense, easily digestible, warm food, brinjal, milk, garlic, dry grapes and berries, nutritious foods and high quality fats. Consider adding calorie rich smoothies to the daily diet containing high calorie fruits (bananas, dates, mangos, avocados) and green leafy vegetables along with powdered greens for extra vitamins and minerals. Healthy fats such as nut butters, coconut milk, and coconut oil will also instantly increase nutrition and calorie count and can be added to smoothies or used as a spread on bread. Leafy greens such as kale, spinach and collards can be added to smoothies and also shredded and added to almost any food: meatballs, pasta, casseroles and sauces. Leafy greens will add extra vitamins and minerals as well as fiber and bulk which can help with constipation.

III. Kaappu (Prevention):

As per Siddha system, Vinaipayan or Kanmavinai" (Genetic disposition) is a cause for certain disease. This type of kanmavinaigal is to be corrected not only by regular treatment but also by the following methods:

- 1. Cultivating good mental thoughts by doing meditation
- 2. Yogaasanam
- 3. Kayakalpam is a transformative approach to health and consciousness to prevent and to be free from the chronic condition.

Thokkanam:

In our Siddha system thokkanam is one of the 32 types of external therapies. The unique remedy of its kind among all and which is subdivided into nine more procedure is called Thokkanam. Thokkanam as a whole focus on treating diseases caused by aggrevation of VATHAM the kinetic force of the body. The humoral theory of siddha states that vatham is the active force responsible for the physiological functioning of neuromuscular as well as musculoskeletal systems. Thokkanam is also useful in diseases where pitham as well kapham is deranged. Simple thokkanam wipes of sedentary feel which is kapham aggravation.

Thokkanam is a word combined by 2 words, Thokku + Anam; Thokku means skin; Anam means support/ tones/ heat. Toning the skin, muscles, nerves where vatham lives. It's also called Marthanam. As per siddha aspect the meeting points of muscles, nerves, joints and skin including hair roots are places of flow of vital Vatham energy. A depletion of vatham vital energy leads to derangements such as pain, altered tone, power, twitching, spasticity, rigidity, numbness and neuritis [25].

Types of thokkanam [106]:

- Thattal (Friction)
- Irukkal (Wringing)
- Pidithal (Draining)
- Murukkal (Kneading)
- Aluththal (Gliding)
- Iluthal (Pulling)
- Kaikattal (Tying)
- Mallathuthal (Supinating)
- Asaithal (flexion or extension of limbs)

Benefits of thokkanam [25]:

- 1. Restore the deranged vatham, pitham, kapham humors in normal ratio.
- 2. Tones the skin, muscles and nerves.
- 3. Disseminates vatham and eliminates if excess
- 4. Improves the nutrition of muscles.
- 5. Relaxes and increases sleep.
- 6. It enhances circulation, expel toxins, aids digestion
- 7. To promotes growth and strength

B. MODERN ASPECTS

Anatomy of the Neurological Lesions:

The brain, spinal cord and peripheral nerves constitute an organ responsible for perception of the environment, a person's behavior with in it, and the maintenance of the body's internal milieu in readiness for this behavior. The human nervous system can be divided into two interacting subsystems, the peripheral nervous system (PNS) and central nervous system (CNS). CNS consists of the brain & spinal cord. The PNS is an extensive network of nerves connecting the CNS to the muscles and sensory structures. The peripheral nervous system divided into somatic nervous system (voluntary) relays information to and from skin, skeletal muscles and autonomic nervous system (ANS) relays information to internal organs. ANS further divided into sympathetic nervous system (controls organs in time of stress) and parasympathetic nervous system (controls organs when body is at rest) [6].

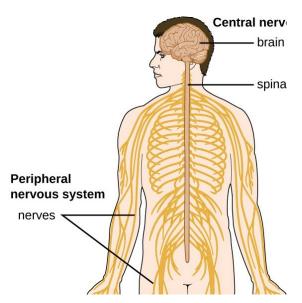


Figure 1 Types of Nervous system

The functioning of the nervous system rest upon the two physiological processes: the generation of an action potential with its conduction down axons, synaptic transmission of impulses between neurons and muscle cells.

The brain is responsible for all functions of the body, to serving as the coordinating center for all sensations, mobility, emotions, movements and intellect ^[7]. It controls and coordinates all essential functions of the body including all other body systems allowing the body to maintain homeostasis or its delicate balance. Protection of the brain is provided by the bones of skull, which in turn are covered by the scalp is composed of outer layer of the skin, which is loosely attached to the aponeurosis, a flat, broad tendon layer that anchors the superficial layers of the skin is called periosteum. Bony layer of the skull are three layers of membranes called meninges that surround brain. The meningeal layers covered by duramater, arachnoid mater and pia mater ^[11].

REGIONS OF THE BRAIN [12]

Cerebellum - Coordination of movement and aspects of motor learning.

Cerebrum - Conscious activity including perception, emotion, thought and planning

Thalamus - Filters and then relays information to various brain regions

Medulla - Vital reflexes as heart beat and respiration

Brainstem - Medulla, pons, midbrain (involuntary responses) and relay information from pine to upper brain.

Hypothalamus -Involved in regulating activities, internal organs, monitoring information from the autonomic nervous system, controlling the pituitary gland and its hormones and regulating sleep and appetite.

CEREBRAL HEMISPHERES:

Cerebrum ^[13] is the largest portion of the brain encompasses about two-thirds of the brain mass. It consists of two hemispheres divided by a fissure is called corpus callosum. It includes the cerebral cortex, medullary body and basal ganglia. Cerebral cortex is the layer of the brain often referred to as gray matter because it has cell bodies and synapses but no myelin. The cerebral cortex constitutes the highest level of nervous function, the anterior half dealing with executive functions and the posterior half constructing a perception of the environment. Each cerebral hemisphere had four functionally specialized lobes. Many of the functions are lateralized.

To which side depends on which of the two hemispheres is dominant i.e where language function is represented. The Frontal lobes are concerned with executive function, movement and behavior. In addition to the primary and supplementary motor cortex, there are specialized areas for control of eye movement, speech and micturition control [12].

The parietal lobes are concerned with the integration of sensory perception. The primary sensory cortex lies in the post central gyrus of the parietal lobe. In the temporal lobes are the primary auditory cortex and primary vestibular cortex. This temporal lobe contains many structures associated with the limbic system including the hippocampus and amygdale, which are involved in processing of memory and emotions. The occipital lobes are principally concerned with the visual processing. Collection of cells in the depths of the hemispheres deal with motor control (basal ganglia), the appropriate attention to sensory perception (the thalamus), emotion and memory (the limbic system), and control over internal bodily functions (hypothalamus). The cerebral ventricles contain the choroid plexus; this produces the cerebrospinal fluid (CSF), which cushions the brain within the cranium [11].

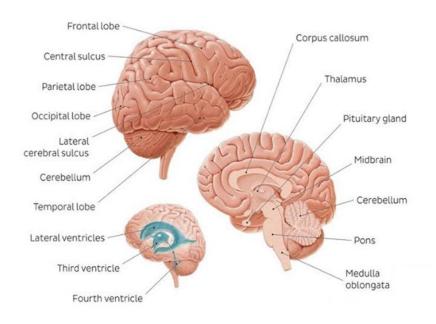


Figure 2: Parts of brain

Table 1:Cortical Lobar Functions: Effects Of Damage [31]

S.	Lobes	Functions	Cognitive / Behavioral
no			
		Personality	Disinhibition
1.	Frontal lobe	Emotional control	Lack of initiation
		Social behavior	Antisocial behavior
		Decision making	Impaired memory
		Contra lateral motor	Expressive dysphasia
		control	Incontinence
		Language	Emotional insensitive
		Micturition	Versive seizures
			Grasp reflex
			DTR exaggerated
		Language	Dysphasia
2.	Parietal	Calculation	Dyscalculia
		Spatial orientation	Dyslexia
		Constructional skills	Apraxia
		Stereognosis	Agnosia
		Sensory motor planning	Focal sensory seizures
		Auditory perception	Receptive aphasia
3.	Temporal	Language	Dyslexia
		Verbal memory	Impaired verbal memory
		Smell	Psychomotor seizures
		Balance	Complex hallucinations
			(smell, sound, vision)
		Visual processing	Visual inattention
4.	Occipital	Facial recognition	Visual loss
			Visual agnosia

The Brainstem [12]

In addition to containing all the sensory and motor pathways entering and leaving the hemispheres, the brainstem houses the nuclei of the cranial nerves. The cranial nerve nuclei provide motor control to muscles of the head and some in the neck,

along with coordinating sensory input from the special senses, organs, face, nose,

mouth and larynx, pharynx. They also control autonomic functions including

papillary, salivary and lacrimal functions and control of conjugate eye movements,

maintenance of balance, cardio respiratory control and maintenance of arousal.

Spinal Cord

It contains collection of the cells which are responsible for lower order motor

reflexes and the primary processing of sensory information, including pain.

Lesions in various parts of the motor system produce negative symptoms of

weakness, lack of coordination, lack of stability and stiffness or positive symptoms

such as tremor, chorea, athetosis, tics and myoclonus [13].

The Motor system:

The programme of the movement formulated by pre-motor cortex is converted into

a series of muscle movements Sin the motor cortex and then transmitted to the

spial cord in the pyramidal tract. The motor system consists of hierarchy of control

mechanisms that maintain body posture and baseline muscle tone upon which a

specific movement is superimposed [11].

Lesions Involving in the Spinal Cord $^{[10]}$:

Paraparesis: Weakness in both lower limbs

Tetraparesis: Weakness in the all four limbs and it's also called as quadriplegia.

Hemiparesis: Weakness down one side of the body

Monoparesis: weakness in the one extremity only.

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Table 2: Features of Localization in Spinal Cord $^{[6]}$ $^{[10]}$

Cord	Clinical features	Muscle paralyzed	Reflexes
segment			
C ₃ -C ₄	Pain in neck and occipital	Lower parts of	
	pain paresthesia and	trapezius, supra spinatus	
	weakness in upper limb	and infra	
	early relative anesthesia of	Spinatus Muscle of	
	face paralysis of 6th, 10th	upper limb, Diaphragm	
	and 11th cranial nerve.		
\mathbf{C}^7	Quadriplegia	Triceps and	Triceps (C6-7) lost
	Paraplegia	extensors of wrist	
		and fingers	
C ₈₋ T ₁	Spastic paralysis of trunk	Triceps and extensors of	Triceps (C6- 7) lost
	and lower limbs Paralysis of	wrist and fingers	In upper limb normal,
	ocular sympathatheic	Flexors of wrist and	exaggeration in lower
T_6	sometimes Spastic paralysis	fingers and muscles Of	limb Upper
	of muscles of	hand. Intercostals, upper	abdominals and lower
	abdomen and lower limbs	and lower rectus	abdominals lost
		abdominis, oblique	
		abdominis.	
T ₉ -T ₁₀	Spastic paraplegia	Lower half of rectus	Upper abdominals
		abdominis	normal lower
			abdominals lost
T1 ₂ L ₁	Spastic paraplegia	Lower fibers of oblique	
		abdominis, transversalis	
		lliopsoas	
L ₃₋₄	Spastic paraplegia	Quadriceps,	Knee jerk (l2-4) lost.
		abductors of hip	Ankle jerk + (S ₁₋₂).

S ₁₋₂	Flexion of hip, adduction of	Glutei, calf muscles	Knee jerk and Ankle
	thigh, extension of knee and	anterior tibial and	jerk lost, plantar
	dorsi flexion of	peroneal, small	reflexes lost
	foot possible. All other	muscles of foot	
	movements in lower		
	extremities weak		
S ₃₋₄	No paraplegia.	Paralysis of external	Anal and Bulbo
	Retention of urine	sphincter	cavernous reflexes
	and feces		lost. DTR normal
Cauda	1.Whole cauda aesthesia	Paralysis of lower	Absent deep reflexes
equina	below folds of groin,	limb	
	including genitals, loss of		
	control of bladder and		
	rectum		
	2.Upper Sacral and L3-		
	sensory loss over front and	Paralysis of gluteal.	Knee jerk and ankle
	posterior and outer	Hamstring and all	jerk lost
	aspect of thigh	muscles below knee	
	3.Below S ₂ – Saddle shaped		
	area of anaesthesia,		
	incontinence of urine and		
	feces		
	4. S4-5 and coccygeal	No paralysis of	All reflexes in lower
	roots – anesthesia of	lower limb	limb normal
	anus and rectum		
		Paralysis of levator ani	

Weakness:

Motor weakness [11] [13] has been defined as a difficulty ingenerating the necessary voluntary muscle force for effective motor and movement performance. Weakness is a characteristic and common motor neurodeficit, which may or may not be

accompanied by other symptoms. Disturbance of voluntary movements in the form paresis or paralysis are the usual consequence of pyramidal tract dysfunction, cerebro vascular diseases being one of the cause. Voluntary movement disorders may also be due to non pyramidal cause, such as loss of sensory of afferent pathways, coordination disorders related to cerebellar lesions, lesions of extra pyramidal tract and alteration of cortical motor programming causing apraxia. It should be categorized into an upper motor (UMN) or lower motor (LMN) type weakness. UMN weakness predominantly affects extensor of upper limbs and flexors of lower limbs.

Table 3: Types of Neuron Lesions

	UMN LESION	LMN LESION
Tone	Spastic	Flaccid
Wasting	Minimal/ nil	Significant wasting
Fasciculation	Absent	May be present

Causes Of Limb Weakness:

- 1. Vascular lesions
- 2. Neoplastic lesions
- 3. Inflammatory lesions
- 4. Degenerative disorders
- 5. Traumatic injury

Paresis

Paresis [8][10] describes weakness or partial paralysis. Incontrast, both paralysis and the *suffix* –plegiar efer to no movement. Keeping these terms in mind, we turn our attention to spinal cord syndromes that occur when a select region of the spinal cord is damaged, resulting in a predictable pattern of neurologic deficit.

Muscle weakness in the muscle group associated with the infected dermatome may be observed before, during, or after an episode of herpes zoster. The paralysis usually occurs in the first 2 to 3 weeks after rash onset and can persist for several weeks. The weakness results from the spread of the virus from the dorsal root gangliato the anterior root horn.

The location of the damage determines which of two forms exists [9]:

• Central paresis

Damage to the nerve between the brain and the anterior horn cell of the spinal cord (upper motor neuron).

• Peripheral paresis

Damage to the nerve between the anterior horn cell of the spinal cord and the neuromuscular junction of the muscle (lower motor neuron).

Peripheral pareses can affect one or more nerves. Examples of isolated pareses are pareses of the radial, peroneus, or facial nerve. Damage to several nerves in the area of a nerve plexus is called plexus paresis. A distinction is made between a brachial plexus palsy (brachial plexus) and a lumbar plexus palsy (lumbar plexus).

Central paresis is classified according to the affected limb:

Monoparesis

The incomplete paralysis affects only one limb, e.g. one arm.

Paraparesis

Both legs are paralyzed; arms are not affected.

Hemiparesis

The arm and leg of one side of the body are partially paralyzed.

• Tetraparesis

It involves partial paralysis of all four limbs (arms and legs) as well as impaired control over the torso and head.

In the case of central paresis, paralyzed muscles are always on the side opposite to the brain damage. This means that damage to the left brain hemisphere paralyses the right side of the body and vice versa. In the case of peripheral paralyses, the paresis is always on the same side as the injury.

Causes of paresis [1] [12]:

The paresis is caused by damage to the motor nerve which initiates muscle movement. The nerve can be damaged by pressure, accidents, infarctions or hemorrhages in the brain, or along its peripheral course. Pressure damage is often caused by tumors or herniated discs, which inhibit signal transmission via the spinal canal (vertebral canal).

Paresis usually occurs with the following conditions [17]:

- Tetraplegia
- Multiple sclerosis
- Infantile cerebral palsy (early childhood brain damage)
- Stroke
- Traumatic brain injury
- Herniated disc
- Carpal tunnel syndrome
- Tumours
- Post polio syndrome
- Guillian barre syndrome
- Spinal muscular dystrophy
- Lambert eaten syndrome
- Thrombosis, embolism

Progression of paresis [10]:

If the cause of the nerve damage cannot be corrected, the continuous paralysis usually causes a loss of muscle mass (atrophy). It may also cause abnormalities of the connective tissue (fibrosis) in muscle fibers and increased fat deposits. The extent of atrophy and fibrosis is linked to the severity of the paralysis. Thus there is a relatively rapid loss of muscle mass in the case of severe paralysis.

Depending on the extent of the paresis, spasticity (increased muscle tension) is seen in the case of central damage because the brain cannot adequately control the spinal cord. This is why multiple sclerosis or a stroke often causes spastic paresis. The stronger the paresis, the stronger the spasticity. The combination of diminished muscle strength and increased muscle tension usually causes limited joint mobility, which may result in joint stiffness (contractures) over time.

Signs and Symptoms:

The list of signs and symptoms of paresis are [9]

- 1. Impaired movements
- 2. Weakness
- 3. Tingling
- 4. Myalgia
- 5. Numbness
- 6. Balance issues
- 7. Appearance of pathological reflexes
- 8. Speech difficulties
- 9. Increased muscle tone

The affected body part of the body is

Stiff (spastic paresis) with occasionally muscular spasm

Floppy (flaccid paresis)

Numb or painful (tingly)

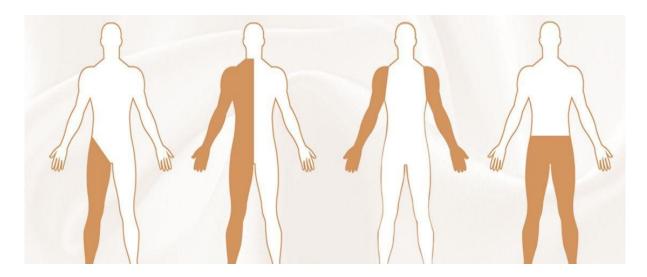


Figure 3: Types of Paresis

Hemi paresis [17] [1]:

Weakness of upper limb, trunk and lower limb of one side of the body. Hemiplegia means complete loss of motor function on that side ^[4]. Hemiparesis is usually due to involvement of contra lateral cortico-spinal tract from cerebral cortex to lower medulla or ipsilateral CST in case of a high cervical cord lesion. Hemiplegia or hemiparesis is less common in children compared to adults, but the pathological conditions varied out. ^[1,7] In children, number of conditions caused apart from stroke such as encephalitis, meningitis and abscess, neoplastic space occupying lesions, trauma, developmental anomalies of the brain. ^[5-7] a previously healthy child without hereditary predisposition suddenly becomes ill from a few months to 3 years of age. The etiology of the illness still unknown or occurring infectious diseases. ^[5] It affects one side of the body more than the other (though both sides may be affected).

- Upper limb affected more than lower.
- Hand preference obvious at an early age.
- Delayed walking (18-24 months) with a circumductive gait.

Circumductive gait: one leg is stiff and upon stepping it is rotated away from the body, and then towards it (i.e., a semicircle shape). The stiffness in the affected leg limits flexion and the patient has to raise the pelvis to swing the leg out to lift the leg enough to clear the ground ^[13].

Primary causes:

- CNS infection
- Subarachnoid haemorrhage

Secondary causes:

- Congenital heart disease
- Bronchiectasis
- Haematological causes
- Malignancy- leukemia
- Bleeding disorders such as thrombocytopenia

Features [17]:

- Difficult with gait
- Difficulty with balance while standing or walking
- Having difficulty with motor activities like holding, grasping or pinching
- Increasing stiffness of muscles
- Muscle spasms
- Difficulty with speak
- Bowel bladder involvement
- Headache and vomiting

Table 4: Site of lesion

Site of lesion	Features
Cerebral lesion	Contra-lateral cortex: distal predominant
	distribution of mild to moderate weakness with
	seiures,loss of corticalsensations,aphasia,etc.
	Contra-lateral subcortical: faciobrachial weakness
	with aphasia, homonymous visual defects.
	Internalcapsule: dense hemiplegia, hemianopia.
Brainstem	Cranial nerve palsy LMN type with crossed
	hemiparesis.
Cervical cord lesion	Ipsilateral hemiparesis sparing face
	Ipsilateral vibration and joint position sense with
	contra-lateral pain and temperature loss.

Investigations:

- **♦** CBC
- Xray spine
- **❖** MRI
- **❖** CSF study,EMG
- ❖ Nerve conduction study
- ❖ Serum calcium
- Serum electrolytes
- Genetic studies

Paraparesis:

Weakness affecting both lower extremities, paraplegia is paralysis of the lower extremities. Although weakness can be caused by peripheral nerve or muscle disease. Sudden paraplegia occurs due to spinal cord dysfunction.

The four main etiological groups in children are trauma such as falls, vascular (including anterior spinal artery infarction), inflammatory (primary infection or abscess and para infectious processes like transverse myelitis, encephalomyelitis) and compression (tumour, spingomyelia). Two most common causes of acute flaccid paralysis were guillian-barr'e syndrome and transverse myelitis with GBS.Some evidence that children have a better neurological recovery than adults.two types of paraplegia occurs. Spastic paraparesis is most commonly occurs in children. Bilateral spasticity of the limbs with legs more affected than arms.

- First clinical signs appear around the time when the child starts to crawl.
- Commando crawl: the child uses arms in a normal reciprocal manner but drags legs behind rather than using legs as well.

Intracranial – motor cortical representation for the legs is in the parasagittal region. Hence anylesion affecting the parasagittal region on both sides leads to paraplegia.

- Cerebral palsy
- Brain tumour

- Acute demylination
- Multiple sclerosis

Spinal: may be on compressive or non compressive

- Vitamin B 12 deficiency
- Vasculities
- Herpes zoaster
- Trauma
- Demyelinating disorder
- Cerebral cause accompanied by seizure, headache
- Myopathy
- Motor neuron disease
- Progressive spinal muscular atrophy in children [8]
- Viral infection

Miscellaneous:

- Drugs
- Periodic paralysis (hypokalemia or hyperkalemia)
- Tick paralysis
- Conversion disorders
- Injuries
- Genetic factors

Classification:

Based on the injury to the spinal cord

- Complete paraparesis
- Incomplete paraplegia

Based on tone:

Spastic paraplegia: it is an UMN type of paraplegia and occurs due to lesion in corticospinal tract. Causes are as follows:

- Infectious disorder
- Traumatic-spinal cord transaction

- Congenital developmental disorders like cerebralpalsy, hereditary spastic paraplegia
- Degenerative disorders
- Compressive lesions of spinal cord

Flaccid Paraplegia:

It is an LMN type of paraplegia and occurs due to lesion in anterior horn cells peripheral nerves.

Symptoms:

Weakness

Unsteadiness

Heaviness or stiffness of lower limbs

Circumduction gait

Monoparesis:

Weakness of one limb only is called monoparesis. Isolated weakness of one extremity is usually caused by a spinal cord injury or peripheral nerve lesion. Age of onset is from 1 to 11 years, and the male to female ratio is 7:4. It is occurs in 90%, with the arminvolved twice as often as the leg. The other 10% have hemiplegia or diplegia. Sensation is intact, but the paralyzed limb is painful in half of the cases.

Causes:

- 1. Birth injuries
- 2. Cerebral anoxia
- 3. Faulty myelination
- 4. Maternal infection

Clinical features:

- ❖ The limbs are clumsy
- Stiffness of muscle
- ❖ Delayed motor development with or without cognitive function

Quadriplegia:

It is also known as tetraplegia and refers to partial or total loss of use of all four limbs and torso, usually due to spinal involvement between C1 and C 7 vertebrae.

Quad is a latin word which means four: plegia is Greek word which means inability to to move. Apart from the paralysis of limbs there is autonomic and sensory dysfunction. Quadriparesis refers to weakness of all the four limbs with the upper limbs involved more than the lower limbs. Weakness may be associated with the spasticity or flaccidity. High association with cognitive deficiencies and seizure disorders [15].

- Increased difficulty swallowing due to supranu clears bulbar palsies, which can cause the child to have aspiration pneumonias.
- Most common neuropathologic lesion is PVL, but may also include basal ganglia damage.

Depending on the tone: spastic quadriplegia

- Vertebral causes- infections, trauma, disc prolapse, cranio vertebral anomalies
- Intravertebral causes: epidural abscess, leukaemia, lymphoma, neurofibroma, dermoid cyst, seeding from cerebral tumors, tumours, haemangioma, meningomyelocele.
- **Flaccid quadriplegia**: acute poliomyelitis, spinal shock, hereditary motor sensory atrophy.

Features: injuries are depend on the site,

- o Functional impairment in the arms, trunk, legs and pelvic organs.
- o Loss of sensation, loss of bowel bladder control
- Exaggerated reflexes activities or spasms
- o Pain and tingling
- Respiratory problems
- Muscular spasms

Complications of paresis:

- Difficulty breathing, coughing and risk for pneumonia.
- Blood clots and deep vein thromposis
- Speech or swallowing problems
- Depression and anxiety
- Urinary incontinence and loss of bowel control

Diagnosis:

It depends on the medical history and physical exam. To find out the underlying cause this condition. Tests that your child might have include, Abnormalities of tone posture, involuntary movements and neurological Deficits should be recorded. Evaluation includes perinatal history, detailed neurological and developmental examination and assessment of language and learning disabilities. Inborn Errors of metabolism may need to be excluded by screening of plasma amino acids and urine organic acid, reducing substance.

Laboratory investigations:

- MRI, which can identify some causes of paralysis
- Nerve conduction studies, which test how well a child's nerves can send electrical signals from one site to another
- Gait analysis
- Tests that look at the connection between the nerve and muscle
- Lumbar puncture spinal tap, which enables the care team to look at the spinal fluid and test for certain causes of paralysis
- Genetic testing, which can help identify an underlying cause that has genetic roots
- Muscle biopsy, which gives information about the muscles
- Blood work.
- Serology
- Cytoalbuminological dissociation
- Electromyography
- X-ray skull, spine.

Management:

It is aimed at minimizing the volume of brain that is irreversibly damaged, preventing complications, reducing the child's disability and handicap through rehabilitation, reducing the risk of recurrent episodes. Early admission of patients to a specialized paralysis unit facilitates coordinated care from a specialized multi-disciplinary system. There isn't a cure for permanent paralysis. The spinal cord can't heal itself. Temporary paralysis like Bell's palsy often goes away over time without treatment. Physical, occupational and speech therapy can accommodate

paralysis and provide exercises, adaptive and assistive devices to improve function. These rehabilitation services can help people with all types of paralysis live independently and enjoy a better quality of life. Treatment is depends on the site of lesions on various types of paresis. It aimed to treat the identified cause.

Physiotherapy- it influences the physical and functional status of the children.Improves posture and integrates reflexes of child. It makes movement easier by training more typical patterns of movements. Also improves the gross motor skills, muscle strength, power, mobility, gait, range of motion.

Rehabilitation-

To improve the abilities that you need for daily life. These abilities may be physical, mental, and cognitive. In all cases, the major aim of rehabilitation is to regain maximum function and quality of life. Both physical and occupational therapy can significantly improve the quality of life [13].

Occupational therapy –

It is branch of healthcare that helps people all the ages that have physical, sensory or cognitive problems. It helps to regain the independence in all areas of their lives in childhood. It also develops fine motor skills, hand eye coordination and sensory processing problems. Therapists may also recommend a hand splint for active use or for stretching at night. OTs educate patients and family on compensatory techniques to continue participating in daily living, fostering independence for the individual - which may include, environmental modification, use of adaptive equipment, sensory integration, etc.

- > Speech therapy
- > Symptomatic treatment
- Surgical treatment
- > Supportive care:
- Respiratory support
- ➤ Nutritional care adequate nutritional supplementation
- Chest physiotherapy- respiratory exercise
- ➤ Release of pressure- decompression surgery
- Decreasing the spasticity using the drugs

- > Maintenance of temperature
- > Psychological therapy to prevent depression
- Counseling
- > Prevention of clots- physiotherapy, special inflatable pumps placed over the legs to improve circulation
- > Prevention of further injury

C. REVIW OF DRUG LITERATURE

Internal Medicine: Maha AnaluruvaChooranam

1. Chukku (Zingiber offinale Linn.)

வேறுபெயர்கள்; அருக்கன் ,ஆர்த்ரகம் ,உலர்ந்தஇஞ்சி ,உபகுல்லம் ,கடுபத்திரம் ,சுக்கு , சொண்டி, சௌவர்ணம்,சௌபன்னம், நவசுறு , நாகரம்,விச்வபேஷஜம், மநௌஷதம் , விடமூடியஅமிர்தம் , வேர்கொம்பு.

Taxonomical classification *Kingdom - Plantae; Division - Magnoliophyta; Order- Zingiberales; Family- Zingiberaceae; Genus- Zingiber; Species- Z. officinale

General characteristics:

வாதபிணிவினறூதற்செவிவாய் வலிதலைவலிகுலைவலியிருவிழிநீர் சீதத்தொடுவரிபேதிபலரோ சிகமலிமுகமகமுகமடிகபமார் சீதச்சுரம்விரிபேதச்சுரநோய் தெறிபடுமெனமொழிகுவர்புவிதனிலே ஈதுக்குதவுமிதீதுக்குதவா தேனும்விதியிலைநவசுறுகுணமுனவே

-தேரன் குணவாகடம்

சூலைமந்தம் நெஞ்செரிப்பு தோடமே பம்மழை மூலம் இரைப்பிருமல் மூக்குநீர் வாலகப தோடமதிசாரந் தொடர்வாத குன்மநீர்த் தோடம்ஆமம் போக்கும் சுக்கு

-அகத்தியர் குணவாகடம்

Organoleptic characteristics: Useful part - Rhizome; Taste - Pungent; Potency - Hot; Division - Pungent

Habitat: Ginger plants can grow to about 1 m tall. The upright shoots sprout from the rhizome at the base of the plant. Rhizomes are aromatic, thick lobed, knobbly and fleshy, covered in ring-like scars. The rhizome grows undergroundand it appears pale yellow in colour. Leaves are green, long and 2-3 cm broad with Sheathing bases, the blade gradually tapering to a point. The flowering spikessprout directly from the rhizomes and are about 30 cm long and which begin to drywhen the plant matures. [40]

Action: Anti-thrombotic activity, Immuno-modualtory, Anti- bacterial, Anti-tumor Neuro-protective activity, Anti-viral, Anti-ulcer, Antifungal, Anti-oxidant activity, 10. Effects on Blood Clotting [41]

Phytochemicals^[41]:Cardiac glycoside, Alkaloids, Saponins, Flavanoids, Polyphenools, Reducing Sugar, Gingerol and ginerol, Paradol - Anti oxidant, Shogol - Anti oxidant, Antiinflammatory activity, Ginger flavanoids - Anti oxidant activity, Ginger and its constituents shows- Antioxidant activity and preventthe Damage of oxidative stress. **Flavanoids** - improve the cardiac circulation, Calcium - use as calcium supplement in incidence of Infants or adults

Minerals: Calcium, Sodium, Iron, Copper, Zinc, Magnese, Chromium, Cadmimum, Led Nicle Mercury

Vitamin contents of ginger: Thiamin (B1), Riboflavin (B2), Niacin (B3), Panthenic acid (B5), Vitamin B6, Vitamin C, Vitamin E. [40]

Medicinal use: Ginger possess several important medicinal properties and used extensivelyin Siddha for the treatment of vaatha diseases, cough, nausea, pain and diarrhoea. In combination with other herbal products, Ginger is used to cure several diseases such as vomiting, pitha diseases, indigestion, tastelessness, gastritis, vomiting, and loss of appetite, dyspepsia, head ache, cough, back pain, abdominal pain, hepatomegaly, sinusitis, gingivitis, otitis pharyngitis, peptic ulcer, dysmenorrhoea and toxic fever. Ginger is very good in pacifying vata dosha by its oiliness and hot properties. Ginger also acts as anti tumor via modulation of genetic pathways [53].

Scientific review: *zinigifer officinale* could increase the neurons' density in hippocampus and improved the spatial memory. Although the neuro-degeneration in hippocampus is reported to be associated with the spatial memory deficit. [41][55]

2. Kadukkai (TerminaliachebulaLinn,)

வேறுபெயர்கள்:அக்கோடம், அபையன், அமுதம், அரிதகி, ஏமவதிஐயவி, சேதகி, பத்தியம், மேகம், பூதன், வரிக்காய், வனதுர்க்கி, ரோகிணி, ஜீவனிகா, ஜீவந்தி, ஜெயா, திவ்யா.

Taxonomical classification:

Kingdom: Plantae, Division: Magnoliophyta, Class: magnoliopsida, Order: Myrtales, Family: combretaceae, Genus: Terminalia, Species: chebula

General characteristics:

தாடை கழுத்தக்கி தாலு குறியிவிடப் பீடைசிலிப்பத முற்பேதி முடம்ஆடை யெட்டாத் தூலமிடிபுண் வாதசோணிகா மாலையிரன் டாலமிடி போம் வரிக்காயால்

Organoleptic characteristics: Useful part: fruit; Taste; Thuvarppu; Potency: Hot;

Division: Inippu

Habitat ^[43]: *Terminalia chebula* Retz. Wild. Is a mediumto large deciduous tree, younger stems glabrescent, woody growing up to 30 m (98 ft.) tall, with a trunk upto 1 m (3ft. 3 inch) in diameter leaves: opposite in arrangement. Terminaliachebulais found throughout South East Asia like India, Sri Lanka, Bhutan, Nepal, Bangladesh, and Pakistan, Myanmar, Cambodia, bLaos, VietnamandThailand.In India, itis found in the Sub Himalayan tracks from Ravi eastwards to West Bengal and Assam, ascending up to the altitude of 1500 meter in the Himalayas.

Action [43] [65]: Anti-oxidant and free radical scavenging activity, Anti-spasmodic or anti- vaatha activity, Anti-vaatha activity, Anti-caries activity, Anti-bacterial, Anti-fungal, Anti-viral activity, Anti-convulsant, Hepato-protective activity, Anti-inflammatory activity, Anti-arthritic, Laxative

Phytochemicals: A number of glycoside, triterpenes, Arjunglucoside I, arjungenin, chebulosides I and II, gallic acid, ethyl gallate, punicalagin, terflavin A, terchebin, luteolin, and tannic acid^[66]. The major bio-active constituents of the fruit are tannins, anthraquinones, chebulinic acid, chebulagic acid, chebulic acid, ellagic acidand gallic acid, corilegin, β-D-glucogallin, Glucose and sorbitol. Polyphenolic compounds, triterpene glycosides, terchebulin, punicalagin, terflavin, flavonoids, reducing sugars and starch are other constituents of thefruit. Terpenene glycosides, arjungenin and arjunglucoside-I.18 amino acids and a small quantity of phosphoric, succinic, syringic and quinicacids^{[52][64]}.

Medicinal uses ^[63]: This plant displayed anti-spasmodic activity similar to that of papaverine. It is helpful as antitiode against snake bite. It improves memory because of its supportive effect on the brain nerves. In chronic fever it acted as adjuvant herb. This had capability of halt haemorrhage, fresh fruit consumption before mealtime accelerated digestion, when if used with meals. Raised memorypower, nurtures the senses and disinfects the gastrointestinal and geniti urinary system.

Scientific review [53][62]:

Oxidative stress plays an important role in the pathogenesis of many diseases. Therefore, reducing oxidative stress by reducing reactive oxygenspecies and increasing antioxidant defence may be effective in the treatment of many pathological conditions. *T. chebula* is known to be a good anti-oxidant and very helpful in the balance of nervous system. It stimulates the receiving power of five senses.

3. Pungan (Pongamia pinnata Linn.)

வேறுபெயர்கள்:புன்கு, பூந்தி ,கரஞ்சகம், கரஞ்சம்

Taxonomical Classification:Kingdom-Plantae; Division-Magnoliophyta; Class-Magnoliopsida; Order-Fabales;Family-Leguminoseae;Genus-Pongamia; Species-Pinnata.

General characteristics:

புங்கின்விதை காற்கிரந்தி புண் கரப்பான் காதெழுச்சி அங்கசன்னி கண்ணோய்க்கும் ஆம்பேதி யுங்கட்டும் காட்டு புங்கின் விதைக்கு கண்டதே மற்சொரிமெய்ப் பூட்டுப்பங் கின் வாய்வும் போம்.

-அகத்தியர் குணவாகடம்

வாதக்கடுப்பு மகா மூர்ச்சை தாபசுரம் வாதகுன்மம் ரத்தத்தால் வந்திடு நோய் ன்றஓதுகி -பண்புரையும் வல்விடமும் போகும் திரண்டருண்டே பண்புறுபுங் கம்வேர்க்குப் பார் -அகத்தியர் குணவாகடம்

Organoleptic characters: Useful part- Root; Taste-kaippu, thuvarppu; Potencyveppam; Division- kaarppu.

Habitat: Pongamia pinnata [34], It is a medium size glabrous tree, belongs to family fabaceae (papillonaceae), popularly known as karanj or karanja in Hindi. It is widely distributed in India, bangaladesh, china, Florida, Hawaii, and Malaysia. It is amultipurpose legume tree indigenous to the Indian subcontinent, south East Asia and one of the non-edible oil yielding tree with high potential for seed yield. All parts of this plant have been widely used as traditional medicine to treat a broad spectrum of diseases and wounds.

Actions [34][51]: Astringent, Alterative, Parasiticide, anti-septic , Stimulant, Antioxidant, Anti-inflammatory, Neuro-protective, Anti-viral, Anti-bacterial, Anti, hyperglycaemic, Anti-lipid per-oxidative, Anti-diarrhoeal, Anti-ulcer and, Anti-Hyperammonemic, Anti Plasmodial activities.

Chemical constituents: Pongamia pinnata seeds contain six compounds (two sterols, three sterol derivatives and one disaccharide) together with the eight fatty acids (three saturated and five unsaturated). The metabolites, β-sitosteryl acetate galactoside, stigma sterol, galactoside and sucrose. The saturated and unsaturated fatty acids (two monoenoic, one dienoic and two trienoic) Oleicacid occurred in highest amount (44.24%), stearic (29.64%) and palmitic (18.58%) acids were the next in quantity. Hiragonic, octadecatrienoicacids (0.88%).Karangin, pongamol, pongagalabrone pongapin, pinnatin and kanjone^[51].

Scientific review ^[51]: Neuro-protective effect of PP, which could be due to the various phytoconstituents such as flavonoids (furanoflavonoids) and chalcones as the plants containing these phytoconstituents have been reported to be beneficial in neurodegenerative diseases. It can be concluded that PP exerts neuroprotective property, which may be due to furanoflavonoids or chalcones possessing its potent antioxidant property and either GABAergic or nmda receptor antagonising property.

4. Vaivilangam (Embeliaribes Linn.,)

வேறுபெயர்கள்:வாயுவிளங்கம்,கேரளம்,வாய்விலங்கம்,வர்னனை,வாய்விடங்கம்

Taxonomical Classification: Kingdom- Plantae; Phylum- Angiosperms; Order-Ericales; Family-Myrsinacae; Genus-Embelia; Species-ribes.

General characteristics:

பாண்டுகுட்டம் குன்மம் பருந்தூலநோய் வாதத் தீண்டு திரிவிடஞ் சிரந்துண்டம் - பூண்டமடி நோய் விளங்கக் காட்டாதநுண் கிருமி யாசனப்புண் வாய்விளங்கங் காட்ட விருமார்

-அகத்தியர் குணவாகடம்

வாதகுருவாயுடம்புவாதமருத்தப்படியே வேதையிலோகங்களிலேவேண்டினாற் -பாத விரதமுதற்கையாடலென்றாலிசையும் வர்னனை நீ மனத்தில்வை

-தேரன்வெண்பா

Organoleptic characters: Usefulpart-Seed; Taste-kaippu; Potency-veppam; Division-kaarppu.

Habitat [69] [70]: It is an indo-malaysian species. Distributes throughout mountainous region of India up to an altitude of 1500 m, mainly in states of

Maharashtra, Karnataka, and kerala in Western Ghats and Tamil nadu in Eastern Ghats. It is reported that the plant is in threat in Karnataka and Maharashtra and at a little danger position in Kerela.

Actions: Anthelminthic, Carminative, Stomachic, Stimulant, Anti-oxidant, Anti-inflammatory, CNS depressant activity, Neuro-protective activity, Anti-bacterial, Anxiolytic activity, Anti-hyperlipidemic, Anti-cancer, Cardio-protective activity, Anti-convulsant, Anti-anxietic, Hepato-protective [67].

Chemical constituents^[68]: The vilangin compound was extracted from the dry ripe berries of E. ribes plant, volatile oils, fixed oil, resin, tannin, christembine (alkaloid), phenolic acids such as caffeic acid, vanillic acid, chlorogenic acid, cinnamic acid, o-cumaric acid from the berries of E. ribes plant. Embelinol, embeliaribyl ester and embeliol. The embelin found is 4.33% in the fruit part. It ^[71] also contains components like potassium embelate, 2-5 dihydroxy-4-undecyl-3-6-benzoquinone, quercitol and fatty ingredients.

Minerals [68]: Cr, K, Ca, Cu, Zn and Mn along with carbohydrates, steroids, cardiac glycosides, alkaloids, anthraquinones, tannins and phenolics.

Medicinal uses ^[37]:To expel excess vathathosha, our energy and mobility, as well as nerve impulses are all controlled by vatha. Vaatha manifest itself breathing, speech, circulation and digestion. It detoxifies blood, hence useful in wide range of skin diseases. It has contraceptive effect, along with Pippali (long pepper) it improves skin complexion and also used for rejuvenation purpose. Its water decoction is used for oil pulling to relieve dental caries and bad breath. In skin diseases, it is used both orally and externally in the form of paste. It has mild diuretic action. It is useful against vomiting, bloating, indigestion. To expel excess Vata dosha (Vata Dosha is made up of the characteristics of the elements ether Scientific review^[37] ^[71]: The aqueous extract of the E. ribes plant increases the antioxidant defense against middle cerebral artery occlusion induced cerebral infarction in rats by a significant increase in the post-stroke grip strength activity. In another study, the ethanolic extracts wereadministered orally to methionine-inducedhyperhomocysteinemic rats. Results showed a significant reduction in the

homocysteine, LDH, totalcholesterol, triglycerides, and LPO level in brain homogenates and a significant increase in serum HDL-C levels and GSH content in brain homogenates was observed when compared with pathogenic control rats.

5. Aaviliyamver (Holoptelia integrifoliaLinn,.)

வேறுபெயர்கள்: பூதிகம்

Taxonomical classification : Kingdom -Plantae ;Division - Magnoliophyta ; Class - Dicotyleydons ;Order-Rosales ;Family-Ulmaceae ; Genus - Holoptelia ; Species-Integrifolia.

General characteristics:

ஆயிலுரியை யடுநீறு நித்திய மெய் யாயிலுரியை யெனி லாவிமிசை - யாயில் வரிசையாக் கற்கு நிகர் வல்லியட்டுண் மெய்க்கு வரிசை யாக்கத்தை யுறுவை

-தேரன்யமகம்

Organoleptic characteristics: Useful part - Rhizome, bark; Taste - Pungent; Potency - Hot; Division – Pungent.

Habitat ^[75]: The plant belongs to family Ulmaceae. It is commonly known as Indian Elm Tree. A small genus of trees distributed in tropical and sub-tropical parts of Asia and Africa. One species occurs in India (*Holoptelea integrifolia*]. It is found in Punjab, M.P, Bihar, Assam, Bundelkhand, Tamil Nadu and Sub Himalayas region in India.

Actions^[74] [72]: Counter-irrestena, counter- irritant, Febrifuge, anti oxidant, anti viral, analgesic, CNS depressant activity, anti-fungal, anti- bacterial, anti-inflammatory, hepato-protective, anti-tumour.

Chemical constituents:

Two triterpenoid fatty acid esters Holoptelin-A and B, 2- -sitosterol and its β -D-glucose (stem bark); β amino - naphthaquinone, fiedelin, epifriedelinol, dihydroxyelan β , α -12-en-28-oic acid and hederagenin (heartwood); sitosterol-2 amyrin (leaves); carbohydrates, pigments, α 3 hexacosanol, octacosanol,

acids,βsitosterol and βoils, glycosides, sterols, tannins, proteins, free amino acids, oleicβmajor fatty acids- palmitic acid, -sitosterol and acid, myristic, stearic, linoleic and linolenic acids; and steroids- stigmasterol (dried seeds); histamine and 5 hydroxtryptamine (pollens)

Medicinal uses ^[73]: This holoptelia integrifolia plant root and bark is used for vaatadhosas and mukkutradhosas. This powder is to given vaadha diseases.Plant is useful in treatment of obesity, edema, and bronchitis. It has been known to be protease inhibitor. Mucilage and juice obtained from boiled bark has been reported to be useful in rheumatism, intestinal tumourwhen applied externally. Bark juice is applied to rheumatic swellings ^[76]. Bark juice is useful as oxytoxic in pregnancy. Paste of seeds and bark stem is externally useful in ringworm, eczema and cutaneousaffections. Paste ofstem bark is applied externally to treat inflammation.

They are useful in inflammations, acid gastritis, dyspepsia, flatulence, colic, intestinal worms, vomiting, wounds, skin diseases, vitiligo, leprosy, filariasis, obesity, diabetes mellitus, haemorrhoids and rheumatism. Seeds are useful in infected ulcers and as a deodorant for foul smell of body.

Scientific review ^[76]:The findings revealed that the test extract caused significant reduction in exploratory behavioral pattern in head dip test and reduction in muscle relaxant activity in rota rod and traction tests. These findings confirmed the CNS depressant activity in tested animal models. *H.Integrifolia* was screened for antioxidant activity by 1,1-diphenyl-2-picrylhydrazyl (DPPH) using HPLC method, and total phenolic content was also estimated. MSBE was found to be most potent antioxidant and had more phenolic content than the MLE. The higherphenolic content of MSBE might have contributed to higher antioxidant activity of MSBE.

6. Thippili (piper longum Linn.,)

வேறுபெயர்கள்:அம்பினடி கிரந்திவேர் கிரந்திகம் தன்மன்மூலம், திப்பிலிக்கட்டை, ரதிந்திகம், நதிகரந்தை, நறுக்குதிப்பிலி, மோடிவேர் **Taxonomical classification:**Kingdom – Plantae;Division – Magnoliophyta;Class – Dicotyleydons, Order- Rosales; Family – Ulmaceae; Genus – Piper; Species – Longum.

General characteristics:

பாண்டுகுட்டம்குன்மம்பருந்தூலநோய்வாதத் தீண்டுதிரிவிடஞ்சிரந்துண்டம் - பூண்டமடி நோய்விளங்கக்காட்டாதநுண்கிருமியாசனப்புண் வாய்விளங்கங்காட்டவிருமார்

- அகத்தியர்குணவாகடம்

வாதகுருவாயுடம்புவாதமருத்தப்படியே வேதையிலோகங்களிலேவேண்டினாற் -பாத விரதமுதற்கையாடலென்றாலிசையும் வர்னனைநீமனத்தில்வை - **தேரன்வெண்பா**

Organoleptic characteristics: Useful part- Rhizome, bark; Taste- sweet; Potencycold;

Division- sweet.

Habitat ^[77]: It occurs in the hotter parts of India, from the central Himalayas to Assam, the khasi& the mikir hills, the lower hills of Bengal & the evergreen forests of the Western Ghats from konkan to Travancore.

Actions: Stimulant, carminative, Antibacterial, Anti-oxidant, Anti-Inflammatory, Anti-spasmodic, Anti-convulsant, Anti-tumor, CNS Stimulant ^[79], Anti-tubercular, Hypoglycemic, Cough Suppressor, Anti giardial, Immuno-stimulatory, Hepato-protective, Analeptic ^[78].

Chemical constituents^[79]:Volatile oil, resin, piperine, piperlongumine, piplasterol, pippalartin, piplartine, sylvatin, sesamin, diaeudesmin, piperlingumine, pipermonaline, piperundecalidine, brachyamide A, brachyamide B, brachystine, sterols, glycosides. Essential oil.Mono and sesquiterpenes, caryophyllene (mainly), Pipernonaline, Pipercide, Sesamin, B- sitosterol four aristolactams(cepharanone B. aristolactum A- Il. Piperlactum A and piperolactam B) five 4-5 dioxoaporphines etc.

Medicinal uses [80]: It act as a valuable alternative tonicin paraplegia, chronic cough,

Enlargement of the spleen and other abdominal viscera. Long pepper is used in the composition of several snuffs; boiled with ginger, mustard oil, butter-milk and curds it forms aliniment, used in case of paralysis. In the Konkan region, the roasted fruits are beaten up with honey and given to treat rheumatism; they are also given powdered with black pepper and rock salts (2 parts of long pepper and 1 of salt) in half tola dosesact as a valuable. It strengthens the nervous system, improves the gastrointestinal condition and normalizes the peristaltic movements. Its oil and paste is applied on wounds and skin-related ailments. This herb [42] helps maintain the normalcy of the digestive tract and tones up the urinary tract. Its fruits are used for respiratory tract diseases like cough, bronchitis and asthma. It benefits in anorexia, indigestion, flatulence, pain, hyperacidity, piles, paralysis of the tongue, diarrhoea, cholera, chronic malaria, viral hepatitis, diseases of the spleen and tumours. The decoction of the plant is used in sciatica and hemiplegic. Long pepper is used in the composition of several snuffs, boiled with ginger, mustardoil, buttermilk and curd it forms a liniment used in case of paralysis.

Scientific Review ^[42]: Cognitive enhancing activity of *Piper longum* Madhaviet al. (2012) investigated the cognitive enhancing activity of ethanolic fruit extract of P. longum by using two methods; elevated plus maze and passive avoidance task methods. The results of the study showed significant effect as compared to control; there was significant increase in the step down latency and decrease in the transfer latency, revealing cognitive enhancing activity of P. longum.

7. Kodiveli (plumbago zeylanica Linn.)

வேறுபெயர்கள்: அழல் ,எரி ,கணலி ,சித்திரமூலி ,தழல், திக்கு ,திசைநா, அக்னி ,திகனா, வன்னிபிரியம், கொடிவன்னி ,திவிபிநாமம் ,உதாசனன்

Taxonomical classification:Kingdom-Plantae ;Division – Magnoliophyta; Class –Magnoliopsida; Order – Caryophylales, Family – Plumbaginaceae; Genus – plumbago; Species – Zeylanica.

General characteristics:

கட்டிவிரணங்கிரந்திகால்கள்அரையாப்புக் கட்டிச்சூலைவீக்கங்காழ்மூலம் - முட்டிரத்தத் கட்டுநீறேற்றங்கனத்தபெருவயிறும் அட்டுங்கொடிவேலியாம்

- அகத்தியர் குணவாகடம்

Organoleptic characteristics: Useful part- Rhizome; Taste- Kaarppu; Potency-

veppam

Division- kaarppu.

Habitat ^[44]: *Plumbago zeylanica*, commonly known as chitrak or lead wort-white flowered is innate to South Asia. It is dispersed in tropical and subtropical countries of the world. Budding in deciduous woodland, savannahs, and scrublands from sea level up to 2000 m altitude. In India it is sprinkled in central India to West Bengal, Maharashtra, and Uttar Pradesh to some parts of South India.

Actions ^[81]: Anti-periodic, Diaphoretic, Anti-oxidant, Anti-inflammatory, CNS stimulant activity, Anti-viral, Anti-bacterial, Hepato-protective, Anti-tumour, Anti-microbial, Behavioural activity.

Chemical constituents: Plumbagin contains Plubagic acid, Beta-sitosterol4-hydroxy-benzaldehyde, Trans-cinnamic acid, 2,5-dimethyl1-7-hydroxy chromone, Isoshinanolone, Indole-3-carboxaldehyde.5,7-dihydroxy-8-methoxy-2-methyl-1,4-napthoquinone, (plumbagin), Biplumbagin, Chloroplumbagin, Maritinone, Elliptinone, 2-(1-hydroxy-1-methyl-ethyl) -9methoxy-1, 8-dioxadicy clopenta, Naphthalene-4, 10-dionic,9-hydroxy-2-isopropenyl-1,8-dioxa-dicyclopenta, Isoshinanalone, 2-isopropeny,1-9-methoxy-1,8-di-oxadicyclopenta, Lapachol Coumarins, 5-methoxy seselin, Seselin, Suberosin ,Xanthylctin , Xanthoxylctin Plumbic Acid and 3'-o-β-glucopyranosyl plumbagic acid , 3'-o-β-glucopyranosyl plumbagic acid methyl ester^[82].

Enzymes: Invertase, proteases

Other Compounds: Zeylinone, glucose, fructose, isozeylinone, droscrone, plumbaginol.

Medicinal uses [83]: Its Roots bark and seed are used in variety of alignments. The fresh juice from roots is effective for internal piles, the roots of plant raise the digestion and promote appetite, and small doses excite central nervous system. Roots of the plant have abortifacient and vesicant effects. Paste prepared from roots of the plant is applied to the skin to treat abscesses, other skin diseases including ulcers and scabies also. Operative against chicken pox and acne

Scientific review ^[81]: A study reported that hydro-alcoholic leaf extract of *Plumbagozeylanica* were evaluated for its CNS activity and it was found that the extract showed significant CNS depressant activity with the muscle relaxant properties.

8. Karunjeeragam (Nigella sativa Linn.):

வேறுபெயர்கள்: அரணம் ,உபகுஞ்சிகை

Taxonomical classification:Kingdom- Plantae; Supervision- Spermatophyte; Order- Ranunculales, Family- Ranunculaceae; Genera- Nigella; Species- sativa.

General characteristics:

கருஞ்சீரகத்தான் கரப்பானொடு புண்ணும் வருஞ்சிராய்ப் பீனசமு மாற்றும் - அருந்தினால் காய்ச்சல் தலைவலியுங் கண்வலியுங் போமுலகில் வாய்ச்ச மருந்தென வேவை

-தேரையர் குணவாகடம்

Organoleptic characteristics: Useful part – Seed, Taste – Kaippu, Potency – veppam,

Division - kaarppu.

Habitat [38]: Nigella sativa is a small elegant herb, mostly attained and cultivated in India, Southern Europe, Pakistan, Syria, Turkey, Saudi Arabia, and is a native of

Southern Europe, North Africa and South West Asia. In India, it is found in Punjab, Himachal Pradesh, Gangetic plains, Bihar, Bengal, Assam, and Maharashtra.

Action [39]: Carminative, Diuretic, Emmenagogue, Galactogogue, Anthelmintic, Stomachic, Emollient, parasiticide, Anti oxidant, Anti-viral, Anti- inflammatory, Anti-bacterial, Nervine tonic or anti-depressant' Anti-convulsant' Analgesic activity, Anti-spasmodic [85], Hepato-protective, Neuro-pharmacological activity. Chemical Constituents [86]: Black seed contains protein, fat, carbohydrates, crude fibre, total ash, volatile oil, fatty oil, cellulose and moisture alkaloids, and flavanoids. Nigellone, avenasterol-5-ene, nigellone, nigellicine, nigellimine,nigellimine-N-oxide,avenasterol-7-ene, campesterol, cholesterol, citrostadienol, lophenol, obtusifoliol, stigmastanol, stigmasterol-7-ene, β-amyrin, butyro- spermol, ycloartenol, 24-methylene-cycloartanol, taraxerol, tirucallol, volatile oil (0.5-1.6%), fatty oil (35.641.6%), oleic acid, estersof unsaturated fatty acids with C-15 and higher terpenoids, estersofdehydrostearic and linoleic acid, aliphatic alcohol, melanthin, melanthigenin, bitter principle, tannin, resin, protein, reducingsugar, glycosidal saponin^[87].

Vitamins and minerals ^[87]: potassium, phosphorus, sodium, iron are main element and Copper, Magnesium, Manganese. Zinc and Calcium found at low levels.

Medicinal uses ^[88]: According to Ayurveda, kalonji increases the pitta dosha (Fire+Waterelements), pacifies the Vata dosha (airelement) and reduces the Kaphadosha (Earth+Water+Elements). The plant issuitable for Kapha body type and Vata bodytype and mostly preferred to Vata-Kapha disorders. It is not suitable for Pitta bodytype and pregnant women. It is helpful inthe reduction of the formulation of AmaDosha (Fire element).

Scientific review ^[86]: Methanolic extract of *Nigellasativa* is a potent analgesic and antidepressant. In addition, an anxiolytic activity via increasing serotonin (5-HT) and decreasing hydroxyl indole acetic acid levels were noticed in rat brain. An increased 5-HT secretion along with improving learning and memory capacity were detected. As it caused an augment in tryptophan levels, it may be helpful in

anxiety treatment. The possible neuro-protective activity may be due to its antioxidant, free radicalscavenging and anti-inflammatory capacities along withanti-acetylcholinesterase suggests N. sativa and tq having anticonvulsant activity. Nigella EO is also evident to prevent cerebral edema in hippocampus and tissues of the brain.

9. Kadugu (Brassica juncea linn.):

வேறுபெயர்கள்: ஐயவி

Taxonomic Classification: Kingdom – Plantae, Phylum – Spermatophyta, Subphylum Angiospermae, Class – Dicotyledonae, Family – Brassicaceae, Genus – Brassica, Species - juncea.

General characteristics:

கடிப்பகையெனவரு கடுகினை நாளு மிளகி லவணத்தோடு மூன்று மொன்றாக்கி யடுபுனலருந்து முனயிலவைகறை தொறும் வளிமுதன் மூலிகை வலியெலாமகலும் பச்சடி முதற் கறிபண் பினாலயிலினு நிச்சயமாயுணிகழ்பிணியறுக்குமே

- தேரன்காப்பியம்

மந்த மயக்கம் வாதம் வாய் நீர்ச்சுழற்றலரு முந்து சுகப்பிரசவங்களுண்டா – மிந்து நுதன் மானே கிராணி குன்மமாறு முத்தோடமும்போம் தானே கடுகிற்குத் தான்

- அகத்தியர்குணவாகடம்

Organoleptic charecters: Taste – Kaaram, Potency– veppam, **Division** – Karppu.

Habitat ^[87]: Mustard grows in temperate regions worldwide. It is distributed in Africa: Algeria, Egypt, Libya, Morocco, Tunisia, Eritrea, Ethiopia; Asia: Afghanistan, Cyprus, Iran, Iraq, Palstine, Lebanon, Syria, Turkey, Armenia, Kazakhstan, China.

Action ^[88]: Stimulant, Emetic, Rubefacient, Vesicant, Digestive, and Diuretic, Anti- oxidant, Anti-bacterial, Anti-microbial, Anti-inflammatory, Anti-epileptic, Hepato-protective, nerve stimulant ^[107].

Chemical constituents: Phytochemical studies showed that the plant contained alkaloids, flavonoids, glycosides, carbohydrates, sinapine, myrosin, sinigrin, inosite, albumins, gums, and coloring matters [85]. The total phenol content in the plant was 6.67mg/g of gallic acid. It contained fatty oil (30-35%), Proteins (40%) Phenyl propane derivatives. Including sinapine and glucosinolates, chiefly sinigrin (allyl glucosinolates 1-5%). The seeds are grind into powder and mix with warm water releases the volatile mustard oil, allylisothiocynate. The phenolic compounds gallic acid, quercetin, ferulic acid, caffeic acid and rutin were determined. Brassica nigra was rich in secondary metabolites of volatile oils, anthraquinones, flavonoids and tannins [87].

Medicinal uses [107]: it was applied in neuralgia and spasms, alopecia, epilepsy, toothache. Seeds are used for purging the body of toxins. It is an ingredient of formulation that induces emesis, cleanses the cranial cavity. It improves the intellect [108].

External Medicine – Chennagarapttai Ennai

1. Chennagarapattai (oldanlandia umbellate Linn.)

வேறுபெயர்கள்: இம்பூராவேர்,இன்புறாவேர், சிறுவேர், சாயவேர்

Taxonomical classification: Kingdom – Plantae, Order – gentianales, Family – Rubiaceae, Genera – Oldenlandia, Species – umbellate.

General characteristics:

இன்புறாவேரை இதமாய்அருந்தினர்க்கு பின்புறா தையமொடு பித்தமுமே - துன்பாம் இருமல் சுவாசம் ஏரிசுரம் வயிற்றுப் பொருமலுப்பிசம் பறந்து போம்

அகத்தியர் குணவாகடம்

Organoleptic characters: Taste –Inippu, Potency – Seedham, Division - Inippu Action ^[90]: Expectorant, Styptic, cholagogue, Anti-inflammatory, Anti-oxidant, Anti-tumour, Neuro-protection, Hepato-protective, Anti-bacterial, Anti-fungal, Anti-depressive Immunomodulation.

Chemical constituents [91]: Fatty acids, Tannins, Glycosides, Chlorogenic acid, Saponins, Gum, and Mucilage. Whereas, the leaf contains Flavonoids, Steroids, Tannins, Glycosides, Saponins, Alkaloids, Carotenoids, Fatty acids, Polyuronoids, Chlorogenic acid, Gum, and Mucilage.Presence of proteins, carbohydrates, phenols, tannins, flavanoids, saponins, steroids, terpenoids and glycosides. Some of the isolated compounds from whole plants are Geniposide, iridoid glycosides, 6 alpha – hydroxygeniposide, scandoside methyl ester (6 beta hydroxygeniposide), 10-o-benzoylscandoside methyl ester, asperulosidicacid, asperuloside, deacteylasperuloside, 10-o-p-hydroxy benzoylscandoside methyl ester, rutinand (+)- lyoniresinol-3-alpha -o-beta glucopyranoside.13 The structures of some compounds are given in. Hedyotis corymbosa contains urosilic acid, oleanolic acid and gamma sitosterol. The [91] air dried Hedyotis corymbosa contains 0.12% of alkaloids - bifloron (yellow crystalline powder, M.P 980), biflorin (White crystalline powder M.P 2060), these two alkaloids are interconvertible. It also contains 13.55% of inorganic ash which is mainly responsible for its cooling effect.

Scientific review^[92]:The antioxidant activity of methanolic extract of aerial parts of H.corymbosa was determined by different invitro methods such as; 1,1 diphenyl-2-picryl hydroxyl (DPPH) assay, 2,2'-azinobis-3-ethylbenzothiozoline-6-sulfonic acid (ABTS) cation decolorization test, ferric reducing power (FRP), scavenging capacity towards hydroxyl ion (OH.) radicals and nitric oxide (NO) radical inhibition assay. The methanolic extract of aerial part showed high antioxidant activity against DPPH, ABTS, Nitric oxide and hydroxyl radical at 82, 130, 150, 170 μg/ml respectively.

2. Vasambu (Acorus calamus Linn.,):

வேறுபெயர்கள்: பேர் சொல்லா மருந்து பிள்ளைமருந்து ,சுடுவான்,உக்கிரம், வசம் ,வசை,வேணி,உரைப்பான்

Taxonomical classification: Kingdom – Plantae, Sub-kingdom – Tracheobionta, Superdivision – Spermatophyta, Division – Magnoliophyta, Subclass - Arecidae Order – Arales, Family – Acoraceae, Genus: Acorus, Species – calamus.

General Characteristics:

பாம்பாதிநஞ்சற்புதப்புண்வலிவிடபாகங்குன்மம் சூம்பாரித்தபித்தம்முகநாற்றம்வன்சூலைசன்னி வீம்பாம்பைகாசம்பீலிகஞ்சிலிபதம்வீறிருமல் தாம்பாங்கிருமியிவையேகுமாசிவசம்பினையே

- தேரன்குணவாகடம்

Organoleptic characters: Taste –Kaarppu, Potency – Veppam, Division – Kaarppu.

Habitat ^[93]: It is distributed throughout the tropics and subtropics, especially in India and Sri Lanka. It is found in marshes, wild or cultivated, ascending the Himalayas up to 1800 m in Sikkim. It is regularly cultivated in Koratagere taluk in Karnataka. The plant is grown in clayey loams and light alluvial soil of river bank. Actions: Stimulant, Stomachic, Antiperiodic, Carminative, Emetic, Disinfectant Germicide, Nauseant, Anti-oxidant ^[95], Anti-inflammatory, Anti-microbial, Neuroprotective, Anti-depressant, Memory enhancer, Anti-spasmodic, Neurotransmission, Anti-bacterial, Anti-cancer

Chemical constituents^[93]:Glycosides, flavonoids, saponins, tannins, polyphenol compounds, mucilage, Volatile oil and bitter principle, glucoside, alkaloid andessentialoilcontainingcalamen, clamenol, calameon, asarone and sesquiterpenes. It also contains a bitter glycoside named acorine along with eugenol, pinene and camphene, βasarone, aterpineol and a calacorene, acorone, acoragermacrone, 2- deca -4,7 dienol, shyobunones, linalool and preisocalamendiol are also present. Acorading to galangin, 2,4,5 trimethoxy

benzaldehyde, 2, 5 dimethoxy benzoquinone, calamendiol, spathulenol and sitosterol.

Scientific review ^[95]: The rhizome extract has sufficient amounts of vitamin C and total polyphenolic compounds. It has the potential for increasing the antioxidants capacity and function in the brain. Histological analysis showed normal features in the tissues of cerebral cortex from rats with decrease in the size of daily ip of certain dose of α-asarone before exposure to noise for four hours a day upto days. While in the cerebral cortex of rats that only had this exposure to noise, there was of neurons, as well as histological anomaly in cortical layers. Extract in combination with acrylamide, increases in the content of glutathione and the activity of glutathione-S-transferase in the striate body was found, whereas these decreased with acrylamide. Neural protective effects are attributable to the herb's action of modulation in the antioxidant Capacity.

3. Veppennai (Azadiracta indica Linn.)

வேறுபெயர்கள்: அரிட்டம், நிம்பம் ,துத்தை ,பாரிபத்திரம். பிசுமந்தம், வாதாரி, வேப்பு.

Taxonomical Classification: Order – Rutales, Sub Order- Runiae, Family– Melaiceae, Sub Family- Melioideae, Genus- Azadiracta, Species- Indica.

General Characteristics:

கிருமிகுட்டமாந்தங்கெடுவிடஞ்சுரங்கள் பொருமியமசூரிகையின்புண்கள் - ஒருமிக்க நிம்பத்திலையிருக்கநீடுலகில்நீங்காமல் காம்பத்திலையிருக்கக்காண்

- அகத்தியர்குணவாகடம்

Organoleptic characters: Taste – Kaippu, Potency – Veppam, Division – Pungent, Used Part – Seeds.

Habitat^[96]:There are an estimated 25 million trees growing all over India(15) of which 5.5% are found in Karnataka and it is in the third place next to Uttar Pradesh (55.7%) and Tamilnadu (17.8%) occupying the first two places respectively. The other states of India where neem tree is found growing includes Andhra Pradesh, Assam, Bihar, Delhi, Gujarat, Haryana, Himachal Pradesh, Kerala.

Action^[10]: Anthelmintic, Stimulant, Antiseptic, Insecticide, Discutient, Anti-inflammatory, Reduce the muscle pain, Protects against the free radicalsBalance pitha and kabhakutarm, Anti oxidant, Neuro- protective, Anti- bacterial, Anti-viral, Immune-modulatory, Hepato-protective.

Chemical constituents ^[18]: The most important active constituent is azadirachtin and the others are nimbolinin, nimbin, nimbidin, nimbidol, sodium nimbinate, gedunin, salannin, and quercetin. Leaves contain ingredients such as nimbin, nimbanene, 6-desacetylnimbinene, nimbandiol, nimbolide, ascorbic acid, n-hexacosanol and amino acid, 7-desacetyl-7-benzoylazadiradione, 7-desacetyl-7-benzoylgedunin, 17-hydroxyazadiradione, and nimbiol. Quercetin and β-sitosterol, polyphenolic flavonoids, were found.

Scientific review ^[96]: Anti-oxidant: Free radical or reactive oxygen species are one of the main culprits in the genesis of various diseases. However, neutralization of free radical activity is one of the important steps in the diseases prevention. Antioxidants stabilize/deactivate free radicals, often before they attack targets in biological cell and also play role in the activation of ant oxidative enzyme that plays role in the control of damage caused by free radicals/reactive oxygen species. Medicinal plants have been reported to have antioxidant activity. Plants fruits, seeds, oil, leaves, bark, and roots show an important role in diseases prevention due to the rich source of antioxidant.

4. Pasumpaal (Cow's milk):

வேறுபெயர்கள்: பயம் , கீரம் , சுதை ,பயசு , பாகு , அமுது , துத்தம் , சாறு

Taxonomical Classification: Kingdom – Animalia, Class – Mammalia, Order – Artiodactyla, Family – Bovidae, Genus – Bos, English Name - Cow's milk.

General characteristics:

பாலர் கிழவர் பழஞ்சுரதோர் புண்ணாளி சூலையர் மேகத்தோர் துர்பலத்தோர் ஏழுமிவர் எல்லார்க்கு மாகும்ளைத்தவர்க்குஞ் சாதகமாய் நல்லாய் பசுவின்பால் நாட்டு Chemical Constituents [17]: Fat, Protein, Lactose, Solids Not Fat, Total Solids, Water, Fatty acids.

Mineral Content of Cow's Milk [31: Calcium, Phosphorus, Potassium,

Magnesium, Sodium, Zinc, Iron, Copper, Manganese, and Iodine

Scientific Review: CNS Effects [109]: Antiepileptic activity: PanchgavyaGhrita (PG) was screened for some neurological parameters in rats and it was found that PG protected rats from maximal electroshock (MES) induced convulsions, increased the spontaneous motor activity as measured by actophotometer and inhibited the pentobarbitone induced sleep time in rats without much influence on the general behavior of the rats except increase in the general activity. PG appears to possess anti convulsant property but the degree of protection might not be sufficient to use it as single antiepileptic agent. It is concluded that PG can be used as adjuvant in treatment of epilepsy.

4. MATERIALS AND METHODS

4.1: Preparation of Experimental Formulations

Drug name:

- 1. Maha analuruvachooranam
- 2. Chennagara pattai ennai

Collection and identification of raw drugs:

The required raw drugs for preparation of Maha analuruva chooranam (internal) and Chennagarapattai ennai (External) was purchased from local raw drug market. Raw drugs were authenticated by the Medicinal Botanist in National Institute of Siddha, Chennai. The trial drug was prepared in Gunapadam lab, National Institute of Siddha, Chennai-47, under the supervision of the guide.

Ingredients:

1.	Kodiveliver (Plumbacozeylanica)	-35 gram (1 palam)
2.	Punganver(Pongamiapinnata)	-35 gram (1 palam)
3.	Aailiyamver(Chukrasiatabularis)	-35 gram (1 palam)
4.	Aailiyampattai (Chukrasiatabularis)	- 35 gram (1 palam)
5.	Chukku(zingiber officinale)	-17.5gram (1/2 palam)
6.	Vaividangam (Embeliaribes)	- 17.5gram (1/2 palam)
7.	Kadukkai(Terminalia chebula)	- 17.5gram (1/2 palam)
8.	Thippili(piper longum)	- 17.5gram (1/2 palam)
9.	Kadugu(Brassica nigrum)	- 17.5 gram (1/2 palam)
10.	Karunseeragam (Nigella sativum)	- 17.5gram (1/2 palam)

Purification of raw drugs:

- **1. Kodiveliver:** Root bark was made into a fine powder and heated with vapors milk for 3 hours and dried.
- **2. Punganver:** This root was cleaned and dried.
- 3. Aayiliyampattai: This bark was cleaned and dried.
- **4.** Chukku: chukku was soaked in limestone water for 3 hours and outer layer of the skin was peeled off.
- **5. Vaividangam:** It was cleaned and dried in sunlight.
- **6. Kadukkai:** Seeds were removed and derm was dried.
- **7. Thippili**: It was soaked in kodiveli leaf juice for 24 minutes and dried in sunlight.
- **8. Kadugu:** This seed was direct sunlight for 2 days and fried.
- **9. Karujeeragam:** It was dried under sunlight and fried.
- 10. Aayiliyam ver: The root was cleaned and dried.

Preparation method: 35 gram (1 palam) each of kodiveliver, punganver, aailiyamver, aailiyampattai weretaken. Other drugs such as kadukkai, chukku, vaivilangam, karunjeeragam, thippili, kadugu each weighing 17.5 gram (1/2 palam) were taken. They are dried and made into a coarse powder. Later both powders will be mixed together to complete the preparation.

Dosage: 3-4years – 375mg (twice a day), 5-7 years-500mg (twice a day) and 8-12 years - 750 mg (twice a day)

Duration: 1 Mandalam (48 days)

Drug storage: Prepared medicine in coarse powder form were stored in clean and dry container

Dispensing: Prepared medicine would be given as coarse powder form in separate air lock covers.

1. Internal medicines: Maha analuruva chooranam



Vaivilangam (*Embelia ribes*) sativa)



karunjeeragam (Nigella



Kodiveli (*Plumbago zeylanica*) longum)



Thippili (Piper



Chukku (Zingiber officinalae) chebula)



Kadukkai (Terminalia



Aayiliyamver (Holoptelia integrifolia)



Aayiliyampattai (*Holoptelia Integrifolia*)



Kadugu (Brassica nigra) pinnata)



punganver (Pongamia



Maha analuruva chooranam

Chennagarapattai Ennai

Ingrediants:

Chennagarapattai - 4 palam (140gram)

Neem oil - 660ml

Cow's milk-660ml

Vasambu-1 palam (35gram)

Preparation method: Chennagaraver pattai –140gram was taken and soaked it in a vessel containing of water 5.3 litres and heat till it comes to 1/4th of its volume. Then neem oil and cow's milk each 660 ml both will be mixed well. 35 gram of vasambu will grind with above the decoction and mixed the oil to boil and it will be filter to apply over the whole body like a thokkanam once in a day.

Drug storage: The prepared medicated oil is stored in a clean and dry air tight container.

Method of application: Advised to apply the medicated oil over the affected area and then massage once in a day.

Duration: This medicine was advised to use for 48 days.



Impooral ver (Oldenlantia umbellata)



Vasambu (Acorus calamus)



Vembu (Azadiracta indica)



Cow's milk

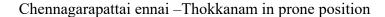


Dispensing medicine

Thokkanam: Thokkanam massage has consisted of nine types of technique which are performed in children once in a day. The method included Thattal (friction/percussive strokes), Irukkal (wringing), Pidithal (draining), Murukkal (kneading), Alutthal (gliding), Iluthal (pulling), Kaikattal (cross arm position and flexion), Mallathuthal (supine position), Asaithal (vibration). Thokkanam was given for thirty minutes a day for 90 days. In Cerebral palsy children based on the classification different to be affected to a different extent. The Thokkanam was likely to be beneficial, it was considered important to whole body including all limbs. Throughout the series of studies whole body of the children were massaged. When performing Thokkanam procedure we sure to practice safely, endeavoring to

adhere to the specific guidelines, scope and ethics of the massage and have fun and be playful with the nine types of strokes and responsibility hold within fingertips.

Thokkanam is application of oil or dry powder over the body or body parts with enough pressure with optimum pressure belong with squeezing of body musculature in appropriate manner. The word massage infers rubbing or kneading the skin with the hands to stimulate or manipulate. Although massage is a more active exchange and can be stimulating, soothing is better when performed in a developmentally sensitive manner.







4.2. Standardization of Maha Analuruva Chooranam

- 4.2.1 Physiochemical analysis.
- 4.2.2 Phytochemical analysis.
- 4.2.3. Biochemical analysis

4.2.1. Physiochemical Investigations of Maha analuruva chooranam

i). Determination of Total Ash: About 2 to 3 g accurately weighed of the ground drug was incinerated in tared platinum or silica dish at a temperature not exceeding 450°C until free from carbon, and was then cooled and weighed. Then the percentage of ash with reference to the air-dried drug was calculated.

ii). Determination of Acid insoluble Ash

To the crucible containing total ash, 25 ml of dilute hydrochloric acid was added. The insoluble matter on an ashless filter paper (Whatman 41) was collected and washed with hot water until the filtrate is neutral. The filter paper containing the insoluble matter was transferred to the original crucible, and dried on a hot-plate and then ignited to constant weight . The residue was allowed to cool in a suitable desiccator for 30 minutes and then weighed without delay. The content of acid insoluble ash with reference to the air-dried drug wascalculated.

iii). Determination of Alcohol-soluble extractive

5g of air-dried, coarsely powdered drug was macerated with 100 ml alcohol of the specified strength in a closed flask for 24 hrs, shaking frequently during 6 hours and was allowed to stand for 18 hrs. Taking precaution against the loss of solvent, the mixture was filtered rapidly and then 25ml of the filtrate was evaporated to dryness in a tared flat bottomed shallow dish, and then dried at 105 °C, to constant weight and weighed. Then the percentage of alcohol-soluble extractive with reference to the air-dried drug was calculated.

iv). Determination of Water-soluble extractive

It was preceded as directed for the determination of alcohol-soluble extractive, except choloroform water was used instead of ethanol.

v). Determination of pH value

pH value was determined using pH meter.

vi). Foreign matter

The sample was spread in a thin layer in a suitable dish /tray. Then it was examined in daylight with unaided eye.

vii). Loss on drying

The drug was taken in a tared evaporating dish and placed in a hot-air oven. It was dried for 5 hours at 105°C and then was weighed. The process was repeated until the weight difference of two consecutive measurements was not more than 0.01 g.

viii). Tap density

The tap density was obtained mechanically by tapping a graduated cylinder containing the sample until little further volume change is observed. It is calculated as mass divided by the final volume of the powder.

ix). Bulk density

The bulk density is obtained by adding a known mass of powder to a graduated cylinder. It is calculated as mass/volume.

x). Determination of Acidity

0.5 g of Phenolpthalein was dissolved in 100ml of 50% ethyl alcohol (v/v) to make indicator. Then 10 g of the sample was taken in a suitable titration flask and dissolved in 75 ml of carbon dioxide free water and mixed thoroughly. then it was titrated against standard sodium hydroxide solution using 4-6 drops of phenolphthalein indicator till pink colour persists for 10 seconds. After correcting the volume of sodium hydroxide solution used, the total acidity by mass was calculated using the formula.

xi. Particle size

Weighed amount of the sample was placed over the 100 mesh and it was agitated for 5 minutes. The particle sizes was calculated by observing the total amount of the sample that passed through the mesh.

4.2.1.1 Heavy Metal Analysis

Equipment & Glassware

- i. Centrifuge tubes 50 ml Disposable, graduated, polypropylene tubes withcap.
- ii. Micropipettes Adjustable, 100 μ L and 1 ml adjustable volume pipettes with disposable polypropylene tips-100 μ L and 1ml.
- iii. Syringe filters 0.22 μm nylonmembrane
- iv. Volumetric glassware glass, 50, 25 and 10ml.
- v. Instrument: ICP-OES (Agilent –5110).

Reagents and Consumables:

- a. Nitric Acid (HNO₃) concentrated (Trace elementGrade)
- b. Hydrogen peroxide Concentrated (Trace metalgrade)
- c. Metal Standard Solution (CertifiedStandards)

Table: 5 Preparation of working Standard solutions for ICP-OES

Working Stand	Vol.of Taken.	Final volume	Final conc	Label
conc(mg/L)	(mL)	(mL)	(mg/L)	
1000	0.100	10	10	WS-1
(H.Metals)				

Preparation of Sample: (Microwave Digestion Method)-1

- a) Take 0.5 g-1g weight of uniform samples to be digested in 7.0 ml trace metal grade concentrated nitric acid (purity 67-69%) in microwave vessel.
- b) The digestion takes place in an inert polymeric microwave vessel that is sealed and heated within the microwave system.
- c) Increase temperature 20 °C per minute to 100°C and hold for 3 minutes

then increase temperature 5°C per minute to 150°C and hold for 5 minutes, then increase temperature to 190°C and hold for 17 minute which allows specific reactions to occur for digestion.

d) In cooled sample diluted to 50 ml with milli-q water. Filter the sample before being analysed.

Preparation of Sample: (Hot Plate Digestion Method)

- a) Take 0.5 g-1g weight of uniform samples (solid) to be digested in 7 ml trace metal grade concentrated nitric acid (purity67-69%).
- b) Place the beaker on hot plate or on heating mental and digest the sample until yellow colour fume is disappear. If required add some quantity of acid and water further to remove yellowfumes.
- c)In cooled sample diluted to 50 ml with milli-q water. Filtered the sample before being analysed.
- d) Then inject to ICP-OES. 5.10 Preparation of Method Blank / ReagentBlank:
- e) Prepare a method blank by following sample preparation procedures (without sample).

Purpose: To detect contamination from reagents, sample handling, and the entire measurement process.

a) Frequency: 1 blank/batch (samples prepared at one time).

Procedure for Injectingsample:

b) Inject the blank, sample and standard solutions (prepared above) as per thesequence.

4.2.1.2. Chromatographic Identification & Fingerprinting Analysis Of By HPTLC

Purpose: Chromatographic identification & Finger printing analysis by HPTLC.

Equipments and Glassware's

i. CamagLinomat 5 sample applicator

- ii. Syringe for application of sample on TLC plate Camag TLC Scanner 4
- iii. HPTLC 60 F 254 silica gel glass-backed layers (Merck)
- iv. TLC developing chamber (Twin trough Chamber)

Reagents and Solvent Sample Preparation

The sample was prepared in polar solvent and sonicated/refluxed the solution and filtered with whatman 41 paper and re-filtered with syringe filter (0.45 μ). Filtered solutions were applied to HPTLC 60 silica gel glass-backed layers (Merck,).

Linomat 5 (sample applicator) Conditions:

- i. Syringe delivery speed, 10 s μL-1;
- ii. Injection volume, 1-10 μL;
- iii. Band width, 6 mm;
- iv. space between bands, 9 mm; start position, 9 mm;
- v. Distance from bottom, 8 mm

Camag TLC Scanner 4 Conditions:

- i. **Deutorium Lamp**: 254 nm;
- ii. **Mercury Lamp**: 366 nm;
- iii. Tungsten Lamp: visible light

Method

For this purpose, a CamagLinomat 5 sample applicator (Muttenz, Switzerland) with nitrogen flow was used. The operating conditions were as follows:

- i. Syringe delivery speed, 10 s μ L-1; Injection volume, 1-10 μ L;
- ii. Band width, 6 mm;
- iii. Space between bands, 9 mm; Start position, 9 mm;
- iv. Distance from bottom, 8 mm.

The HPTLC plates were developed in a horizontal chamber (Camag 20 x10), after saturation with the same mobile phase. The optimised chamber saturation time for the mobile phase was 20 min. at room temperature. The length of the chromatogram run was 80 mm. The developed layers were dried in an oven at 100-105 °C for 15 min and then detected. Initially, The separated components were visually detected. The layers were allowed to dry in air for 30 min and then

analysed under the proper detection way. For the fingerprinting, a Camag TLC scanner 3 linked to win CATS software was set at 350 nm, after multi-wavelength scanning between 250 and 400 nm in the absorption mode had first been tried. The sources of radiation were flourecence, deuterium and tungsten lamps. The slit dimension was kept at 6.00×0.45 mm and the scanning speed used was 20 mm.

4.2.1.3. Microbiological Tests

1. Total bacterial count

Sample preparation

10gm of sample was dissolved in 90ml 0.1% sterile buffer sodium chloride peptone water with 1% polysorbate. Then it was added to Soyabean casein digest agar(SCDA) and incubated at 30-35°C for 5 days.

2. Total fungal count

Sample preparation

The sample was added to Sabouraud dextrose agar (SDA) and was incubated at 20-25°C for 5 days.

4.2.1.4 Pathogen testing

3. Escherichia coli

Sample preparation

1ml of solution was added in 50 ml nutrient broth and was incubated for 18-24 hrs at 37°C±1°C and then 1 ml of inoculum was transferred to 5ml of MacConkey broth tube and then loopful was streaked on MacConkey agar.

4. Samonella

Sample preparation

1 ml of solution was added in 100 ml of nutrient broth and was incubated for 24 hrs at 37°C±1°C. Then 1 ml of the inoculum was transferred to 10 ml of SF (Selenite F broth)and TT (Tetrathionate broth) and then a loopful was streaked on Brilliant green agar (BGA), Xylose Lysine deoxycholate agar(XLDA).

5. Staphylococcus aureus

Sample preparation

1 ml of solution was added in 100 ml SCDM and then was incubated for 24-48 hrs at 37°C±1°C and streaked loopful on Baird-Parker agar(BPA) and Mannitol-salt agar(MSA). Then it was incubated at 37°C±1°C for 18-24 hrs.

6. Pseudomonas aeruginosa

Sample preparation

1 ml of solution was added in 100 ml SCDM and then was incubated for 24-48 hrs at 37°C±1°C and then a loopful was streaked on Cetrimide agar (CA).

4.2.1.5 Aflatoxin Analysis

Equipments and Glassware's

- HPLC: Agilent 1260 series and HPLC Shimadzu RF-10AXL with Autosampler.
- LC column –C18, 150mm x 4.6mm,5μm
- Analytical Balance, 0.10 mgsensitivity
- R-Biopharmcartridges.
- Sonicator
- Vacuummanifold
- Vortexmixer
- Beaker glass, 100 & 50mL.
- Conical flask, 250mL.
- Graduated cylinders, 250mL.
- LC vials 2mL
- LC vials withcaps.
- Micropipettes Adjustable, 100 μL and 1 mL adjustable volume pipettes with disposable polypropylene tips-100 μL and 1mL.
- Volumetric flask glass, 10mL.
- What man no. 4 filterpaper

Solvents & Reagent

- Disodium hydrogenphosphate.
- Methanol.

- Nitricacid.
- Potassiumbromide.
- Potassiumchloride.
- Potassium dihydrogenphosphate.
- Sodiumchloride.
- Water deionized and purified to 0.45μm.
- Aflatoxin B1, B2, G1, G2 Standards with certified purity

Principle

Test portion was extracted with methanol: water. Extract was filtered, diluted with phosphatebuffer and applied to immune affinity column. Aflatoxins were eluted using methanol + water (0.5 mL+0.5 mL). Final extracts were analyzed by reversed phase LC – FLD with kobra cell, using 362nm excitation filter and 453 nm cut-off emission filter.

Extraction Solvent

50% & 50% Methanol in Water was prepared. The mixture and degas was thoroughly mixed with sonicator.

Phosphate Buffered Saline Solution (PBS) pH 7.4:

0.20 gm of KCl, 0.20 gm of KH₂PO₄,1.16 gm of anhydrous Na₂HPO₄, (or 2.92 gm of Na₂HPO₄.12H₂O), and 8 gm of NaCl was dissolved in 900 mL of water. pH was adjusted to 7.4 with 0.1M HCl or 0.1M NaOH and was diluted to 1 L.Then the mixture was thoroughly mixed.

Nitric acid (4 N):

25.7 mL of 69% nitric acid (28.1 mL of 65 % nitric acid or 26.1 mL of 70% nitric acid)was diluted in 100 mL of water. Then the mixture was thoroughly mixed.

Methanol: Water (50:50):

50 mL of methanol was mixed with 50 mL of water. Then the mixture was thoroughly mixed.

Mobile Phase:

Buffer:

To 1000 mL of water, 700 µL of 4N nitric acid was added along with 238

mg of potassium bromide. Then it was sonicated for 5mins. It was then filtered under reduced pressure to remove insoluble substances that may deteriorate pump-seal and clog columns (0.45 μ m or smaller pore size is recommended.)

Mobile Phase: Buffer: Methanol:: 55:45

Preparation of Standard Solutions

Primary Stock Standard Solution:

Individual primary stock 1000 μ g/ml was prepared by taking 1mg diluting to 1mL (acetonitrile).

Secondary Stock Standard Solution:

- i. Individual aflatoxins stock solutions were prepared in a 10 mL volumetric flask. For each stock solution concentration should correspond to apply the purity. Weigh 5±0.1 gm of homogenized sample in 50 mL TarsonTubes.
- 2 gm of sodium chloride was added into it and 25 mL of extraction solvent (80% Methanol for Cereals and 60% Methanol forNuts) was added.
- iii. Then it was shaked well for 10 min, continuously.
- iv. After 10 min, the sample was filtered through whatmann no. 4 filterpaper.
- v. 5 mL of extract was taken with 10 mL of phosphate buffered solution.
- vi. The columns were let to reach room temperature prior to conditioning. Then, the cap was removed from the top of the column and was fixed in the vacuummanifold.
- vii. The diluted filtrate was passed through the column at a flow rate 5 mL per minute. Later air was passed through the column to remove residual liquid.
- viii. The bounded Aflatoxins were eluted from the column at a

flow rate of 1 drop per second using 0.5 mL of 100% methanol and following elution 0.5mL of Millipore water was passed through the column and collect in a HPLC amber glassvial.

Instrument Conditions

Instrument : HPLC with

FluorescenceDetector

Column : 5μ , 4.6 X 150 C18Columns

Columnflow : 1.0 mL/min

Stoptime : 15 mins

Solventprogram : Solvent isocratic

MobilePhase : Methanol: Buffer (55:45) and

add with 700 μL of 4N nitricacid and 238 mg of potassium

bromide

Excitationwavelengt

h : 362 nm Emissionwavelength: 455 nm

Derivatisation : Kobra cell @ 100 μAsettling.

4.2.2 Phytochemical analysis of Maha analuruva chooranam:

Miscellaneous:

i) Test for Starch:

2ml of extract was treated with weak dil. Iodine solution.

ii) Test for reducing sugar:

5ml of Benedict"s qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.

iii) Test for the Alkaloids:

- 1. 2ml of the extract was treated with 2ml of dil. potassium Iodide solution.
- 2. 2ml of the extract was treated with 2ml of dil. picric acid.

3. 2ml of the extract was treated with 2ml of dil. phosphotungstic acid.

iv) Test for Tannic Acid:

2ml of extract was treated with 2ml of dil. ferric chloride solution.

v) Test for Unsaturated Compound:

To the 2ml of extract 2ml of dil. potassium permanganate solution is added.

vi) Test for Amino acid:

2 drops of the extract was placed on a filter paper and dried well.20 ml of Burette reagent is added.

vii) Test for Type of Compound:

2ml of the extract was treated with 2ml of dil. Ferric chloride solution.

4.2.3 Biochemical Analysis

The following medical formulation used in the study was processed by the methods prescribed in standard text books of siddha medicine.

Maha analuruvachooranam was prepared by the method described in Agathiyar aithiya vallathi 600.

Preliminary phytochemical screening preliminary qualitative analysis of drug- Maha analuruvachooranam

Analyzed as per standard procedure at the department of Biochemistry, National Institute of Siddha, Chennia- 47.

Preparation of extract:

5 gram of Maha analuruvachooranamwas measured accurately and placed in the 250ml of cleaned beaker and added with 250ml of the distilled water. Then it is boiled well for 10 minutes. Then it was cooled and filtered in 100ml volumetric flask and made up to 100ml with distilled water.

Test for Acid Radicals:

i) Test for Sulphate:

2ml of the above prepared extract was taken in a test tube to this added 2ml of 4% dil. Ammoniumalate solution.

ii) Test for Chloride:

2ml of the above prepared extract was added with 2ml of dil.HCL is added until the effervescence ceases off.

iii) Test for Phosphate:

2ml of the extract were treated with 2ml of dil. ammonium molybdate solution and 2ml of con.HNO3.

iv) Test for Carbonate:

2ml of the extract was treated with 2ml of dil. magnesium sulphate solution. v) Test for Nitrate 1gm of the extract was heated with copper turning and concentrated H2SO4 and viewed the test tube vertically down.

d) Test for Basic Radicals:

i) Test for Lead:

2ml of the extract was added with 2ml of dil. potassium iodine solution.

ii) Test for Copper:

One pinch (25mg) of extract was made into paste with con. HCL in a watch glass and introduced into the non-luminous part of the flame.

iii) Test for Aluminium:

To the 2ml of extract dil. sodium hydroxide was added in 5 drops to excess.

iv) Test for Iron:

- a. To the 2ml of extract add 2ml of dil. ammonium solution.
- b. To the 2ml of extract 2ml of thiocyanate solution and 2ml of con.HNO3 is added.

v) Test for Zinc:

To 2ml of the extract, dil. sodium hydroxide solution was added in 5 drops to excess and dil. ammonium chloride is added.

vi) Test for Calcium:

To 2ml of the extract was added with 2ml of 4% dil. Ammonium oxalate solution.

vii) Test for Magnesium:

To 2ml of extract dil. sodium hydroxide solution was added in drops to excess.

viii) Test for Ammonium:

To 2ml of extract 1ml of Nessler"s reagent and excess of dil. sodium hydroxide solution are added.

ix) Test for Potassium:

A pinch (25mg) of extract was treated of with 2ml of dil. Sodium nitrite solution and then treated with 2ml of dil. cobalt nitrate in 30% dil. glacial acetic acid.

x) Test for Sodium:

2 pinches (50mg) of the extract is made into paste by using HCL and introduced into the blue flame of Bunsen burner.

xi) Test for Mercury:

2ml of the extract was treated with 2ml of dil. sodium hydroxide solution.

xii) Test for Arsenic:

2ml of the extract was treated with 2ml of dil. Sodium hydroxide solution.

Clinical studies:

A Protocol was prepared and submitted before IEC of National Institute of Siddha. (21-12-2020; NIS/IEC/2020/D-20) and registered in CTRI (CTRI/2021/08/035549). After getting the approval from committee, the clinical study on Baalavatham (Paresis) in children with the trial drug was Maha analuruvachooranam and Chennagarapattaiennai (external) was carried out as per the protocol. The trial drug was given for 48 days. 0thday, 24th day, 48th day the clinical assessment was done and prognosis noted.

Inclusion criteria:

- Children under agrgrou 3-12 years
- Monoparesis
- Diparesis
- Tetraparesis
- Quadriparesis

- Cerebral palsy
- Difficulty in use against gravity of both upper and lowerlimb
- Inability and disability of both upper and lower limb.

Exclusion criteria:

The study will exclude the following conditions based on the symptoms and medication history.

- H/o epilepsy
- H/o severe aggressive with ADHD
- H/o congenital heart disease
- Any other serious illness
- Autism

Withdrawal criteria:

- Intolrence to drug and development of adverse reactions during a trial.
- Poor patient compliance and defaulters.
- Patient turned unwilling to continue in the course of clinical trial.

Clinical assessment parameters:

Table: 6 - Modifie ash worth scale

Grade	Description
0	No increase in tone
1	Slightly increase in tone, manifested by a catch and release at the end of the ROM when the affected part is moved in flexion or extension
1+	Slightly increase in tone, manifested by a catch, followed by minimal resistance throunght the remainder of the ROM
2	More marked increase in tone, throughout most of the ROM, but affected part easily moved.
3	Considerable increase in muscle tone, passive movement is difficult.
4	Affected part righid in flexion or extension.

Table:7 -Medical research council grading (MRC)

Grade	Description			
0	No movement			
1	Palpable contraction, no visible movement			
2	Movement but only with gravity eliminated			
3	Movement againt gravity			
4	Movement against resistance but weaker than normal			
5	Normal power			

Table:8 - Gross Motor Function Classification System (GMFCS)

Levels	Description		
1	Walks and runs independently		
2	Walks independently		
3	Walks with assistance		
4	Stands for transfers		
5	Absent head control and sitting balance		

Table:9- Dynamic gait index (DGI)

Score	Description			
0	Severe impairment: can't step over box without assistance			
1	Moderate impairment: step over box, but must stopbefore stepping			
	over. May require verbal queing			
2	Mild imparment: steps over box, but must slow down and adjust steps			
	to clear box safely			
3	Normal: steps over box without changing gait, no evidence of			
	imbalance.			

Table: 10 -Selective assessment of lower extremities:

Grade	Hip	Knee	Ankle	Stj	Toes
Description					
0	Unable				
1	1 Impaired				
2	Normal				

- Hip flexion / extension contractures
- Knee flexion /extension contractures
- Plantar flexion /extension contracturs
- Subtallor inversion
- Movement of toes

Table:11- Selective assessment of upper extremities

Grade	Shoulder	Elbow	Wrist	Mpj	Pj	
Description						
0	0 No selective motor control					
1	1 Moderately diminished					
2	2 Mildly diminished					
3	Normal					

- Shoulder abduction / adduction
- Elbow flexion / extension
- Forearm pronation/ supination
- Wrist flexion / exextension
- Fingers grasp release

Siddha assessment:

Thinai (Living Place):

- 1. Kurinchi (Hill areas)
- 2. Mullai (Forest)
- 3. Marutham (Fertile land)
- 4. Neithal (Costal area)
- 5. Paalai (Desert)

Kalam (Season)

- 1. Karkaalam
- 2. Koothirkaalm
- 3. Munpanikaalm
- 4. Pinpanikaalam
- 5. Ilavenilkaalam
- 6. Muthuvenilkaalam

Iympulangal(5 Sense Organs)

- 1. Mei (Skin)
- 2. Vaai (Tongue)
- 3. Kan (Eye)
- 4. Mooku (Nose)
- 5. Sevi (Ear)

Kanmenthiriyangal:

- 1. Vaai (Buccal Cavity)
- 2. Kaal (Lower limb)
- 3. Kai (Upper limb)
- 4. Eruvaai (Anorectal region)
- 5. Karuvaai (Uro-genital region)

Ezhu udal kattugal:

- 1. Saram
- 2. Senneer
- 3. Oon
- 4. Kozhuppu
- 5. Enbu
- 6. Moolai
- 7. Sukkilam/Suronitham

Uyirthathukkal:

Vali:

- 1. Praanan
- 2. Abaanan
- 3. Samaanan
- 4. Udhaanan
- 5. Viyaanan
- 6. Naagan
- 7. Koorman
- 8. Kirukaran
- 9. Dhananjeyan
- 10. Devathathan

Azhal:

- 1. Anarpitham
- 2. Prasakam
- 3. Saathakam
- 4. Aalosakam
- 5. Ranjakam

Iyam:

- 1. Avalambagam
- 2. Kilethagam
- 3. Santhigam
- 4. Tharpagam
- 5. Pothagam

Ennvagai Thervu (The Eight types of examination):

- 1. Nadi (Pulse perception)
- 2. Naa (Tongue)
- 3. Niram (Complexion)
- 4. Mozhi (Voice)
- 5. Vizhi (Eyes)
- 6. Sparisam (Palpatory perception)
- 7. Malam (Bowel habits)
- 8. Moothiram (Urine)

Study Enrollment:

- In this study, patients reporting at the NIS OPD Kuzhandhaimaruthuvam department with three or more clinical symptoms of baalavthamwas examined clinically for enrolling in this study based on the inclusion and exclusion criteria.
- 2. The patients who were to be enrolled would be informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and to their informants.
- 3. After ascertaining the patient and informants' willingness, informed consent would be obtained in writing from them in the consent form (Form

II).

- 4. Complete clinical history, complaints and duration, examination findings all would be recorded in the prescribed profoma in the history and clinical assessment forms separately.
- 5. Patients would be advised to take the trial drug and appropriate dietary advice would be given according to the patient informant's perfect understanding.

Data collection forms:

- I. Screening form
- II. Consent form
- III. Case report form (CRF)
- IV. Diet form
- V. Patient Information sheet
- VI. Assent form
- VII. Drug compliance form
- VIII. Withdrawal form
 - IX. Adverse reaction form
 - X. Pharmacovigilance form

Data Management:

- ❖ After enrolling the patient in the study, a separate file for each patient was opened and all forms will be filed in the file. Whenever study patient visits OPD during the study period, the respective patient file was taken and necessary recordings will be made at the assessment form or other suitable form.
- The screening forms was filed separately.
- ❖ The Data recordings will be monitored for completion and adverse event by the Guid and data logical recordings and completeness was monitored by statistician (statistics). All forms were further scrutinized in presence of Investigator by Sr. Research Officer (statistics) for logic errors and incompleteness of data before entering into computer to avoid any bias. No modification in the results was permitted for unbiased report.

- Any missed data found in during the study, was collected from the patient, but the time related data was not be recorded respectively.
- ❖ All collected data was entered using MS access software into computer. Investigators was trained to enter the patient data and cross checked by SRO.

Adverse effects / serious effect Management:

If the trial patient develops any adverse reaction, he /she would be immediately withdrawn from the trial and proper management was given in OPD of NIS and the same reported to regional Pharmacovigilance center. The details of adverse reactions were recorded in prescribed Pharmacovigilance center.

Ethical Issues:

- 1. No other external or internal medicines were used.
- 2. The data collected from the patient"s informant was recorded. The patient"s informant was informed about the diagnosis, treatment and follow-up.
- 3. After the consent of the patient informant (through consent form), patient was enrolled in the study.
- 4. Informed consent was obtained from the patient's informant explaining in the understandable language to the patient's informant.
- 5. Treatment was provided free of cost.
- **6.** In conditions of treatment failure, adverse reactions, patients were given alternative treatment at the National Institute of Siddha with full care.

5. RESULTS AND OBSERVATIONS

A. Preclinical standardization analysis of Maha analuruva Chooranam

Maha analuruva Chooranam was analyzed to obtain parameters, such as, Description—Colour, Odour, flow property, state. Test for heavy metals — Lead, Cadmium, Mercury, Arsenic, Microbial contamination - Total bacterial count, Total fungal count, Test for specific Pathogen - E. coli, Salmonella spp., S.aureus, Pseudomonas aeruginosa, according to the Quality Control Manual of Ayurveda, Siddha, and Unani Medicine (the standard protocol mentioned in books).^[104]

The results showed (Table 6.1-6.4) Maha analuruva Chooranam was brown in color and characteristic pungent and aromatic odor, free flowing property astringent in taste. Physiochemical analysis was done as a preliminary evaluation of the trial drug Maha analuruva chooranam. Loss on drying (LOD) is a method of measuring the amount of water and volatile matter in a sample when the sample was dried. Low moisture content is always a desirable for higher stability of drugs. In Maha analuruva chooranam, the loss on drying at 105°C was found to be 5.34%. So the determination of moisture content shows the good stability of the trial drug Maha analuruva chooranam. The total Ash values are helpful in determining the quality and purity of drugs, especially in powder form. The total Ash value in Maha analuruva chooranam was found to be 1.87%.the minimal level of total Ash value shows the less inorganic residue and purity of this drug. Alcohol soluble and water soluble extractive shows 9.93%, 9.88% respectively and it shows the possibility of tannins, resin, alkaloids and sugars, plant acids, mucilage. And it has shown that all the levels of Lead, Cadmium, Mercury, Arsenic toxic heavy metals analyzed were not detectable. For the evaluation of microbial contamination, total bacterial and fungal content were less Cfu/g.

In specific pathogen analysis E. coli, Salmonella spp., S.aureus Pseudomonas aeruginosa were totally absent. All the pesticide residue and aflatoxins showed absent (Table -6.3). HPTLC study was done to obtain the fingerprints of the Maha analuruva chooranam and it was also done to get standard markers. In the present study, HPTLC analysis, the sample reveals the presence of 7 prominent peaks

which corresponds to presence of seven versatile phytocomponents present within it. RF values peak ranges from 0.000 to 0.903.

Table 12- Physiochemical analysis of Maha analuruva chooranam

State	Solid
Nature	Fine powder
Odour	Pungent – aromatic
Touch / Consistency	Soft
Flow Property	Free flowing
Appearance	Dark Brownish

Table 13 - Physiochemical analysis findings in Maha analuruva Chooranam

S.No.	Test Parameter	Inst. Used	Method	Result
a.	Total ash	Muffle	API	4.60%
		Furnace		
b.	Acid insoluble ash (%w/w)	Chemically	API	1.87%
c.	Alcohol soluble extractives(%w/w)	Chemically	API	9.93%
d.	Water soluble extractives	Chemically	API	9.88%
e.	pH Value	pH Meter	API	5.12
f.	Foreign matter(% by mass)	Visual	API	Absent
g.	Loss on drying	Hot air oven	API	5.34%
h.	Tap Density(gm/ml)		API	0.3862
j.	Bulk density (Untapped)(gm/ml)		API	0.2896
k.	Total acidity (% by mass)	Chemically	API	0.86%
				42.85%
1.	Particle size, % through 100 mesh	SIEVE	API	(Passing
				material on
				100 mesh
				sieve)

Table 14- Heavy metal analysis of Maha analuruva Chooranam

S.N		I	Ieavy metals		
O					
1	Lead (as Pb) (ppm)	ICPOES	ITC/STP/F/INST/0 08	NMT- 10	BLQ(LOQ: 0.5)
2	Arsenic (as as) (ppm)	ICPOES	ITC/STP/F/INST/0 08	NMT-3	BLQ(LOQ: 0.5)
3	Mercury (as Hg) (ppm)	ICPOES	ITC/STP/F/INST/0 08	NMT-1	BLQ(LOQ: 0.5)
4	Cadmium (as Cd) (ppm)	ICPOES	ITC/STP/F/INST/0 08	NMT- 0.300	BLQ(LOQ: 0.25)

A. Chromatographic identification & fingerprinting analysis of by HPTLC of Maha analuruva Chooranam:

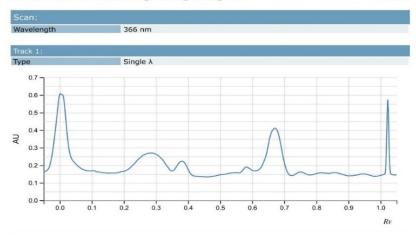


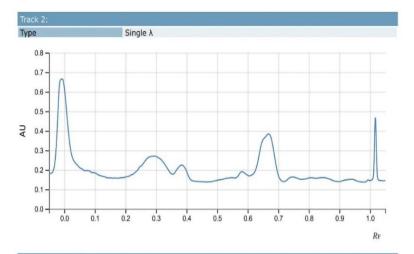


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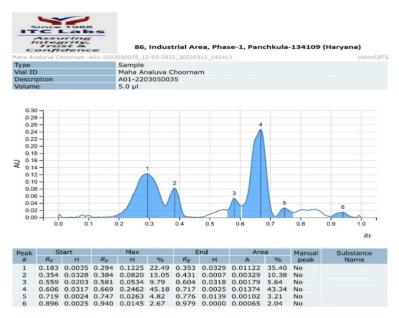
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Evaluation 1:





Fighure: 4 Chromatographic identification & fingerprinting analysis of by HPTLC of Maha analuruva Chooranam

Results:

In the present study, HPTLC analysis, the sample reveals the presence of 7 prominent peaks which corresponds to presence of seven versatile phytocomponents present within it. RF values peak ranges from 0.000 to 0.903.

Table 15- Microbiology test

S.NO.	Microbiological Test				
1	Total viable aerobic	Microbiological	API	Max	30500
	count,cfu/gm			100000	
2	Total fungal count, cfu/gm	Microbiological	API	Max 1000	380
3	E.coli/gm	Microbiological	API	Absent	Absent

4	Salmonella/gm	Microbiological	API	Absent	Absent
5	S.aureus/gm	Microbiological	API	Absent	Absent
6	P.aeruginosa/gm	Microbiological	API	Absent	Absent

Results: This result showed that the total bacterial and fungi were present below the permissible limits.

Table 16 -Aflatoxin detection of maha analuruva chooranam

S.NO		Aflatoxins				
1	B1 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.5	BLQ (LOQ:0.0005)	
2	B2 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.1	BLQ (LOQ:0.0005)	
3.	B3 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.1	BLQ (LOQ:0.0005	
4.	B4 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.1	BLQ (LOQ:0.0005	

Results:

The results shown that there was no spots were being identidied in the test sample loaded on TLC plates when compare to the standard which indicates that the sample were free from Aflatoxin 1, Aflatoxin B2, Aflatoxin G1 and Aflatoxin G2.

4.2- Phytochemical analysis

Table: 17- Phytochemical analysis

S.no	Tests for	Observation	Inference
1	Starch	No blue colour developed	Absence of starch
2	Reducing sugar	Brick red colour developed	Presence of Reducing sugar
3	Alkaloids	white precipitate developed	presence of Alkaloids
4	Tannic acid	black precipitate is obtained	Presence of Tannic acid
5	Unsaturated	Potassium Permanganate is	Presence of
	compound	decolourised	unsaturatedcompound
6	Amino acid	No violet colour developed	Absence of amino acids
7	Test for type of	No Green colour developed	Absence of oxyquinole
	compound:		epinephrine and pyro catechol
			Anti pyrine, aliphatic amino
		No Red colour developed	acid and meconic acid are
			absent
			Apomorphi salicylate and
		No Violet colour developed	resorsinol are absent
		No Blue colour developed	
			Morphine, phenol cresol and
			hydroquinone are absent

4.3- Biochemical Analysis

Table: 18- Biochemical analysis

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1	Appearance of sample	Dark brown in	Light browncolour
		colour.	
2	SOULBILITY:	Sparingly soluble.	Completely
	a) A little of the sample is		soluble
	shaken with distilled water.	Completely soluble.	
	b) Little of the sample is		
	shaken well with conc.		
	HCL/conc. H2SO4.		
3	ACTION OF HEAT: A	White fumes	Presence of
	small amount of the sample	evolved	carbonate
	is taken in a dry test tube and	No brown fumes.	
	heated gently at first and		
	then strong.		
4	FLAME TEST: small	Bluish green flame	Absence of Copper
	amount of the sample is	appeared.	
	made into a paste will		
	conc.HCL in a watch glass		
	and introduced into non		
	luminous part of the Bunsen		
	flame.		
5	ASH TEST: A filter paper is		
	soked into mixture of the	Yellowcolour flame	Absence of
	sample and cobalt nitrate	appeared.	Sodium
	solution and introduced into		
	bursen flame andignited.		

Table: 19- Test for acid radicals

S.no	Procedure	Observation	Inference
1	Test for sulphate	Cloudy appearance	Presence of
		present.	Sulphate
		A white	
		precipitation	
		insoluble in	
		conc.HCL is	
		obtained.	
2	Test for chloride	Cloudy appearance	Presence of
		present.	Chloride
3	Test for phosphate	Cloudy yellow	Absence of
		appearance present.	Phosphate
4	Test for carbonate:	Cloudy appearance	Presence of
		present.	Carbonate
5	Test for nitrate	No characteristics	Absence of Nitrate
		changes.	
6	Test for sulphide	Rotten egg	Presence of
		smelling gas	Sulphide
		evolved.	
7	Test for fluoride and oxalate	Cloudy appearance	Presence of
		present.	Fluoride and
			Oxalate
8	Test for nitrite	No characteristics	Absence of Nitrate
		changes.	
9	Test for borate	Bluish green colour	Absence of Borate
		flame not appeared.	

Table: 20-Test for basic radicals:

S.no	Procedure	Observation	Inference
1	Test for lead	No yellow precipitate is obtained.	Absence of Lead
2	Test for copper	Blue colour flame	Absence of Copper
		Blue colour precipitate not	
		formed.	
3	Test for	Characteristics changes.	Presence of
	aluminium:		Aluminium
4	Test for iron	Blood red colour appeared.	Presence of Iron
5	Test for zinc	White precipitate if formed.	Presence of Zinc
6	Test of calcium	Cloudy appearance and white	Presence of
		precipitate is obtained	Calcium
7	Test for	White precipitate is obtained	Presence of
	magnesium		Magnesium
8	Test for	Brown colour appeared	Presence e of
	ammonium		Ammonium
9	Test for	Yellowish precipitate is obtained	Presence of
	potassium		Potassium
10	Test for sodium	yellow colour flame appeared	Absence of
			Sodium

Results:

The Bio chemical analysis showed the presence of Magnesium, Sulphate, sulphide, Calcium, Carbonate, fluoride and oxalate, chloride, Zinc, Iron, Potassium, Ammonium, Aluminium, alkaloids, unsaturated compounds, tannic acid, reducing sugar and absence of Lead, Borate, Copper, Nitrate, Nitrite, Sodium, Starch, Amino acids, Phosphate, in Maha analuruva choooranam.

Clinical study:

In this study, among the 30 children (Fig 6.49 and Fig 6.50) 19 (63.33%) were between 3-4 years, 8 (26.67%) fell between 5-7 years and 3 (10%) were between 8-12 years, 16 (53.33%) children were boys and 14 (46.66%) children were girls.

We have enrolled only spastic types of paresis only among that Para paresis 8 (26.67%), Hemi paresis 11 (36.67%), mono paresis 9 (30%) and Quadriparesis 2(6.67%). Among the risk factors for Paresis 17 (56.67%) antenatal causes, Natal causes were common in 7 (23.33% cases). Majority belonged to among 30 patients, 8 (26.67%) patients were Upper middle economic status, 2 (6.67%) patients were upper lower class people 17 (56.67%) patients were lower middle class economic status and 3(10%) patients were lower class people. The percentage is more in lower middle economic group.

In the gait characteristics toe walking was the commonest presenting complaint semi circumduction gait 15 (50% cases), toe walking present in 7 (23.33% seen in cases). Ambulation statuses of children, independent were 8 (26.67%). Majority were malnourished with moderate to moderate malnutrition. Severity of impairment varies widely, depending on the site and severity of brain damage.

As shown in the methodology, 30 children enrolled completed treatments and measures clinical parameters were obtained to evaluate efficacy of the medicines and methodologies. While the children in each group were matched on clinical parameters such as spasticity, gross motor functions, fine motor functions, gait analysis, assessment of joints, socio emotional, and language development.

Results of the study were observed with respect to the following criteria.

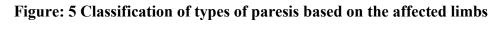
- Reference to Clinical features
- Cranial Nerve Examination
- Motor system examination
 - o Bulk of the Muscle
 - Muscle tone
 - Muscle power
 - Reflex
- Clinical assessment parameters
- Developmental milestone distribution
- Thinai Distribution

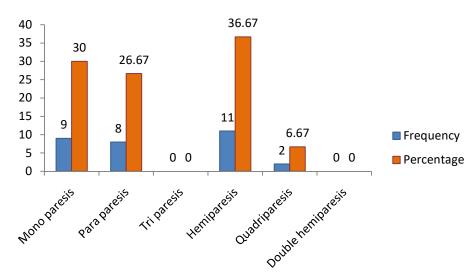
- Paruvakaalam Distribution
- Kanmenthiriyam Distribution
- Reference to Uyirthadhukkal
- Reference to Ezhu Udalkattugal
- Reference to Ennvagaithervugal
- Reference to Neikkuri
- Age Distribution
- Gender Distribution
- Socio economic Distribution
- Dietary distribution
- Family distribution

1. Reference to clinical features

Table: 21 Classification of types of paresis based on the affected limbs

S.no	Paresis types	Frequency	Percentage
1.	Mono paresis	9	30
2.	Para paresis	8	26.67
3.	Tri paresis	0	0
4.	Hemiparesis	11	36.67
5.	Quadriparesis	2	6.67
6.	Double hemiparesis	0	0





Inference: Among 30 cases 11 (36.67%) of the cases were reported as Hemi paresis, 8 (26.67%) as paraparesis, 9 (30%) as Mono paresis 2 (6.67%) as Quadriparesis.

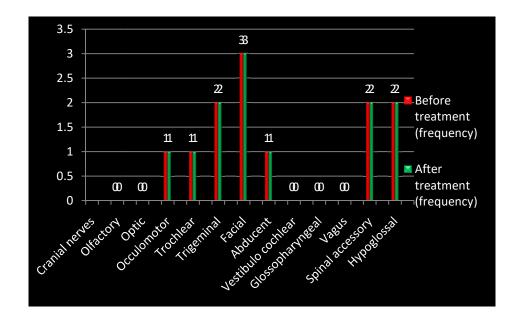
2. Cranial nerves examination:

Table-22 Cranial nerves examination

s. no	Cranial nerves	Before treatment (frequency)	After treatment (frequency)
1.	Olfactory	0	0
2.	Optic	0	0
3.	Occulomotor	1	1
4.	Trochlear	1	1
5.	Trigeminal	2	2
6.	Facial	3	3
7.	Abducent	1	1
8.	Vestibulo cochlear	0	0

9.	Glossopharyngeal	0	0
10.	Vagus	0	0
11.	Spinal accessory	2	2
,212.	Hypoglossal	2	2

Figure: 6 Cranial nerves examination



Inference:During cranial nerve examination 2 children showed abnormality in trigeminal, Facial, 1 child showed abnormality in occulomotor, trochlear and abducent.1 child showed an abnormality in facial, hypoglossal and 2 child showed abnormality in spinal accessory nerve, 2 children showed abnormality in hypoglossal nerve.

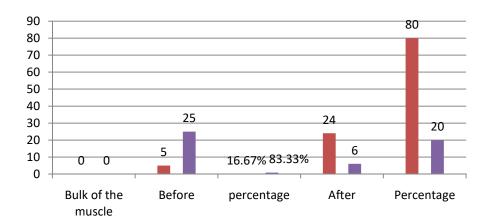
3. Motor examination distribution:

Bulk of the muscle:

Table 23 Bulk of the muscle:

Bulk of the muscle	Before treatment	percentage	After treatment	Percentage
Normal	5	16.67%	24	80
Affected	25	83.33%	6	20

Figure: 7 Bulk of the muscle:



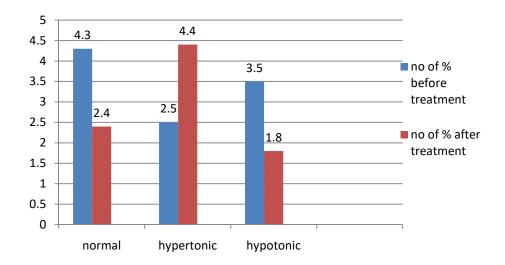
Inference: Among the 30 children, 5 (16.67%) children had a normal bulk of the muscle before the onset of treatment but they had difficulty in using the limbs and the remaining 25 (83.33%) were affected in the muscle bulk. After the course of treatment the 24 (80%) affected children's muscle bulk was gradually improved. 6 (20%) cases had no improvement in their muscle bulk.

Tone of the muscles:

Table :24 - Tone of the muscles:

Muscle	Before T	`reatment	After Treatment			
tone	No of cases	percentage	No of cases	Percentage		
Normal	0	0	27	90		
Hypertonic	30	100	3	10		
Hypotonic	0	0	0	0		

Figure: 8 Tone of the muscles:

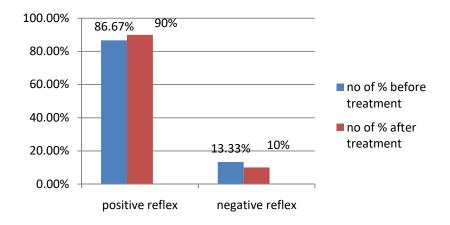


Inference: All the children were found have hypertonic and after treatment the spasticity was reduced in 90% (27) of the children, remains 10% (3) children spasticity were static.

Superficial reflex (Abdominal) Table 25 Superficial reflex (Abdominal)

Abdominal	Before	Treatment	After Treatment		
	No of	percentage	No of cases	Percen	
	cases			tage	
Positive	26	86.67	27	90	
reflex					
Negative	4	13.33	3	10	
reflex					

Figure: 9 Superficial reflex (Abdominal)

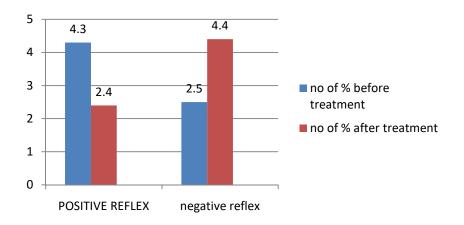


Inference: Among the 30 children, 26 (86.67%) had positive reflexes 4 (13.33%) children had negative reflexes and after treatment was positive in 90% (27) of the children, remains 10% (3) patients had negative reflexes.

Table 26 Superficial reflex (Cremasteric)

Cremasteric	Before T	`reatment	After Treatment			
	No of cases	percentage	No of cases	Percentage		
Positive reflex	26	86.67	28	93.33		
Negative reflex	4	13.33	2	6.67		

Figure: 10 Superficial reflex (Cremasteric)

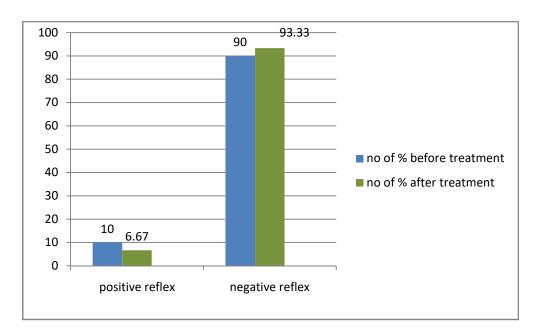


Inference: Among the 30 children, 26 (86.67%) had positive reflexes 4 (13.33%) children had negative reflexes and after treatment was positive in 93.33% (28) of the children, remains 6.67% (2) patients had negative reflexes.

Table:27 Superficial reflex(Plantar reflex)

	Before	e Treatment	After Treatment		
	No of	Percentage	No of cases	Percenta	
	cases			ge	
Positive	3	10	2	6.67	
reflex					
Negative	27	90	28	93.33	
reflex					

Figure: 11: Superficial reflex(Plantar reflex)



Inference: Among the 30 children, 3 (10%) had positive reflexes 27 (90%) children had negative reflexes and after treatment was positive in 6.67% (2) of the children, remains 93.33% (28) patients had negative reflexes.

Table 28 Deep tendon reflexes: (before treatment)

Grade	biceps		triceps		Supinator		knee jerk		Ankle	
	R	L	R	L	R	L	R	L	R	L
0	-	-	-	-	-	-	-	-	-	-
1	-	-	-	-	-	-	-	-	-	-
2	18	19	19	19	19	20	-	-	12	13
3	6	7	10	6	11	10	16	19	18	16
4	6	4	1	5	-	-	14	11	-	1

Figure 12: Deep tendon reflexes: (before treatment)



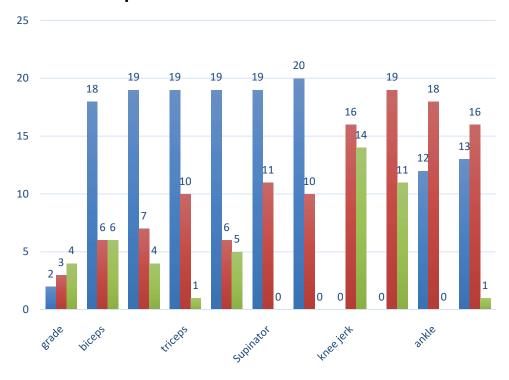


Table 29 Deep tendon reflex (after treatment)

Grade	Biceps		triceps		Supinator		knee jerk		Ankle	
	R	L	R	L	R	L	R	L	R	L
0	-	-	-	-	-	-	-	-	-	-
1	-	-	-	-	-	-	-	-	-	-
2	24	27	27	24	30	28	-	1	24	25
3	6	3	3	6	-	2	29	28	6	4
4	1	-	-	-	-	-	1	1	-	1

Figure 13: Deep tendon reflex (after treatment)





Table 30: Biceps

		Before t	reatment	t	After treatment				
		R		L		R		L	
	No of	percent	No of	percent	No of	percent	No	perce	
	cases	age	cases	age	cases	age	of	ntage	
							case		
0	-		-	-	-		-		
1	-		-	-	-		-		
2	18	60%	19	63.33	24	80	27	90%	
3	6	20%	7	23.33	6	20	3	10%	
4	6	20%	4	13.33	-	-	-	-	

Figure 14:Biceps

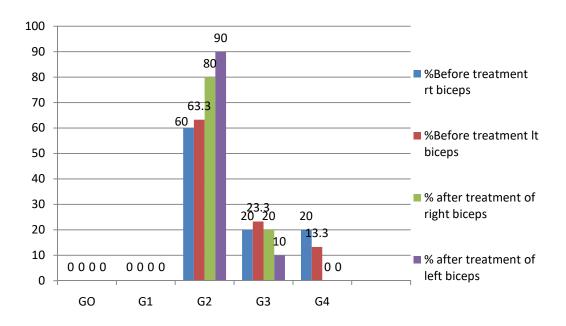


Table 31: Triceps

		Before t	reatment	t		After to	reatmen	t
	R		L		R		L	
	No of cases	percent age	No of cases	Percent age	No of case	percent age	No of case	percent age
G0	-		-	-	-		-	
1	-		-	-	-		-	
2	19	63.3%	19	63.33	27	90	24	80%
3	10	33.33%	6	20	3	10	6	20%
4	1	3.33%	5	16.67	-	-	-	-

Figure 15: Triceps

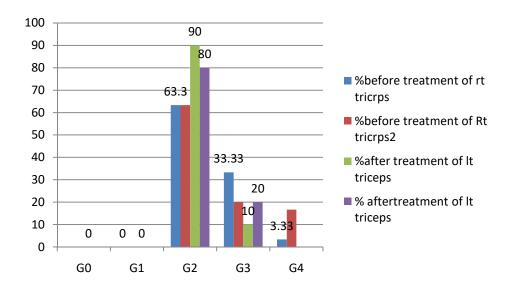
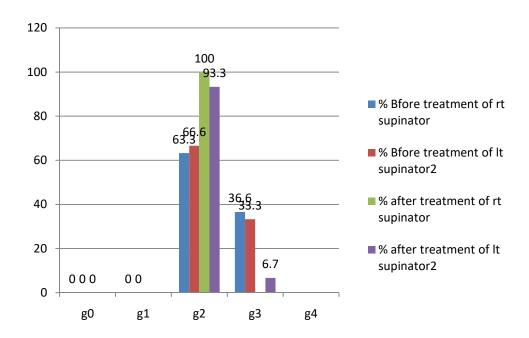


Table 32.Supinator

		Before t	reatment	-	After treatment				
	R		L		R		L		
	No of	percent	No of	Percent	No of	percent	No of	perce	
	cases	age	cases	age	cases	age	case	ntage	
G0	-		-	-	-		-		
1	-		-	-	-		-		
2	19	63.3%	20	66.67	30	100	28	93.3%	
3	11	36.67%	10	33.33	-	-	2	6.67%	
4	-	-	-	-	-	-	-	-	

Figure 16: supinator



3. Table 33. KNEE JERK

		Before t	reatment	t	After treatment					
	R		L			R		L		
	No of	percent	No of	Percent	No of	percent	No of	Percen		
	cases	age	cases	age	cases	age	case	tage		
G0	-		-	-	-		-			
1	-		-	-	-		-			
2	-	-			-		1	3.33%		
3	16	53.33	19	63.33	29	96.67	28	93.3%		
4	14	46.67	11	36.67	1	3.33	1	3.33%		

Figure 17: knee jerk

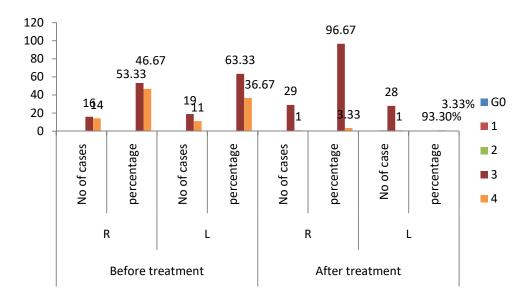
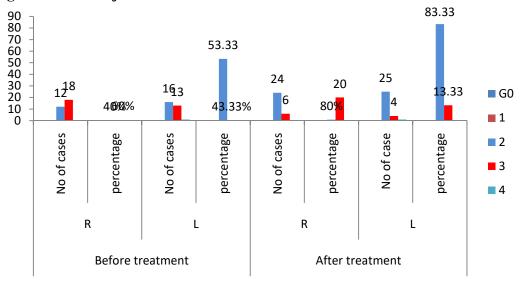


Table:34 Ankle jerk

		Before t	reatment	t	After treatment				
	R			L		R		L	
	No of	percent	No of	percent	No of	percent	No of	percen	
	cases	age	cases	age	cases	age	case	tage	
G0	-		-	-	-		-		
1	-		-	-	-		-		
2	12	40%	16	53.33	24	80%	25	83.33	
3	18	60%	13	43.33%	6	20	4	13.33	
4	-		1	3.33%	0	0	1	3.33%	

Figure 18: Ankle jerk

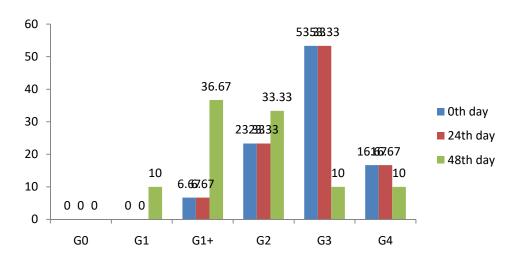


4. Clinical Assessment parameters:

Table 35: Modified Ash worth scale:

	Modified ash worth scale							
Grade (score)	0 th day		24 ^t	^h day	48 th day			
	No	%	no	%	no	%		
0 (S4)	0	0	0	0	0	0		
1 (S3)	0	0	0	0	3	10		
1+	2	6.67	2	6.67	11	36.67		
(S2.5)								
2 (S2)	7	23.33	7	23.33	10	33.33		
3 (S1)	16	53.33	16	53.33	3	10		
4 (S0)	5	16.67	5	16.67	3	10		

Figure 19: modified ashworth scale

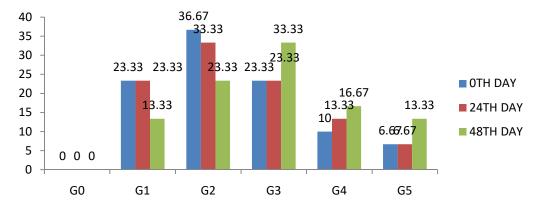


Inference: From the above table 0% of children had Grade-0 on 0th day and 0% of children had on 48th day. 6.67% of children had Grade-1+ on 0th day and 36.67% of children had on 48th day. 0% of children had Grade-1 on 0th day and 10% of children had on 48th day. 23.3% of children had Grade-2 on 0th day and 33.33% of children had on 48th day. 53.33% of children had Grade-3 on 0th Day and 10% of children had on 48th day. 16.67% of children had Grade-4 on 0th Day and 10% of children had on 48th day.

Table: 36: Medical research council scale

Grade (score)	0 th day		24 th day		48 th day	
	No	%	No	%	no	%
0	0	0	0	0	0	0
1	7	23.33	7	23.33	4	13.33
2	11	36.67	10	33.33	7	23.33
3	7	23.33	7	23.33	10	33.33
4	3	10	4	13.33	5	16.67
5	2	6.67	2	6.67	4	13.33

Figure 29: MRC

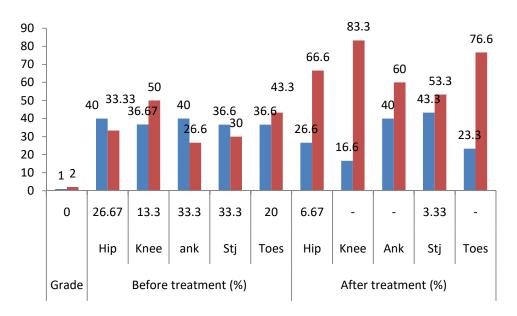


Inference: From the above table 6.67% of children had Grade-5 on 0th day and 13.33% of children had on 48th day. 10% of children had Grade-4 on 0th day and 16.67% of children had on 48th day. 23.33% of children had Grade-3 on 0th day and 33.33% of children had on 48th day. 26.3% of children had Grade-2 on 0th day and 23.3% of children had on 48th day. 23.33% of children had Grade-1 on 0th Day and 13.33% of Children had on 48th day. 0% of children had Grade-0 on 0th Day and 0% of Children had on 48th day.

Table 37: Selective assessment of lower extremities

Gr ade	Before treatment (%)					After treatment (%)				
	Hi p	Knee	ank	Stj	Toes	Hip	Knee	Ank	Stj	Toes
0	26. 67	13.3	33.3	33.3	20	6.67	-	-	3.33	-
1	40	36.67	40	36.6	36.6	26.6	16.6	40	43.3	23.3
2	33. 33	50	26.6	30	43.3	66.6	83.3	60	53.3	76.6

Figure 30: Selective assessment of lower extremities

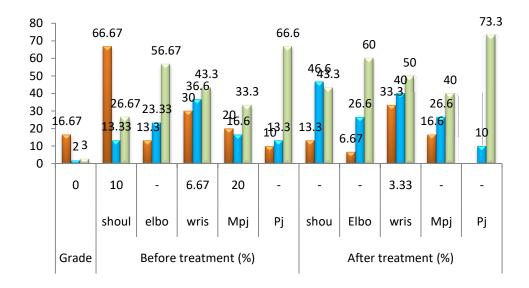


Inference: Before treatment among 30 patients, 6 children had Grade-0 and 4 children had Grade-0 on after treatment. 10 children were affected in grade 1 and 6 children were affected in after treatment.14 children were grade 2 in before and 20 children were grade 2 on after treatment.

Table: 38 Selective assessments of upper extremities

Gr ade			After treatment (%)							
	shoul	elbo	wris	Mpj	Pj	shou	Elbo	wris	Mpj	Pj
0	10	-	6.67	20	-	-	-	3.33	-	-
1	16.67	66.67	13.3	30	20	10	13.3	6.67	33.3	16.6
2	13.33	23.33	36.6	16.6	13.3	46.6	26.6	40	26.6	10
3	26.67	56.67	43.3	33.3	66.6	43.3	60	50	40	73.3

Figure 31: Selective assessments of upper extremities

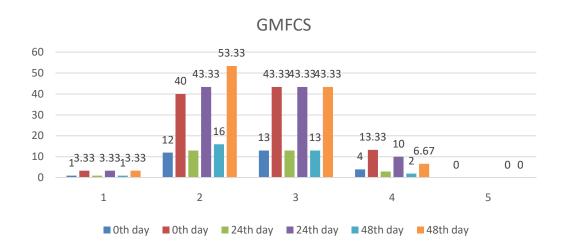


Inference: Before treatment among 30 patients, 5 children had Grade-0 and 1 children had Grade-0 on after treatment. 9 children were affected in grade 1 on before treatment and 6 children were affected in after treatment.6 children were affected in grade 2 on before and 10 children were grade 2 on after treatment. 10 children were had grade on before treatment a, 13 children were grade 3 on after treatment.

Table 39 GMFCS (Gross motor classification functional system)

	0 th day		24 th	day	48 th day	
Grade	no	%	No	%	no	%
1	1	3.33	1	3.33	1	3.33
2	12	40	13	43.33	16	53.33
3	13	43.33	13	43.33	13	43.33
4	4	13.33	3	10	2	6.67
5	-		-		-	-

Figure 32: GMFCS

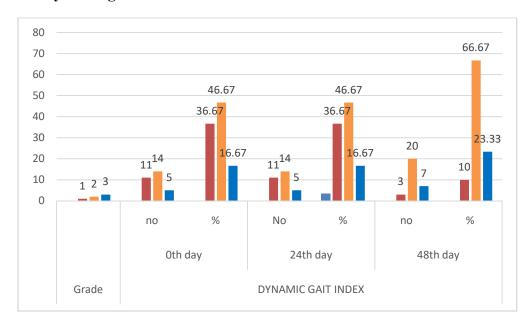


Inference: From the above table 3.33 % of children had Level-1 on 0th day and 3.33% of children had on 48th day. 40% of children had Level-2 on 0th day and 43.33% of children had on 48th day. 43.3% of children had Level 3 on 0th day and 43.33% of children had on 48th day. 13.33% of children had Level-4 on 0th day and 6.67% of children had on 48th day. 0% of children had Level-5 on 0th Day and 0% of children had on 48th day.

Table 40.Dynamic gait index-

Grad		Dynamic gait index						
e								
	0 th day 24 th day				48 ^t	^h day		
	no	%	No	%	no	%		
0	0	0	0	3.33	0	0		
1	11	36.67	11	36.67	3	10		
2	14	46.67	14	46.67	20	66.67		
3	5	16.67	5	16.67	7	23.33		

Figure 33: Dynamic gait index

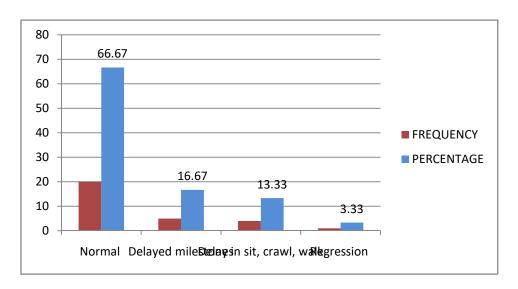


Inference: From the above table 0% of children had severe impairment on 0th day, 24th day and 0% of children had on 48th day. 36.67% of children had moderate impairment on 0th day, 24th day and 10% of children had on 48th day. 46.67% of children had mild impairment on 0th day, 24th day and 66.67% of children had on 48th day. 16.6% of children had normal on 0th day, 24th day and 23.3% of children had on 48th day.

Table 41: Miletones distribution

Milestones	Frequency	Percentage
Normal	20	66.67
Delayed milestones	5	16.67
Delay in sit, crawl, walk	4	13.33
Regression	1	3.33

Figure 34: Miletones distribution

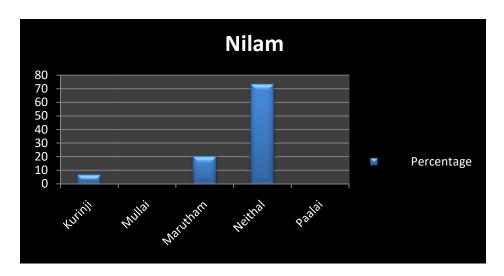


Inference: Among 30 patients, 20 (66.66%) patients had normal milestones attained appropriate to age, 5(16.67%) patients had a delayed milestones, 4 (13.33%) patients had delayed in sit, crawl, walk and 1 (3.33%) patient had regression of milestones.

Table 42. Thinai distribution

Thinai	Frequency	Percentage		
Kurinji	2	6.67		
Mullai	0	0		
Marutham	6	20		
Neithal	22	73.33		
Paalai	0	0		

Figure 35: Thinai distribution



Inference: Among 30 patients, 73.33 % were from Neithal land, 20% from Marutham land, 0 % from Mullai land and 6.67% from Kurinji land.

Table 43. Paruvakaalam distribution

S.no	Paruvakaalam	Frequency	Percentage
1	Kaarkalam	1	3.33
2	Koothirkaalam	19	63.33
3	Munpanikaalam	4	13.33
4	Pinpanikaalam	3	10
5	Ilavenirkaalam	3	10
6	mudhuvenilkaalam	0	0

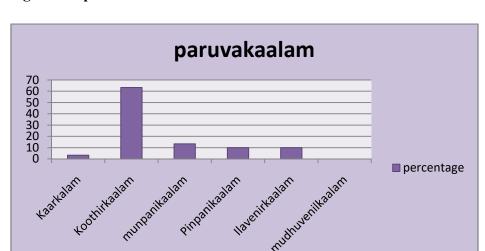


Figure 35: paruva kaalam distribution

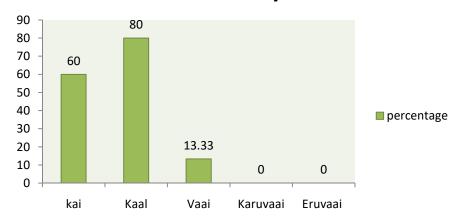
Inference: According to paruva kaalam, high incidence of cases 63.33% were reported in koodhirkaalam, 13.33% cases were reported in Munpani kalam, 10% cases were reported in pinpani kaalam and 10% were from ilavenirkaalam and 3.33% from kaarkalam.

Table 44. Kanmenthiriyam distribution

S.no	Kanmendhiriyam	frequency	percentage
1.	Kai	18	60
2.	Kaal	24	80
3.	Vaai	4	13.33
4.	Karuvaai	0	0
5.	Eruvaai	0	0

Figure 36: kanmendhiriyam distribution

kanmendhriyam



Inference: In Kanmendrium, Kai was affected in 18 cases (60%) and Kaal was affected in 24 cases (80%) and vaai was affected in 4 (13.33%) patients.

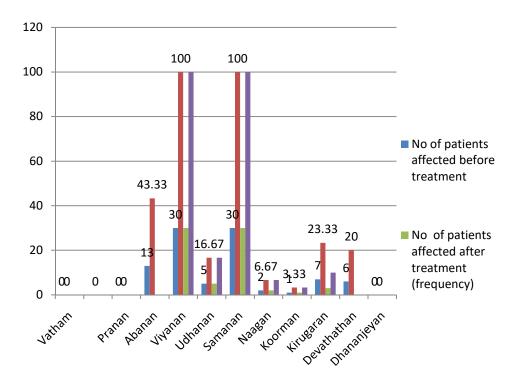
Table 45: Reference to mukkutram:

A)Vatham

Vatham	No of patients affected before treatment (frequency)	Before treatment (%)	No of patients affected after treatment (frequency)	After treatment (%)
Pranan	0	0	0	0
Abanan	13	43.33	0	0
Viyanan	30	100	30	100
Udhanan	5	16.67	5	16.67
Samanan	30	100	30	100
Naagan	2	6.67	2	6.67

Koorman	1	3.33	1	3.33
Kirugaran	7	23.33	3	10
Devathathan	6	20	0	0
Dhananjeyan	0	0	0	0

Figure 37: Reference to mukkutram: A)Vatham



Inference: Before treatment among 30 patients, **Abanan** was affected in 13 (43.33%) patients noted as irregular bowel habit. **Viyanan** was affected in 30 (100%) patients noted as pain, numbness and tingling sensation and restricted movements. **Udhanan** was affected in 5 (16.67%) noted as difficulty in speech before the treatment. **Samanan** was affected in 30 (100 %) patients noted as loss

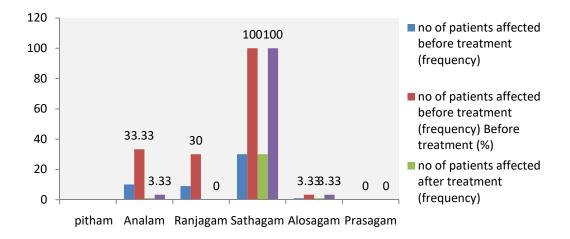
of appetite, pain, numbness, restricted movements and fatigue. **Naagan** was affected in 2 (6.67%) patients noted as squint eyes. **Koorman** was affected in 1 (3.33%) patients. Kirugaran was affected in 7 (23.33%) patients noted as loss of appitite. **Devathathan** was affected in 6 (20) patients noted as fatigue.

After treatment, **Abanan** was affected in 5 (16.67) patients, **Samanan** was affected in 30 (100%) patients, **Naagan** was affected in 2 (6.67%), **Kirugaran** was affected in 3 (10%) patients, **Abanan**, **Devathathan** was normal in all patients.

Table 46: PITHAM:

pitham	no of patients affected before treatment (frequency)	Before treatment (%)	no of patients affected after treatment (frequency)	After treatment (%)
Analam	10	33.33	1	3.33
Ranjagam	9	30	0	0
Sathagam	30	100	30	100
Alosagam	1	3.33	1	3.33
Prasagam	0	0	0	0

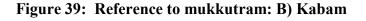
Figure 38: Reference to mukkutram: B) Pitham

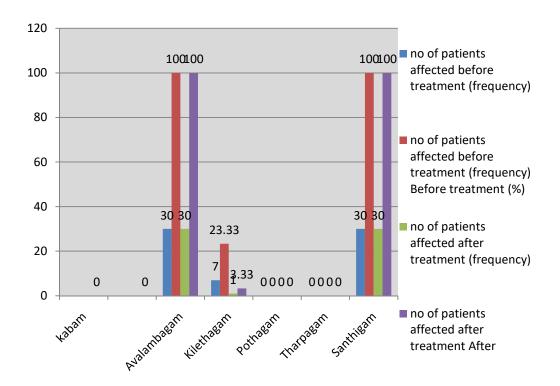


Inference: Before treatment among 30 patients, Analam was affected in 10 (33.33%) patients noted as loss of appetite. Ranjagam was affected due to pallor in 9 (30%) patients. Sathagam was affected in 30 (100%) patients noted as difficulty in walk; stand. alosagam was affected in 1 (3.33%) patients noted as vision problems. After treatment Sathagam was affected in 30 (100%) patients, Alosagam was affected in 1 (3.33%) patients; Analam was affected in 1(3.33%) patients.

Table 47: KABAM

kabam	No of patients affected before treatment (frequency)	Before treatment (%)	No of patients affected after treatment (frequency)	After treatment (%)
Avalambagam	30	100	30	100
Kilethagam	7	23.33	1	3.33
Pothagam	0	0	0	0
Tharpagam	0	0	0	0
Santhigam	30	100	30	100



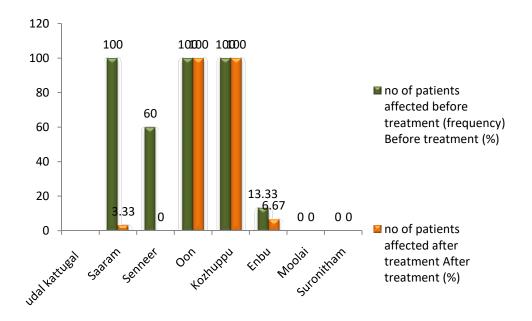


Inference: Before treatment among 30 patients, Avalambagam was affected in 30 (100%) patients, noted as basis of all other types of kabam. Kilethagam was affected in 7 (23.33%) patients noted as poor appetite. Santhigam was affected in 30 (100%) patients noted as restricted movements of joints. After treatment, Avalambagam was affected in 30 (100%) patients, Kilethagam was affected in 1 (3.33%) patients, santhigam was affected in 30 (100%) patients.

Table 48: Reference to ezhu udalkattugal:

udal kattugal	no of patients affected before treatment (frequency)	Before treatment (%)	no of patients affected after treatment	After treatment (%)
Saaram	30	100	1	3.33
Senneer	18	60	0	0
Oon	30	100	30	100
Kozhuppu	30	100	30	100
Enbu	4	13.33	2	6.67
Moolai	0	0	0	0
Suronitham	9	0	0	0

Figure 40: Reference to ezhu udalkattugal



Inference: Before treatment 30 patients, Saaram (noted as fatigue) and Senneer (noted as pallor) were affected in all 18 (160%) patients. Oon was affected in 30 (100%) patients noted as pain weakness of muscles, Kozhuppu was affected in 30 (100 %) patients, Enbu was affected in 4 (13.33%) patients. After treatment, Saaram was affected in 1 (3.33 %) patients, Oon was affected in 30 (100%) patients, Kozhuppu was affected in 30 (100 %) patients, Enbu was affected in 2 (6.67%) patients, seneer was normal in all patients.

Table 49: Reference to envagai thervugal

Envagai Thervugal	no of patients affected before treatment (frequency)	Before treatment (%)	no of patients affected after treatment (frequency)	After treatment (%)
Vali Azhal	1.4	46.67	16	52.22
1.1 .1	14	46.67	16	53.33
pitha vatham	4	13.33	8	26.67
pitha kabam				
	0	0	3	10
vatha kabam	7	23.33	1	3.33
Kaba vatham	3	10	0	0
kaba pitham				
	2	6.67	2	6.67
Sparisam	12	40	6	20
Naa	6	20	0	0
Niram	0	0	0	0
Mozhi	5	16.67	5	16.67
Vizhi	7	23.33	1	3.33
Malam	9	30	0	0
Moothiram	0	0	0	0

Figure 41: Reference to Envagai thervugal

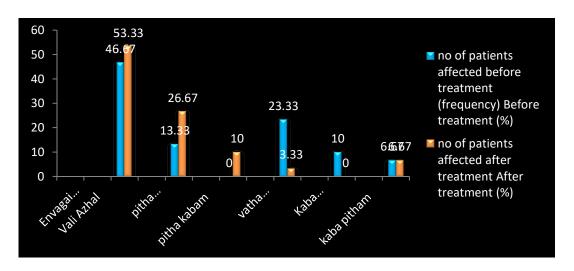
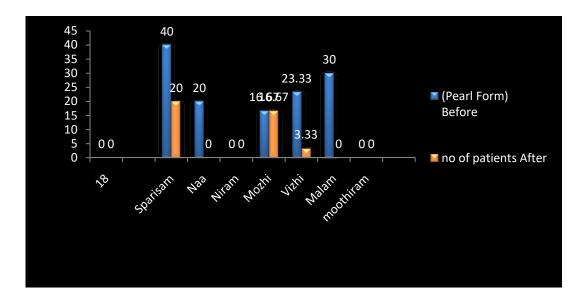


Figure 42: Reference to Envagai thervugal



Inference: Before treatment among 30 patients, 14 (46.67%), 4 (13.33%), 7 (23.33%), 3 (10%), 2 (6.67%) patients were observed in Vali azhal, Azhal vali, Vali Iyyam, iyya vali, iyya azhal naadi and 16 (53.33%), 8 (26.67%), (6.67), 1 (3.3%) and 3(10%) were observed in pithakabam

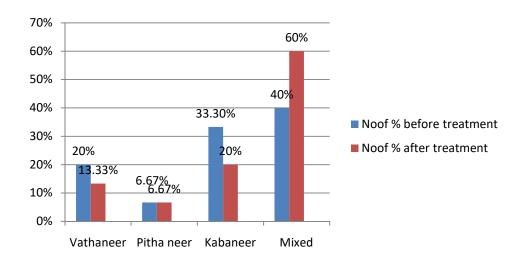
after treatment respectively. **Sparisam** (noted as dryness, cold sensation,) was affected in 12 (40%) patients, **Naa** (pallor, coated, fissure, dryness) was affected in 6 (20%) patients. **vizhi** (pallor) was affected in 7 (23.33 %) all patients. **Malam** (noted as constipation) was affected in 9 (30%) patients, **Mozhi** was affected in 5 (16.67%)and **Niram** and **Moothiram** were normal in all patients.

After treatment **Sparisam** was affected in 6 (20 %) patients, **mozhi** was affected in 5 (16.67%) patients, **Vizhi** (pallor) was affected in 1 (3.33 %) patients, **Malam**, **moothiram**, **Niram** and **Naa** were normal in all patients.

Table 50: Reference to neikkuri-

Neikkuri	no of patients affected before treatment (frequency)	Before treatment (%)	no of patients affected after treatment (frequency)	After treatment (%)
(Snake form) Vatha Neer	6	20	4	13.33
(Ring Form) Pitha Neer	2	6.67	2	6.67
(Pearl Form) Kaba Neer	10	33.33	6	20
Mixed form	12	40	18	60

Figure 43: Reference to neikkuri

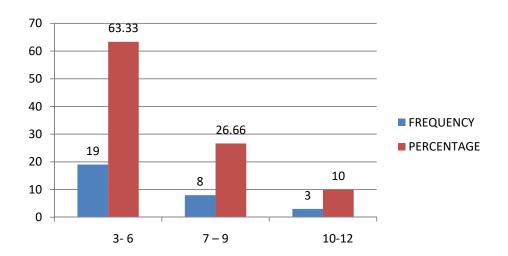


Inference: Before treatment among 30 patients, 6 (20%), 2 (6.67%), 10 (33.33%) 12 (40%), patients were observed in Vatha Neer (oil spreads like snake form), Pitha Neer (oil spreads like ring form), Kaba Neer (oil spreads like peral form) and Mixed form (Vatha pitham, Vatha kabam, Pitha vatham, Pitha kabam, Kaba vatham, Kaba pitham) and 4 (13.33 %), 2 (6.67%), 6 (20%) and 18 (60%) patients were observed after the treatment respectively.

Table 51: Age distribution

Age In Years	Frequency	Percentage
3-6	19	63.33
7 – 9	8	26.66
10-12	3	10

Figure 44: Age distribution

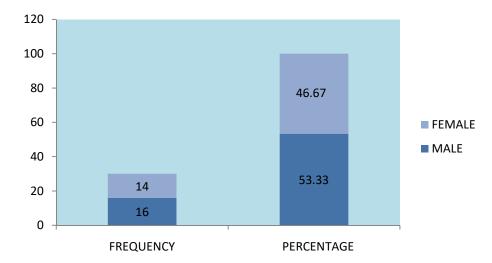


Inference: Among the 30 patients treated 19 (63.33%) patients were reported from the age 3–6 years, 8 ((26.66%)) patients were reported from the age 7 – 9 years, 3 (10%) patients were reported from the age 10 - 12 years.

Table 52: Gender distribution

Gender	Frequency	Percentage
Male children	16	53.33
Female children	14	46.67

Figure 45: Gender distribution

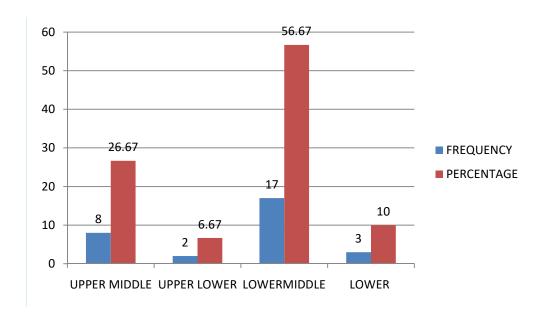


Inference: Among 30 patients 16 (53.33 %) were male children and 14 (46.66 %) patients were female children.

Table 53: Parent's socio – economic status:

Socio Economic Status	Frequency	Percentage
Upper Middle	8	26.67
Upper Lower	2	6.67
Lower middle	17	56.67
Lower	3	10



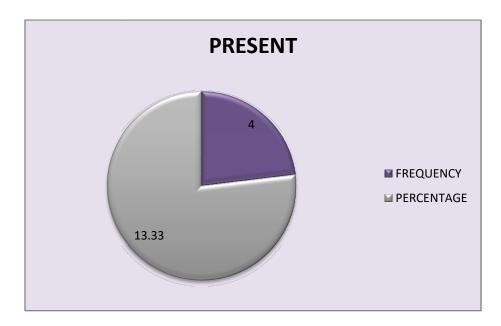


Inference: Among 30 patients, 8 (26.67%) patients were Upper middle economic status, 2 (6.67 %) patients were upper lower class people 17 (56.67%) patients were lower middle class economic status and 3(10%) patients were lower class people. The percentage is more in lower middle economic group.

Table 54: Family History Distribution

Family History Of Neurological Disorders	Frequency	Percentage
Present	4	13.33
Absent	26	86.67

Figure 47: Family History Distribution

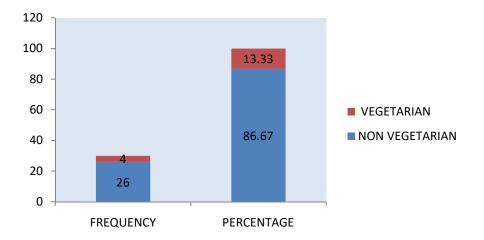


Inference: Among 30 patients, 4 (13.33%) patients had family history of neurological conditions, 26 (86.67%) patients did not have family history of neurological disorders.

Table 54: Diet distribution

Dietary Habits	Frequency	Percentage
Non Vegetarian	26	86.67
Vegetarian	4	13.33

Figure 48: Diet Distribution



Inference: Among 30 patients, 26 (86.67%) patients had non – vegetarian dietary habit and 4 (13.3) patients had vegetarian dietary habit.

5.3.Statistical Analysis

Table 55: Modified ash worth scale

MAS	Sample size	Mean	Standard	T value	P value
			deviation		
Before	30	3.933	2.167	22.494	<0.0001
treatment					
After treatment	30	0.6397	0.6989		

Observation:

Statistical analysis reveals that there has been a significant reduction in MAS scale after treatment indicating the improvement in children doing their daily activities.

Table 56: Medical research council grading for left upper limb

MRC	Sample size	Mean	Standard deviation	T value	P value
Before treatment	30	4.033	1.426	3.616	<0.0001
After treatment	30	4.600	0.6215		

Table 57: Medical research council grading for right upper limb

MRC	Sample size	Mean	Standard	T value	P value
			deviation		
Before	30	3.867	1.592	t = 3.898	<0.0001
treatment					
After	30	4.500	0.7311		
treatment					

Table 58: Medical research council grading for right lower limb

MRC	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	3.433	4.300	5.277	<0.0001
treatment					
After	30	1.547	0.7497		
treatment					

Table 59: Medical research council grading for left lower limb

MRC	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	3.300	4.367	5.573	<0.0001
treatment					
After	30	1.442	0.6687		
treatment					

Statistical analysis reveals that there has been a significant reduction in MRC scale after treatment indicating the improvement in children doing their daily activities.

Table 60: Gross motor functional classification system

GMFCS	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	2.667	0.7581	3.266	<0.0001
treatment					
After	30	2.300	0.5350		
treatment					

Observation:

Statistical analysis reveals that there has been a significant reduction in gmfcs scale after treatment indicating the improvement in children doing their daily activities

Table 61: Dynamic gait index

DGI	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	1.533	0.9371	4.871	<0.0001
treatment					
After	30	2.133	0.5713		
treatment					

Statistical analysis reveals that there has been a significant reduction in DGI scale after treatment indicating the improvement in children doing their daily activities.

Table 62: selective assessment of upper extremities

SLE UL	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	2.433	0.8584	3.340	<0.0001
treatment					
After	30	2.767	0.5040		
treatment					

Observation:

Statistical analysis reveals that there has been a significant reduction in SMC scale after treatment indicating the improvement in children doing their daily activities

Table 63: Selective assessment of upper extremities: left elbow

SLE-UL	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	2.333	0.4795	3.247	<0.0001
treatment					
After treatment	30	2.067	0.2537		

Statistical analysis reveals that there has been a significant reduction in SMC scale after treatment indicating the improvement in children doing their daily activities

Table 64: Selective assessment of upper extremities: right wrist

SLE-UL	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	2.333	0.9942	3.010	<0.0001
treatment					
After	30	2.667	0.6609		
treatment					

Observation:

Statistical analysis reveals that there has been a significant reduction in SMC scale after treatment indicating the improvement in children doing their daily activities.

Table 65: Selective assessment of upper extremities: left wrist:

SLE-UL	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	2.500	0.7768	2.283	<0.0001
treatment					
After	30	2.767	0.5040		
treatment					

Table 66: Selective assessment of lower extremities

SLE-UL	Sample	Mean	Standard	T value	P value
	size		deviation		
Before treatment	30	1.467	0.5713	3.612	<0.0001
After treatment	30	1.833	0.3790		

Statistical analysis reveals that there has been a significant reduction in SMC scale after treatment indicating the improvement in children doing their daily activities.

Table 67: Selective assessment of lower extremities: right ankle

SLE-UL	Sample	Mean	Standard	T value	P value
	size		deviation		
Before	30	1.433	0.7279	3.808	<0.0001
treatment					
After	30	1.767	0.4302		
treatment					

Observation:

Statistical analysis reveals that there has been a significant reduction in SMC scale after treatment indicating the improvement in children doing their daily activities

Table 68: Selective assessment of upper extremities:

SLE-UL	Sample size	Mean	Standard deviation	T value	P value
Before treatment	30	1.200	0.8052	5.135	<0.0001
After treatment	30	1.867	0.3457		

Statistical analysis reveals that there has been a significant reduction in SMC scale after treatment indicating the improvement in children doing their daily activities

6. DISCUSSION

Paresis is a condition in which muscular weakness by impaired movement. It may be also referred to as mild paralysis or partial paralysis. The most common symptoms are, difficult to lift the arm or leg, hand or shoulder movement, decreased sensation in the affected area, a tingling or pins and needles feeling, muscle stiffness. The global burden disease estimates the number of children aged 0-14 years experiencing moderate or severe disability. (WHO 2018) in India, 1.67% of the 0-19 population have the disability.35.29% of all people living with disabilities are children [7]. Other estimates say that India has 12 million children living with disabilities. (Child line 2018).

Muscle weakness in the muscle group associated with the infected may be observed before, during, or after an episode of herpes. The paralysis usually occurs in the first 2 to 3 weeks after rash onset and can persist for several weeks. The weakness results from the spread of the virus from the root of the anterior root horn. ^[6]

In our Siddha classical pediatric book, the definition For Baalavatham has been described as "Baalavatham enbathu kaium, kaalum vilangidathu, nadaka ottathu, kai kaalgali sakthi kurainthu kaanum, sthe symptoms of Baalavatham are nearly correlated with paresis. Signs and symptoms of paresis vary between people. Often, symptoms include poor coordination, stiff muscles, and weak muscles, there may be problems with sensation, vision, and hearing, swallowing, and speaking disorder.

The particular aim of this reach work was to investigate the use of Siddha medicines and methodologies with including Thokkanam in children with paresis. In the Siddha system of medicine, herbs, minerals, metals and salts all have been used for pediatric population. However, scientific research, using modern techniques is needed to provide additional evidence on the drug standardization.

The major challenges include the authentication as to the quality, quantity i.e. dosage, safety and efficacy, especially in regard to single or minimal drug combinations of herbal products. In this context, the need exists to evaluate many Siddha drugs and therapies in contemporary use.

Siddha literature suggested the use of compositions such as *Maha analuruva chooranam, Chennagara pattai ennai*, Thokkanam (Massage) external therapies. The history of usage of these formulations and procedures are very old. However, the exact standard methodologies in the treatment are unavailable till now. A number of individual formulations and procedures currently used in the management of Paresis have been shown to have minimal action when it used alone. However, combinations of internal and external therapies have been reported successfully. In this view, the study was undertaken to evaluate the combined therapy for the management of Paresis.. This study made quantitative measure of different clinical parameters. Efforts have been made to reduce the Spasticity, Muscle tone, stiffness in the joints. Through the use of Siddha medicines in cerebral palsy children. The outcomes of the three treatments were compared at intervals of up to 48 days.

Maha analuruva chooranam were also been studied. With these above objectives, a detailed study plan was undertaken as detailed earlier with materials and methods described. The trial drugs were prepared in Gunapadam lab of National Institute of Siddha after the authentication of the raw drugs by Assistant professor of Medicinal Botany NIS, Chennai. The trial drug was prepared by standard operating procedure as mentioned in the Protocol. i.e. Internal Medicine: maha analuruva chooranam and External therapy: chennagarapattai ennai.

Preclinical study of Physiochemical analysis: The prepared trial drug maha analuruva chooranam is a dark brownish powder with an aromatic odor and pungent in taste. Physiochemical analysis was done as a preliminary evaluation of the trial drug Maha analuruva chooranam. Loss on drying (LOD) is a method of measuring the amount of water and volatile matter in a sample when the sample was dried. Low moisture content is always a desirable for higher stability of drugs. In Maha analuruva chooranam, the loss on drying at 105°C was found to be 5.34%. The total Ash value in Maha analuruva chooranam was found to be 1.87% the minimal level of total Ash value shows the less inorganic residue and purity of this drug. Alcohol soluble and water soluble extractive shows 9.93%, 9.88% respectively and it shows the possibility of tannins, resin, alkaloids and sugars, plant acids, mucilage. And it has shown that all the levels of toxic heavy metals analyzed were not detectable. In HPTLC analysis, there is presence phytocomponents. The Bio chemical analysis showed the presence of Magnesium, Sulphate, sulphide, Calcium, Carbonate, fluoride and oxalate, chloride, Zinc, Iron, Potassium, Ammonium, Aluminium, alkaloids, unsaturated compounds, tannic acid, reducing sugar and absence of Lead, Borate, Copper, Nitrate, Nitrite, Sodium, Starch, Amino acids, Phosphate, in Maha analuruva choooranam.

Clinical Study: 30 Patients with confirmed diagnosis of with satisfying the inclusion criteria were enrolled after obtaining written informed consent and were to receive maha analuruva chooranam with External therapy chennagarapattai ennai massage. A Protocol was prepared and submitted before IEC of National Institute of Siddha. The IEC approval was obtained No: NIS/IEC/2020/D-20/21-12-2020. The trial was registered in Clinical trial Registry of India with Reg.No. CTRI/2021/08/035549 and informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them. Signed the informed consent obtained.

The criteria were family history, sex predominance, age distribution, occupation, antenatal and natal history, milestones distribution, Dietary habits and incidence of the disease with reference to thinai, seasonal variation, clinical manifestations and assessment of the improvement in the prognosis of the disease with the trial drug. After obtaining approval from the committee, the clinical study on Baalavatham (paresis) in children treated with drug *Maha analuruva chooranam* (Internal) and *Chennagarapattai ennai for* thokkanam therapy as external carried out as per the protocol. Chooranam prescribed for children based on the age i.e.3 to 4 years – 35mg (bds), 5 to 7 years – 500mg (bds), 8-12 years 750mg (bds) for 48 days. Total treatment period was 48 days. Clinical assessments were recorded on 0th day and followed by every 24th day.

Age: In the present study, out of 30 patients, 63.33% patients were reported from the age 3-6 years, 26.66% patients were reported from the age 7-9 years, and 10% patients were reported from the age 10 - 12 years. Sex: Out of 30 patients 5333% were male children and 46.67% were female children. Male children are affected more than female children. Socio-economic status: 26.67% patients were Upper middle economic status, 6.67 % patients were upper lower class people 56.67% patients were lower middle class economic status and 10% patients were lower class people. The percentage is more in lower middle economic group. Seasonal variation: Out of 30 patiets, high incidence of cases 63.33% were reported in koodhirkaalam, 13.33% cases were reported in Munpani kalam, 10% cases were reported in pinpani kaalam and 10% were from ilavenirkaalam and 3.33% from kaarkalam. Family history: Among 30 patients, 13.33% patients had family history of neurological conditions, 86.67% patients did not have family history of neurological disorders. Milestones history: Among 30 patients, 66.66% patients had normal milestones attained appropriate to age, 5(16.67%) patients had a delayed milestone, 13.33% patients had delayed in sit, crawl, walk and 3.33% patient had regression of milestones. Food habits: According to diet, Vegetarian 17%, Mixed 83.5% were noted. The highest Incidence of cases was observed in mixed diet. Kanmenthiriyam: Out of 30cases, Kai was affected in 60% and Kaal was affected in 24 cases 80% and vaai was affected in 13.33% children.

Nilam: Among 30 patients, 67 % were from Neithal land,33% from Marutham land, 0 % from Mullai land, and 0% from Kurinji.

Vali (Vatham): Before treatment among 30 patients, Abanan was affected in 43.33% patients noted as irregular bowel habit. Viyanan was affected in 30 100% patients noted as pain, numbness and tingling sensation and restricted movements. Udhanan was affected in 516.67% noted as difficulty in speech before the treatment. Samanan was affected in 100 % patients noted as loss of appetite, pain, numbness, restricted movements and fatigue. Naagan was affected in 2 6.67% patients noted as squint eyes. Koorman was affected in 1 3.33% patients. **Kirugaran** was affected in 23.33% patients noted as loss of appitite. **Devathathan** was affected in 20% patients noted as fatigue. After treatment, Abanan was affected in 16.67% patients, Samanan was affected in 100% patients, Naagan was affected in 6.67%, Kirugaran was affected in 10% patients, Abanan, Devathathan was normal in all patients. Azhal (Pitham). Before treatment among 30 patients, Analam was affected in 33.33% patients noted as loss of appetite. Ranjagam was affected due to pallor in 30% patients. Sathagam was affected in 100% patients noted as difficulty in walk, stand. Alosagam was affected in 3.33% patients noted as vision problems. After treatment Sathagam was affected in 100% patients, Alosagam was affected in 3.33% patients; Analam was affected in 3.33% patients. **Iyyam** (Kabam). According to Kabam. Derangement of Avalambagam was deranged in 100% of Cases, Kilethagam was affected in 33.33% and Santhigam was affected in 100% cases. After treatment Avalambagam was deranged in 100% of Cases, Kilethagam was affected in 3.33% and Santhigam was affected in 100% case.

Ezhu udarkattugal: Before treatment 30 patients, **Saaram** and **Senneer** were affected in all 160% patients. **Oon** was affected in 30 100% patients noted as pain weakness of muscles, **Kozhuppu** was affected in 100 % patients, **Enbu** was affected in 13.33% patients. After treatment, **Saaram** was affected in 3.33 % patients, **Oon** was affected in 100% patients, **Kozhuppu** was affected in 100 %) patients, **Enbu** was affected in 6.67% patients, seneer was normal in all patients.

Envaigai Thervugal: Before treatment among 30 patients, 46.67%, 13.33%, 23.33%, 10%, 6.67% patients were observed in Vali azhal, Azhal vali, Vali **Iyyam, iyya vali, iyya azhal naadi** and 53.33%, 26.67%, 6.67, 3.3% and 3 10% were affected in **pithakabam** after treatment respectively. **Sparisam**: out of 30 children, before treatment sparisam was affected in 40% patients, after treatment Sparisam was affected in 20 % patients. Naa: out of 30children, 20% children were affected on before treatment. Naa was normal in all patients after treatment. Vizhi: out of 30 patients, 23.33 % children were affected in before treatment. Vizhi was affected in 3.33 % after treatment. Malam: out of 30 patients, 30% children were affected in before treatment, malam wasnormal in all patients after treatment. Mozhi: out of 30 children, 16.67%children were affected in before treatment. mozhi was affected in 16.67% children after treatment. Neikuri. Before treatment among 30 patients, 20%, 6.67%, 33.33%, 40%, patients were observed in Vatha Neer, Pitha Neer, Kaba Neer and Mixed form. 13.33 %, 6.67%, 20% and 60% patients were affected after the treatment. Clinical features: Out of 30 cases 36.67% of the cases were reported as Hemiparesis, 26.67% as paraparesis, 30% as Mono paresis 6.67% as Quadri paresis.

Cranial nerve examination: Out of 30 cases, 6.67% children showed abnormality in trigeminal, Facial, 1 child showed abnormality in occulomotor, trochlear and abducent.3.33% child showed an abnormality in facial, hypoglossal and 6.67% child showed abnormality in spinal accessory nerve, 6.67% children showed abnormality in hypoglossal nervebefore and after treatment. Motor system Examination, Bulk of the muscle: Out of 30 children, 16.67% children had a normal bulk of the muscle before the onset of treatment but they had difficulty in using the limbs and the remaining 83.33% were affected in the muscle bulk. After the course of treatment the 80% affected children's muscle bulk was gradually improved. 20% cases had no improvement in their muscle bulk.

Tone of Muscles: Out of 30 children, all the children were found have hypertonic in before treatment and spasticity was reduced in 90% of the children, remains 10% children spasticity was static in after treatment.

Superficial reflexes: Out of 30 children, 86.67% had positive reflexes 13.33% children had negative reflexes and after treatment was positive in 90% of the children; remains 10% patients had negative reflexes. **Deep tendon reflexes:** In the right biceps muscle was affected in 40% children and it was reduced 20 % to after the treatment.

In left biceps muscle was affected in 36.6% children and it was reduced 10% to after the treatment. In the right triceps muscle was affected in 36.6% children and it was reduced 10% to after the treatment. In the Left triceps muscle was affected in 36.6% children and it was reduced 20% to after the treatment. In the Right Supinator muscle was affected in 36.67% children and it was reduced 0% to after the treatment. In the Left Supinator muscle was affected in 33.3% children and it was reduced 6.67% to after the treatment. In the Right knee jerk was affected in 46.67% children and it was reduced 3.33% to after the treatment. In the Left knee jerk was affected in 36.67% children and it was reduced 3.33% to after the treatment. In the Right Ankle jerk was affected in 60% children and it was reduced 20% to after the treatment. In the Left Ankle jerk was affected in 46.66% children and it was reduced 16.67% to after the treatment. The spasticity assessment was done in all the 30 children based on Modified Ashworth scale.

Clinical Assessment Parameters:

Parameter 1: Modified Ashworth Scale: The overall value of the parameter was 0 of children had score- 4 on 0th day, 24th day and 0 of children affected on 48th day. 2 children had score- 2.5 on 0th day, 24th day and 11 children were improved on 48th day. 0 of children had score-3 on 0th day, 24th day and 3 of children were improved on 48th day. 7 children had score -2 on 0th day, 24th and 10 children were improved on 48th day. 16 children had score- 1 on 0th Day, 24th day and 3 children improved on 48th day. 5 children had score-0 on 0th Day and 3 children improved on 48th day.

Parameter 2: muscle research council grading: The overall value of the parameter was 2 children had Grade-5 on 0th day, 24th and 13.33% of children had on 48th day. 10% of children had Grade-4 on 0th day, 13.33% on 24th day and 16.67% of children had on 48th day. 23.33% of children had Grade-3 on 0th day, 33.33% on 24th day and 33.33% of children had on 48th day. 26.3% of children had Grade-2 on 0th day, 24th day and 23.3% of children had on 48th day. 23.33% of children had Grade-1 on 0th Day and 13.33% of Children had on 48th day. 0% of children had Grade-0 on 0th Day, 24th day and 0% of Children had on 48th day. Parameter 3: gross motor functional classification system (GMFCS): The overall value of the parameter was 3.33 % of children had Level-1 on 0th day, 24th day and 3.33% of children had on 48th day. 40% of children had Level-2 on 0th day, 43.33% children had Level-2 on 24th day and 53.33% of children had on 48th day. 43.3% of children had Level 3 on 0th day, 24th % and 48th day. 13.33% of children had Level-4 on 0th day, 10% of the children had grade 4on24th day and 6.67% of children had on 48th day. 0% of children had Level-5 on 0th Day, 24th day and on 48th day.

Parameter 4: Dynamic gait index (DGI): The overall value of the parameters was 0% of children had severe impairment on 0th day, 24th day and 0% of children had on 48th day. 36.67% of children had moderate impairment on 0th day, 24th day and 10% of children had on 48th day. 46.67% of children had mild impairment on 0th day, 24th day and 66.67% of children had on 48th day. 16.6% of children had normal on 0th day, 24th day and 23.3% of children had on 48th day.

Parameter 5: selective assessment of lower extremities: The overall value of parameter was before treatment among 30 patients, 6 children had Grade-0 and 4 children had Grade-0 on after treatment. 10 children were affected in grade 1 and 6 children were affected in after treatment.14 children were grade 2 in before and 20 children were grade 2 on after treatment.

Parameter 6: selective assessment of upper extremities: The overall value of parameter was before treatment among 30 patients, 5 children had Grade-0 and 1 child had Grade-0 on after treatment. 9 children were affected in grade 1 on before treatment and 6 children were affected in after treatment.6 children were affected in grade 2 on before and 10 children were grade 2 on after treatment. 10 children were had grade on before treatment a, 13 children were grade 3 on after treatment.

This study shows among 30 spastic type of paresis only enrolled and given maha analuruva chooranam (internal) and Chennagarapattai ennai (external) as thokkanam for 48 days. In every 24th day monitored the each child. In this study reveals out of 30 children, paresis commonly affected in the age group of 3-8 years (90%) 27 children. It is equally affected in both sexes 16 (53.33%) children were boys and 14 (46.66%) children were girls. In this study shows mostly hemiparesis 11 (36.675) types of children were seen. 23(76.67%) Term children were affected in paresis, due to natal causes such as low birth weight 9(30%), birth injury (13.33%)children and neonatal causes such as fever(33.33%), convulsion 6 (20%) and delayed milestones were 10 (33.33%) children and also 96.67% children had a normal IQ level there is no mental retardation. Mostly four limbs were affected in paresis but lower limb involvement 26 (86.67%) is more common in this study. Based on the clinical assessment parameters, statistical analysis reveals extremely treatment aspect all the cases were treated with Maha significant. In this analuruva chooranam (Internal) and Chennagarapattai ennai (External) medicine for 48 days and also with varmam and physiotherapy treatments were given. This study showed that the trial medicine and procedure were clinically safe and effective in treating paresis children and marked improvement in the paresis children.

7. SUMMARY

Paresis is a condition typified by a weakness of voluntary movement, or by partial loss of voluntary movement or by impaired movement. Neurologists use the term *paresis* to describe weakness, and *plegia* means paralysis in which all voluntary movement is lost. The term *paresis* means'letting go' from 'to let go, to let fall'.

Spasticity defined as increased, involuntary, velocity dependent muscle tone that cause resistance to movement is a complex condition that often cause pain, contractures, and impairment of basic self-care activities of daily living, such as eating, dressing and attending to the personal hygiene. Spastic paresis is broader, including muscle over activity, dystonia and co- contracions.

Disability prevalance is higher in developing countries; people with disabilities are more likely to experience adverse socioeconomic outcomes such as less education, poor health outcomes, lower levels of employment, higher poverty rates.

Children with multiple disabilities associated with impairments which range across sensory, motor, physical, socio emotional, behavior and cognitive domains known as "Special children" There are many physical disabilities that can affect children. But paresis is the most common mental disability in childhood.

However, modern drugs can be said to partially fulfill desirable requirements in some extent. It is in the context that we have undertaken a review of the Siddha formulation which could help management of baalavatham (paresis). In the view of the above, great efforts have been made to find out the alternate Siddha medicines and methodologies to improve the life style of special children with baalavatham.

Siddha literature suggested the internal and external therapies which include the *Maha analuruva chooranam* and *Chennagarapattai ennai* Thokkanam. Children who are attending the outpatient department of Kuzhandhai Maruthuvam in National Institute of Siddha having the complaints of baalavatham (Paresis) as weakness of any one or more limbs, difficulty in walk, difficulty in climbing stairs,

pain or tingling sensation in both limbs, stiffness of muscles, gait disturbances, acquired speech and lost it. Clinical diagnosis of baalavatham was done on the clinical features described in Siddha texts.

The Authentication of ingredients of the trial drug Maha analuruva chooranam and chennagarapattai ennai was obtained from Medicinal Botanist, National Institute of siddha, Chennai. Purification of raw drugs and preparation of trial drug was done at Gunapadam Laboratory, Department of Gunapadam, National Institute of siddha, Chennai, under the supervisor of the guide & supervisor.

The *Maha analuruva chooranam* (Internal medicine) is a typical medicine indicated for baalavatham in the Siddha text book Agathiyar vallathi 600 and *Chennagarapattai ennai* (External medicine) is placed in Madhalai noi thoguthi III. In treatment aspect all the cases were treated with this medicine for 48 days. The observation made during this study showed that the trial medicine and procedure were clinically effective. It is showed safe and efficacies in treating paresis children.

Biochemical Qualitative analysis of trial drug was done in Biochemistry Laboratory, Department of Biochemistry, National Institute of Siddha, and Chennai-47. Physicochemical analysis and phytochemical analysis was done in Noble Research Solutions, Chennai-11. Heavy metal analysis, aflatoxin analysis is done at ITC labs, Panchkula; there is absence of heavy metals and aflatoxins in this maha analysis chooranam.

The trial medicine *Maha analuruva chooranam* shows the presence of Sulphate, chloride, sulphide, fluride and oxalate, Carbonate by acidicradi calstest. Iron, Calcium, ZincMagnesium, potassium, ammonium and Aluminium present by Basic radicals test. The Miscellaneous test shows the presence of Starch, Alkaloids, tannic acid, unsaturated componds.

Evaluation of the drug maha analuruva chooranam (internal) and chennagarapattai ennai (external medicine) was done after getting approved by IEC of National Institute of Siddha. The IEC No is 21-12-2020;

NIS/IEC/2020/D-20 and the trial are registered in Clinical trial Registry of India with Reg.No CTRI/2021/08/035549.

Paresis Children were treated with trial drug *Maha analuruva chooranam* with dosage 350 mg for 3-4 years, 500mg for 5-7 years and 750mg for 8-12 years bid with honey for 48 days. The external therapy thokkanam also given for 48 days.

Assessment of spasticity based on MAS, MRC muscle tone, Dynamic gait index, Gross Motor Function Classification System (GMFCS), selective assessment of upper and lower extremities. After the treatment of 48 days, the assessment of clinical study shows all the Paresis childrenhadimproved. Based on the Modified Ashworth scale – Totally 30 children were treated for Balavaatham no children were reported with Grade 0 (No increase in muscle tone) Grade 1. Out of 7(23.33%) children reported with Grade 2 at 0th day and no improvement in 24th day. out of them 10 (33.3%) children had which exhibits Grade 1, and 2 (6.67%) children had Grade 1+ at the end of the treatment which good improvement. Out of remaining 23 children, 6.67% children were reported with grade 1+ on 0th day no improvement in 24th day, after 36.6% children were improved at 48th day. Out of 9 children with Grade 3 at 0th day.no improvement in 24th day5 (23.33%) child improved to Grade 1 and (91.6%) children had improvement to Grade 1+. Out of 5 children with grade 4, no improvement in 24th day, 6.67% children were improved in grade 2, 1+. As there is a very good improvement after treatment as noted above it can be concluded that the drug has reduced the spasticity of the affected children.

After the treatment they were reduced symptoms are stiffness of muscles, weakness of limbs, pain during flexion or extension, difficult to walk, stand, climbing stairs, difficult to hold the objects, semi-circumduction gait.

The result of the study showed that severely affected 30 children had turned to moderate state. The trial drugs have showed good response in treating the baalavatham, it showed reduced spasticity.

8. CONCLUSION

In Siddha literature Paresis is under the Vatha disease therefore, the therapeutic management is considered to be internal medicine, (Thokkanam) massaging. Siddha system of medicines has certainty with safer medications to treat children. Children with paresis have multiple symptoms for which no curative treatment exists. Manipulative and body-based methods such as Thokkanam, Podithimirthal to improve the quality of life of paresis children.

The trial drug Maha analuruva chooranam along with chennagarapattai ennai massage was treated to the children. Maha analuruva chooranam is primary used to enhance neurological function. The Alkaloids, Quinones, Diterpenes, Flavanoids, Saponin, Carbohydrates are responsible for increase in the muscle tone through enhancing the nerve impulse transmission.

Massage with Chennagara pattai ennai which soothe the sensory nerve endings, they produce a hyperaemic effect causing the arterioles dilate in musculature, and reduce stiffness. Massage is also thought to provide a soothing, sedative, invigorating feeling and can give the comfort. In clinical analysis we observed motor function like spasticity, muscle tone, Gross motor function analysis and Gait analysis showed significant improvement in children. But the results had shown significantly differed each other.

However, children had shown significant improvement in all clinical parameters in children. Thus, Siddha protocol of management can provide some benefit by giving possible improvement in the present condition and minimize the disability of those innocent children and improve their quality of life and give active and self-supporting happy life.

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DISSERTATION PROTOCOL

CLINICAL EVALUATION AND THERAPEUTIC MANAGEMENT OF BAALAVATHAM [PARESIS] BY MAHA ANALURUVA CHOORNAM ALONG WITH CHENNAGARAPATTAI ENNAI (EXTERNAL) IN CHILDREN





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PROTOCOL

TITLE OF THE STUDY:

CLINICAL EVALUATION AND THERAPEUTIC MANAGEMENT OF BAALA VATHAM (PARESIS) BY MAHA ANALURUVA CHOORANAM ALONG WITH CHENNAGARAPATTAI ENNAI(EXTERNAL) IN CHILDREN.

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JUSTIFICATION OF THE STUDY:

Siddha classic texts described the Balavatham is a condition in children with symptoms such as weakness and difficulty in walking. Paresis is a condition in which muscular weakness by impaired movement. It may be also referred to as mild paralysis or partial paralysis. The most common symptoms are, difficult to lift the arm or leg, hand or shoulder movement, decreased sensation in the affected area, a tingling or pins and needles feeling, muscle stiffness⁽¹³⁾. The --global burden disease estimates the number of children aged 0-14 years experiencing moderate or severe disability. (WHO 2018) in India, 1.67% of the 0-19 population have the disability. 35.29% of all people living with disabilities are children [7]. Other estimates say that India has 12 million children living with disabilities. (Childline 2018).

At Present, Supportive therapies for training the children with paresis like occupational therapy, physiotherapy, therapy, conventional therapy,neurophysiological approaches, modified constraint induced therapy (MCIT), functional electrical stimulation to use improve range of motion, mental practise useful to helping walk are being used^[8]. Certain medication like Antispastic drugs also used in severe condition. But, it's quite challenges to manage the children with paresis existing therapy. Certain medications like, stretching medical

therapies like long term, short term various technique and effect is undocumented. Anti spastic drugs (benzodiazepines, baclofen, alpha2 adrenergic agonists^[5] to cause the adverse effects and other complications. Because a number of major physical problems facing the children with paresis in their life, they cannot fulfil the expectation in the society.

As we strive to develop an effective management, the childhood conditions vary dramatically in their severity and impact on the quality of life of the child and family. In present scenario there is no health care profession has convincingly assumed the responsibility of thehealth for children with paresis. Although drug therapy may not completely correct the complications associated with childhood disability, evidence does show that it helps manage problems. Hence, its essential need to find out traditional theapy for the children with paresis. We have chosen siddha herbal formulation MAHANALURUVA CHOORANAM (375-750mg/twice a day,48 days) as internal medicine and CHENNAGARAPATTAI ENNAI as external medicine (Thokkanam)in the treatment of baalavatham. Most of the ingredients in the experimental formulation have neuro-protective activity and balance the equilibrium of mukutram. And, Thokkanam plays a vital role in the management of vatha diseases, its stimulate the blood circulation release the muscle tension. So, by rejuvenating the depleted vaayus through thokkanam it is easier to treat and prevent the disability if intervened earlier [6]. We are expecting this research might fulfil the lacuna in the management of paresis in children.

AIM:

A clinical evaluation and therapeutic management of baalavatham [paresis] by mahaanaluruvachoornam (internal) along with chennagarapattaiennai (external)in children.

PRIMARY OBJECTIVE:

To evaluate the effectiveness of siddha herbal formulation

mahaanaluruvachoornam(Internal) and chennagarapattaiennai(External) for the

management of baalavatham in children.

SECONDARY OBJECTIVE:

To of study the disease baalavatham the basis on

mukutram,envagaithervu,udalthathukkal,neerkuri and neikuri.

To access the spasticity, intensity of muscle tone, muscle strength, gait

index, and range of motion for the treated children.

METHODOLGY:

Study design: an open clinical study.

Study type: clinical trial

Study place: National Institute of Siddha,

Number of patients: 30 children

Study period:18 months.

Trail drug

Internal medicine: Maha analuruvachoornam

External medicine: Chennagarapattaiennai

Dosage:

3-4years - 375mg

5-7 years-500mg

8-12 years - 750 mg

190

Duration :48days (1மண்டலம்)

Reference: Agathiyarvaithiya

vallathy 600 (page no:112)

Inclusion criteria:

- Monoparesis
- Children under age group of 3-12 years
- Diparesis
- Tetraparesis
- Cerebral palsy
- Quadriparesis
- Loss of power and tone in the muscle
- Difficulty in use against gravity of both upper and lowerlimb
- Inability to walk.
- Inability and disability of both upper and lower limb.

Exclusion criteria:

The study will exclude the following conditions based on the symptoms and medication history.

- H/o epilepsy
- H/o severe aggressive with ADHD
- H/o congenital heartdisease
- Any other seriousillness
- Autism

Withdrawal criteria:

Intolerance to the drug and development of adverse reaction during trial.

Poor patient compliance and defaulters

Patient turned unwilling to continue in the course of clinical trial

CLINICAL PARAMETERS:

SPASTICITY:

Modified Ashworth scale

Medical research council grading

Range of motion

Muscle tone:

- Consistency
- Extensibility
- Passivity
- Posture in prone
- Posture in supine
- Posture in supine prone

Gross motor function classification system (GMFCS)

Dynamic gait index

Selective assessment of lower and upper extremities.

STUDY ENROLMENT:

- ➤ In this study, children reporting at the NIS OPD with three or more clinical symptoms will be examined clinically for enrolling in this study based on the inclusion and exclusion criteria
- > The patients who are to be enrolled would be informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and to their informants
- After ascertaining the patient and informants' willingness, informed consent would be obtained in writing from them in the consent form (Form II).

- All these patients will be given unique registration card in which patient's Registration number of the study, Address, Phone number and Doctors phone number etc. will be given, so as to report easily should any complication arise.
- ➤ Complete clinical history, complaints and duration, examination findings all would be recorded in the prescribed Proforma in the history and clinical assessment forms separately.

CONDUCT OF THE STUDY:

The trail drug maha analuruva choornam will be given continuously for twice in 48 days. After that patient will be requested to attend the OPD for clinical assessment and recorded in the clinical assessment form (Form IV) and prognosis noted. The patient's informant are requested to bring back the unconsumed trial drug if any. For IP patients the drug will be provided daily and prognosis will be noted. Laboratory investigations will be done on the day before the start of my study. After the completion of the treatment, the patient is advised to visit our OPD for follow up.

DATA COLLECTION FORMS:

- Screening form
- Consent form
- Case report form (CRF)
- Diet form
- Patient Information sheet
- Assent form
- Drug compliance form
- Withdrawal form
- Adverse reaction form
- Pharmacovigilance form

DATA MANAGEMENT:

- After enrolling the patient in the study a separate file for each patient
 will be opened and all forms will be filed in the file. Whenever study
 patient visits OPD during the study period, the respective patient file
 will be taken and necessary recordings will be made at the assessment
 form or other suitable form.
- The screening forms will be filed separately.
- The Data recordings will be monitored for completion and adverse event by HOD and data logical recordings and completeness will be monitored by statistician (statistics). All forms will be further scrutinized in presence of Investigators by Senior Research Officer (statics) for logic errors and incompleteness of data before entering onto computer to avoid any bias. No modification in the results is permitted for UN biased report.
- Any missed data found in during the study, it will be collected from the patient, but the time related data will not be recorded respectively.
- All collected data will be entered using MS access software onto computer.

DATA ANALYSIS:

All of the analyses were performed using the SPSS statistical software, version 20.0. The results are expressed as mean values +SD. Clinical efficacy parameters comparison between groups using one way ANNOVA followed Turkey HSD test and friedman test was used for comparing between days for each group. Values were considered statistically highly at 1% level significant when at p <0.01; statistically significant 5% level was measured p < 0.05.

ADVERSE EFFECTS / SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reaction, he /she would be immediately withdrawn from the trial and proper management will be given in OPD of NIS and the same will be reported to regional Pharmacovigilance center. The details of adverse reactions will be recorded in prescribed Pharmacovigilance center.

ETHICAL ISSUES:

- To prevent infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of lab equipment's will be used
- No other external and internal medicines will be used. There will be no infringement on the rights of patient.
- The data collected from the children's parent /guardian will be kept confidentially. The patient's parent /guardian will be informed about the diagnosis, treatment and follow up.
- After the consent of the patient (through consent form) they will be enrolled in the study.
- Informed consent will be obtained from the patient's parent / guardian explaining in the understandable language to his / her for the enrolment of the study.
- Treatment would be provided free of cost.
- In condition of treatment failure, adverse reactions, patients will be given alternative treatment at the NIS with full care.

OUTCOME OF THE STUDY:

1) PRIMARY OUTCOME:

To develop establish the standard treatment methodology for the management of paresis in Siddha System of medicine through various clinical parameters such as the power and spasticity, muscle tone, reflex and gait.

Annexure 1

Internal medicine;

MAHA ANALURUVA CHOORANAM

Ingredients:

1.	Kodiveliver(Plumbacozeylanica)	-35 gram
2.	Punganver(Pongamia pinnata)	- 35 gram
3.	Aailiyamver (Chukrasiatabularis)	-35 gram
4.	Aailiyampattai (Chukrasiatabularis)	- 35 gram
5.	Chukku (zingiber officinale)	-17.5gram
6.	Vaividangam (Embeliaribes)	- 17.5gram
7.	Kadukkai (Terminalia chebula)	- 17.5gram
8.	Thippili(piperlongum)	- 17.5gram
9.	Kadugu (Brassica nigrum)	- 17.5 gram
10.	Karunseeragam (Nigella sativum)	- 17.5gram

The ingredients will be procured from local raw drug market required drugs authenticated by the medicinal botanist of NIS All the ingredients mentioned in the formulation is purified as per the direction described in the siddha literature. The experimental formulation will be prepared in Gunapadam lab of NIS.

Purification;

- 1. Kodiveliver (*plumbago zeylanica*); root bark alone will be taken and made into a fine powder.then it will be treated with vapours milk for 3 hours and will be dried.
- 2. Punganver(pongamia pinnata): root will be cleaned and dried.
- 3. Aailiyampattai(Chukrasiatabularis);bark will be cleaned and dried
- 4. Chukku (zingiber officinale);rhizome will be soaked in limestone water for

3 hours and outer layer will be removed.

5. Vaividangam(Embeliaribes); will be cleaned and dried in sunlight.

6. Kadukkai (Terminalia chebula); seedswill be removed and will be dried.

7. Thippili(piper longum); will be soaked in kodiveli leaf juice for 24

minsand then will be dried under sunlight.

8. Kadugu(Brassica nigrum); seed will be cleaned and dried in direct sunlight

for 2 days.

9. Karunseeragam (Nigella sativum); seed will be cleaned, driedin sunlight

and later will be fried.

PREPARATION METHOD:

35 gram (1palam) each of kodiveliver, punganver, aailiyamver, aailiyampattai will

be dried and then pulverised. Other drugs each weighing 17.5 gram (1/2 palam)

will be sauted and pulverised. Later both powders will be mixed together to

complete the preparation.

Dispensing: Prepared medicine will be given as powder.

Adjuvant: Honey

External medicine: Chennagarapattai ennai

Reference book: Madhalainoithoguthi 3 (page no: 244)

Chennagarapattai - 4 palam - 140gram

2. Veppaennai-660ml

3. Cow's milk- 660ml

4. Vasambu-1 palam - 35gram

Sutha neer- 1 kuruni- 5.3litre

Purification:

Vasambu (acorus calamus); burn until it turns into carbon

neem oil (azadiracta indica); burn the neem oil with equal amount of bark

decoction of neem and filter it to get the purified oil

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- keeripurandanverpattai (*opiorrhizamungos*); Bark will be wipe with cotton and peel of the skin.

PREPARATION OF METHOD:

Chennagaraverpattai –140gram

Sutha neer -5.3 liter

Ingredients mentioned above will be made as a powder and will be soaked it in a vessel containing of water 5.3 liter and heat till it comes to 1/4 th of its volume.

Neem oil each 660 ml both will be mixed well.35 gram of vasambu will

Cow's milk grind with above the decoction and mixed the oil to boil and it will be filter to apply over the whole body like a thokkanam once in a day.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Clinical evaluation and therapeutic management of baalavatham (paresis) by mahaanaluruva chooranam along with chennagarapattai ennai (external) in children"

FORM I – SCREENING FORM

1. S l.no: 2. OP/ IP No: 3.Name:

4. Age: 5.Gender: 6. Date of Enrollment:

7. Date of completion: 8.Informant: 9.Reliablity:

INCLUSION CRITERIA:

S.NO	Inclusion	Yes	No
1.	Children of group under 3-12years		
2.	Clinically diagnosed as Paresis		
3.	Mono/Para/hemi/tri/double/tetra/Quadri paresis		
4.	Loss of power tone in the muscle of the affected limb		
5.	Difficulty/ inability in using against gravity and resistance		
6.	Difficulty in using the affected limb		
7.	Cerebral palsy		

EXCLUSION CRITERIA:

S.NO	Exclusion	Yes	No
1.	H/O Epilepsy		
2.	Attention Deficit Hyperactivity Disorder [ADHD]		
3.	Autism		
4.	Congenital heart disease		
5.	Any other serious illness		

ADMITTED TO TRIAL: YES/NO Signature of the investigator Signature of the

NATIONAL INSTITUTE OF SIDDHA

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DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Clinical evaluation and therapeutic management of baalavatham (paresis) by mahaanaluruva chooranam along with chennagarapattai ennai (external) in

children

FORM II- CONSENT FORM

CERTIFICATED BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms

readily understood by the parent/guardian

Name:

Signature:

CONSENT BY PARENT: I have been informed to my satisfaction, by the

attending physician, the purpose of the clinical trial, and the nature of drug

treatment and follow-up including the laboratory investigations to be performed to

monitor and safeguard my son/daughter's body functions.

I am aware of my rights to opt my son/daughter out of the trail at any time

during the course of the trail without having to give the reasons for doing so.

I, exercising my free power of choice, hereby give my consent to include my

son/daughter as a subject in the clinical trial entitled "Clinical Evaluation and

Therapeutic Management of Baalavatham (paresis) by mahaanaluruva

chooranam along with Chennagarapattai ennai (thokkanam) in children". I also

give my consent to take photography when and where it is considered as

essential.

Date:

Signature:

Name:

Signature of witness

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தேசியசித்தமருத்துவநிறுவனம்

அயோதிதாசபண்டிதர்மருத்துவமனைசென்னை 600 047

குழந்தைமருத்துவம்

பாலவாத நோயின் மதிப்பீட்டினை கண்டறியும் ஆய்விற்கான ஒப்புதல்படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது நான்இந்த மருத்துவஆய்வு குறித்து அனைத்து விபரங்களையும் குழந்தையின் பெற்றோருக்கு புரியும் வகையில்

எடுத்துரைத்துள்ளேன் என உறுதிஅளிக்கிறேன்

தேதி:

இடம் :

கையொப்பம்:

பெயர்:

குழந்தையின் பெற்றோர் ஒப்புதல்படிவம்

என்னிடம் இந்த மதிப்பீட்டினை கண்டறியும் ஆய்வின் காரணத்தையும் மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும் புறமருத்துவ சிகிச்சையின் அவசியம் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கி கூறப்பட்டுள்ளது.

நான் இந்த மதிப்பீட்டினை கண்டறியும் மருத்துவ ஆய்வின்போது காரணம்எதுவும் கூறாமல் எப்போது வேண்டுமானாலும் என்குழந்தையை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கிறேன். நான் என்னுடைய சுதந்திரமாக தேர்வுசெய்யும் உரிமையைகொண்டு பாலவாதநோயின் மதிப்பீட்டினை கண்டறியும் மருத்துவ ஆய்வு மற்றும் இதற்கான மருந்து "மகாஅனலுருவசூரணம்" (உள்மருந்து) "சென்னகரப்பட்டை எண்ணெய்" (வெளிமருந்து) பரிகரிப்புதிறனை கண்டறியும் ஆய்விற்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன் .மேலும்இந்த ஆய்வின்போது தேவைபடும் இடத்தில் எனது மகன் (அ) மகளை புகைப்படம் எடுப்பதற்கு நான் ஒப்புதல் அளிக்கிறேன் .

தேதி:

இடம்: பெற்றோர்பெயர்:

கையொப்பம்:

சாட்சிக்காரர்பெயர் :

கையொப்பம்:

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Department of kuzhandhai maruthuvam

clinical evaluation and siddha therapeutic management of Baalavatham (paresis) by Maha analuruva chooranam along with Chennagarapattaiennai (external) in children

Form III-CASE RECORD FORM

DEMOGRAPHIC DATA:

Patient Id:	OP/IP No.	Visit Date: (//
Name		
Age		
Gender Male	Female	Date Of Birth: (//)
Father/ Mother /Guardian	n Name	
Father's Occupation		
Father's Monthly Income	;	
Religion		
Socioeconomic Status		
Patient Informant		
Reliability		
Address		
Contact No:		

- 1. COMPLAINTS AND DURATION
- 2. PRESENT ILLNESS

3. HISTORY OF PAST ILLNESS:		
4. ANTENATAL:		
5. NATAL:		
	Yes	No
Prolonged labour		
Preterm delivery		
Nature of delivery		
Forceps / c – section		
Birth injury		
6. NEONATAL HIISTORY:		
	Yes	No
Fever / rash		
Petichial haemorrhages		
Neonatal jaundice		
Cyanosis		
Breathlessness at birth		
Poor feeding		
Neonatal convulsions		
Resuscitation done		
Low birth weight		
7. Family History		
Any Hereditary/ Familial Disease Yes	No	
ICV D 4 II		
If Yes, Details		
Family H/O similar condition		

8. Immunisation	on History		
Immunizati	ion complete	Incomplete	Complete but time lag
Food habits:			
1. Veg [2. Non-Veg	3. Mi	ixed
Habits:			
1. Pica	YES	NO [
2. Nail biti	ng YES	NO [
3. Bowel n	novements YES [NO [
4. Thumb	sucking YES	NO [
5. Enuresis	YES [NO [
General Exam	ination		
1. Pallor		YES	NO
2. Jaundice	2	YES	NO
3. Cyanosi	S	YES	NO
4. Clubbin	g	YES	NO
5. Pedal oc	edema	YES	NO
6. Lymph	adenopathy	YES	NO
Vital signs:-			
1. Pulse ra	te / mint -		
2. Heart ra	te / mint -		
3. Respirat	cory Rate / mint -		
4. Tempera	ature -		

Anthropometry:-

Height	-						
Weight	Weight						
Head circumfe	-						
Mid arm circu	mference	-					
Chest circumfe	erence	-					
HEAD TO TOE EXAMINA	ATIONS:						
Head:							
Eyes:							
Face:							
Neck:							
Limb:	Limb:						
Upper limb: length Rt Lt							
Lower limb: length Rt Lt							
Skin							
Other systems:							
Respiratory system:	Normal		Affected				
Cardio vascular system:	Normal		Affected				
Gastro intestinal system:	Normal		Affected				
Musculo skeletal system:	Normal		Affected				
Central nervous system:	Normal	Affe	Affected				

Endocrine system:	Normal	Affected					
EXAMINATION OF TH	IE CENTRAL N	ERVOUS SYSTEM:					
1.Level of consciousne	ess-						
2.Appearance and mer	2.Appearance and mental state-						
3. Nutritional status-	3. Nutritional status-						
4.Orientation-	4.Orientation-						
5.Memory-							
6.Intelligence-							
7.Speech-							
8.Handedness							
CRANIAL NERVES:	Right	left					
1.Olfactory nerve	-						
2.Optic nerve	-						
3.Occulomotor	-						
4.Trochlear	-						
5.Abducent	-						
6.Trigeminal	-						
7.Facial	-						
8.Vestibulococclear	-						
9.Glossopharyngeal	-						
10.Vagus	-						

11.Spinal accessory

12.Hypoglossal

Motor functions:

		Right	Left
1. Nutritio	Upper limb		
n	Lower limb		
2. Tone	Upper limb		
	Lower limb		
3. Power	Upper limb		
	Lower limb		

> Coordination :

> Involuntary movements :

> 8. Gait :

SENSORY FUNCTION:

a) Superficial

1)Pain -

2)Touch -

3)Temperature -

S.No	Superficial reflex	Right side	Left side
1.	Corneal		
2.	Conjunctiva		
3.	Abdominal		
4.	Cremasteric		
4.	Plantar		

S.No	Deep tendon reflex	Right side	Left side
1.	Knee jerk		

	٥.	Supmator						
	4.	Triceps						
	4.	Biceps						
A	uton	omic nervous	s system:	:				
		bladd	ler movei	ments:				
		bowe	el movem	ents:				
		Exan	nination o	of spine & crar	nium:			
Si	iddha	a system of ex	xaminati	on:				
<u>N</u>	ilam:	<u>-</u> Kurinji	Mullai	Maru	tham No	eithal	Paalai	
<u>K</u>	<u>[aalar</u>	<u>n:-</u>						
		Kaarkalam		Koothirkaala		Munpan	ikaalam	_
		Pinpanikaala	ım	Illavenirkaala	ım			
		Muthuvenirk	taalam					
Y	aaka	i						
		Vatham		Vatha	Pitham	V	VathaKabam	n
		Pitham		Pithavatham		PithaKa	bam	
		Kabam		KabaVatham		KabaPit	ham	
G	unan	n						
		Sathuvam		Rasat	ham	J	Γhamasam	

Ankle jerk Supinator

Pori / Pulangal

	Normal		Affected	Remarks		
Mei / unarvu						
Vaai / suvai						
Kan / paarvai						
Mooku/naatra	m					
Sevi / olli						
Kanmendhirium / Kanmavidayam						
	Norm	nal	Affected	Remarks		
Kai / dhanam						
Kaal / ghaman						
Vaai / vaaku						
Eruvai / visark	ram					
Karuvai / Aana	antham					
UyirThathukkal						
VATHAM:	Norma	1	Affect	ed Remarks		
Pranan						
Abanan						
Viyanan						
Uthanan						
Samanan						
			209			

Nagan			
Koorman			
Kirukaran			
Devathathan			
Dhanajeyan			
PITHAM	Normal	Affected	Remarks
Analam			
Ranjagam			
Saathagam			
Alosagam			
Prasagam			
KABAM	Normal	Affected	Remarks
Avalambagam			
Kilethagam			
Pothagam			
Tharpagam			
Santhigam			
Udalthathukkal	Normal	Affected	Remarks
Saaram			
Senneer			
Oon			
Kozhuppu			

Enbu					
Moola	ai				
Sukila	am / Suronitha	\Box			
Enva	gai Thervugal				
		Normal	Aff	ected	Remarks
Naa:	Niram				
	Thanmai				
	Suvai				
Niran	n				
Mozh	i				
Vizhi					
	Niram				
	Thanmai				
	Parvai				
Spari	sam				
Mala	m	Norma	.1	Affected	
	Niram				
	Nurai				
	Elagal				
	Erugal				
Moot	hiram				

Neerku	ıri:				
	Niram				
	Edai				
	Nurai				
	Manam				
	Enjal				
Neikur	i:				
	Vatham		Pithai	$\underline{\mathbf{n}}$	
	Kabam	Others	ر ا		
Naadi:			(
	Vadham	Pitham		Kabam	
	Vathapitham	Pitha vatham		Pitha kaban	
	Vatha kabam	Kaba vatham		Kabapitham	1
Date	:	 			
Station	:				
Signatu	re of Guide			Signature	of Investigator

Clinical Evaluation And Therapeutic Management Of Baalavtham (Paresis) By Maha Analuruva Chooranam (Internal)Along With Chennagarapattai Ennai (External In Children

CLINICAL ASSESSMENT PARAMETERS (Before Treatment / After Treatment)

(0th day, 24th day, 48thday)

Patient Id :	OP/IP No:	Visit Date : (//)
Name :		

	Parameter	Scales	0	1	2	3	4	5
S.No								
	Spasticity	Modified Ashworth						
		Scale						
		Muscle power scale						
		(MRC)						
2.		Walks without						
		limitations						
	Gross Motor	Walks with limitations						
	Function	Walks using a hand-held						
	Classification	mobility device						
	System (GMFCS)	Self-mobility with						
		limitations						
		Transported in a manual						
		wheelchair						
3.	Dynamic Gait							
	Index							

Grade	Hip	Knee	Ankle	STJ	Toes	Hip	Knee	Ankle	STJ	Toes
		Left			Right					
Normal										
2 points										
Impaired										
1 point										
Unable 0										
point										
Total										
limb										
scores										
6.	Selective a	Selective assessment for upper extremities								
			1							
Grade	Shoulder	Elbow	Wrist	MPJ	PJ	Shoulder	Elbow	Wrist	MPJ	PJ
		L	eft			Right				
Normal										
2 points										
Impaired										
1 point										
Unable 0										
point										
Total										
limb										
scores										

National Institute Of Siddha

AyothidossPandithar Hospital, Chennai – 600 047.

Department Of KuzhandhaiMaruthuvam

Clinical Evaluation AndTherapeutic Management Of Baalavatham(Paresis) By Maha AnaluruvaChooranam Along With ChennagarapattaiEnnai (External) In Children"

IV-DIETARY ADVICE FORM

THINGS TO TAKE

- Increased intake of vitamins and minerals
- Intake of almond milk
- A natural food as organic which is easily digestible and absorbed
- Vegetable soup
- Fibre content foods

THINGS TO AVOID

- Gluten like wheat be avoid
- Casein like dairy products, yoghurts and soy should be avoided
- Avoid junk food, pasta pizza burger and artificial food items etc..
- Avoid broiler chicken and white sugar
- Fish

ஆகும் உணவுபொருட்கள் :

- இருமுறை வடித்தசோறு, கத்தரிபிஞ்சு,அவரைப்பிஞ்சு
 வெள்ளாட்டுக்கறி.
- கீரைவகைகளில் முடக்கத்தான், அறுகீரை ,தூதுவேளை ,மூக்கிரட்டை பொன்னாங்கண்ணி
- பருப்புவகைகளை துவரை ஒன்றே ஆகும்

ஆகாத உணவுபொருட்கள் :

- மொச்சை ,காராமணி ,கொள்ளு
 ,உளுந்துபோன்றபருப்புவகைகள்
- சுரை, பூசணி, வெள்ளரி, பீர்க்கு முதலிய நீர்காய்கறிகள்.

National institute of siddha

Ayothidosspandithar hospital, chennai 600 047.

Department of kuzhandhammaruthuvam

"Clinical evaluation and therapeutic management for Baalavatham (Paresis) by Mahaanaluruvachooranam along with Chennagarapattaiennai (external) in children"

FORM V - PATIENT INFORMATION SHEET

Name of Principal Investigator :

Name of the institute : National Institute of Siddha, Tambaram

Sanatorium, Chennai-

47.

I, _____Studying as PG Scholar at National Institute of Siddha, Tambaram Sanatorium is doing a clinical trial entitled on the study "BAALAVATHAM (Paresis)".

In this regard, I am in need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree your child to be a participant in this study, he/she will be included in the study primarily by signing the consent form and then you will be given the internal medicine.

Maha analuruvachooranam at a dose is 375mg for 3 -4 years,500mg for 5-7 years and 750mg for 8-12 years twice a day orally and Chennagarapattaiennai(external) for a period of 48 days. If you are not willing to take part of this study you will be treated with the medicine available in NIS with

full care.

The information I am collecting in this study will remain between you and the principal investigator (myself). If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.K. KAVITHALAYA, I-year PG Scholar principal investigator of this study through 7708705884. Till now that is no adverse effect noted with this medicine. However if you experience any of the symptoms such as vomiting, diarrhoea, nausea, tiredness, you can contact me through at any time. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel no: 91-44-22380789, for rights and participation in the study

தேசிய சித்தமருத்துவ நிறுவனம் அயோதிதாச பண்டிதர் மருத்துவமனை சென்னை-600 047 குழந்தைமருத்துவம்

தகவல்படிவம்:

பாலவாதநோயின் மதிப்பீட்டினை கண்டறியும் ஆய்வு மற்றும் சித்தமருந்து மகாஅனலுருவசூரணம் (உள்மருந்து) மற்றும் சென்னகரப்பட்டை எண்ணெய் (வெளிமருந்து) பரிகரிப்புத்திறனை கண்டறியும் மருத்துவ ஆய்விற்கான தகவல்படிவம்

முதன்மைஆராய்ச்ச்சியாளர் : மரு.க.கவிதாலயா

நிறுவனத்தின்பெயர் : தேசிய சித்தமருத்துவ நிறுவனம்

தாம்பரம் சானட்டோரியம்

தேசிய சித்தமருத்துவ நிறுவனத்தில் பட்டமேற்படிப்பு பயின்று வரும் நான் "பாலவாதம்" என்னும் நோயின் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன் .இந்நோயானது பாதித்து கை ,கால்களை அசைக்க முடியாமல் தளர்வுற செய்யும் ஆற்றலும் குறைந்து காணப்படும் ,கைகால்கள் விலங்கிடாது. நரம்பெல்லாம் தளர்ந்து நிற்கும் விசை தளரும் சீதம் தோன்றும் தேகத்தில் குளிர்ச்சி உண்டாகும் .தேகம் விறைத்து காணப்படும் என்னும் இயல்புடைய நோயாகும். இந்த ஆராய்ச்சி சம்மந்தமாக சிலகேள்விகளை தங்களிடம் கேட்கவும் பரிசோதனைக்கு தங்களது குழந்தையை உட்படுத்தவும் உள்ளேன் சம்மந்தமான **தங்கள**து குழந்தையின் .இது அனைக்து விபரங்களையும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன்.இதில் பயணப்படி எதுவும் கொடுக்கப்படமாட்டாது இந்த ஆராய்ச்சியின் போது தங்களது குழந்தையின் உடலுக்கு வேறு. **பாதிப்பு ஏற்படும் பட்சத்தில் தேசியசித்த** மருத்துவமனையில் தக்க **சிகிச்சை** அளிக்கப்படும்.

இந்தஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் குழந்தையை உட்படுத்தும் பட்சத்தில் (உள்மருந்தாக) "மகா அனலுருவசூரணம்" (3-44) 4ஆண்டுகள்-375மிகி.,5-7ஆண்டுகள்-500மிகி.,8-12ஆண்டுகள்-750மிகி)

தேனிலும் நாட்கள் எடுக்க வேண்டும் (வெளிமருந்தாக) 48 சென்னகரப்பட்டை எண்ணெய்" அளிக்கவேண்டும். நாட்கள் தங்களின் விருப்பத்திற்கேற்ப வெளிநோயாளர் (அ)உள்நோயாளர் பிரிவில் கலந்து சிகிச்சை மேற்கொள்ளலாம். இம்மருந்து கடையிலிருந்து வாங்கிபின்பு பொருட்களை நாட்டு மருந்து குணபாடம் ஆய்வகத்தில் உள்ளதக்க மருத்துவ அதிகாரியின் வழிகாட்டுதலின் மூலம் மருந்துதயாரிக்கப்படும்.

இந்த ஆராய்ச்சியில் நோயினராக சேர்ந்தபிறகு தங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் தங்களது குழந்தையை இந்த ஆய்விலிருந்து விலக்கிக்கொள்ளலாம். இந்த ஆரய்ச்சி சம்மந்தமான மற்ற விபரங்களுக்கும் நோயின் தன்மையை பற்றியும் அறிவதற்கும் முதன்மை ஆராய்ச்சியாளரான மரு.க.கவிதாலயா (பட்டமேற்படிப்பாளர் குழந்தைமருத்துவபிரிவு) கைபேசிஎண்:6379625508 எப்போதும் தொடர்பு கொள்ளலாம்.

மேலும் இந்தஆராய்ச்சிக்கு IEC (நிறுனநீதிநெறி குழு)சான்று பெறப்பட்டுள்ளது .இந்த மருந்து சிறப்பாக பாலவாத நோய்க்காக அங்கீகரிக்கபட்ட சித்தமருத்துவ நூலில் கூறப்பட்டுள்ளது. மேலும் உணவுமுறையில் பத்தியம் காக்குமாறு அறிவுறுத்தப்படுகிறது.

National Institute Of Siddha

Ayothidosspandithar Hospital, Chennai – 600 047.

Department Of Kuzhandhai Maruthuvam

Clinical evaluation and therapeutic management of baalavatham(paresis) by mahaanaluruvachooranam along with chennagarapattaiennai (external) in children

FORM ASSENT -VI FORM

	and that my parents (Mom and Dad) / guardian have / has for me to take part in the project above done by
I have been told that I ca happen to me if I want to stop.	an stop at any time I want to participate and nothing will
	Signagture:
தேசி	ய சித்தமருத்துவ நிறுவனம்
	ாடிதர் மருத்துவமனை சென்னை 600 047 குழந்தை மருத்துவம்
பாலவாதநோயின் மதிப்பீட்	டினை கண்டறியும்ஆய்வு
ஒப்புதல்படிவம் குழந்தைக்க	எனது
நிறுவனத்தில் பட்டமேற்படி .கவிதாலயா அவர்களால் அனலுருவசூரணம் (உள்ம (வெளிமருந்து) பரிகரிப்ப	ஆகிய நான் தேசிய சித்த மருத்துவ ப்பு குழந்தை மருத்துவதுறையில் பயிலும் மரு. க நடத்தப்படும் பாலவாத நோய்க்கான மகா ருந்து) மற்றும் சென்னகரப்பட்டை எண்ணெய் புதிறனை கண்டறியும் மருத்துவ ஆய்வில் நோர் /காப்பாளர் திரு/திருமதி
இவ்வாராய்ச்சியில்இருந்து	ற்றிபுரியும் வகையில் எடுத்துரைக்கப்பட்டுள்ளது. எப்போது வேண்டுமானாலும் விலக எனக்கு தை பற்றியும் நன்கு தெரிந்து கொண்டு இந்த ம்மதிக்கிறேன்.
தேதி:	
இடம்: கு	நழந்தையின்பெயர் :
கையொப்பம் :	
பெற்றோர்பெயர் :	
கையொப்பம்	

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL CHENNAI - 600 047.

"Clinical Evaluation And Therapeutic Management For Baalavatham (Paresis) By Mahaanaluruvachooranam Along With Chennagarapattaiennai (External) in children

Form vii - drug compliance

1. S.I.No:	2. OP/IP No:	3.Name:
4. Age: Enrolment:	5.Gender:	6.Date of
7. Date of completion:	8.Informant:	9.Reliablity:
INTERNAL MEDICINE		
Name of the drug: mah	aanaluruvachooranam	
Form of the drug :choo	oranam	
Administratio: per oral		
Dose &duration:	375 mg (3-4 years) & 48days	
	500mg (5-7 years)	
	750mg (8-12 years)	
No of drug packets giv	en:	
No of drug packets retu	ırned:	
EXTERNAL MEDICINE	:	
Name of the drug: Che	nnagarapattai Ennai	
Administration:Thokka	ı	
nam		
DURATION: 48 days		
Date:		
Investigator:		
Signature of the		

Principal

DAYS	MORNING	NIGHT	DAYS	MORNING	NIGHT
1			29		
2			30		
3			31		
4			32		
5			33		
6			34		
7			35		
8			36		
9			37		
10			38		
11			39		
12			40		
13			41		
14			42		
15			43		
16			44		
17			45		
18			46		
19			47		
20			48		
21					
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26					
27			\blacksquare		

National institute of siddha

Ayothidosspandithar hospital, chennai – 600 047.

Department of kuzhandhaimaruthuvam

"clinical evaluation and therapeutic management of Baalavatham (Paresis) by Mahaanaluruvachooranam along with Chennagarapattaiennai (external) in children"

Form IX - ADVERSE REACTION

1. S.I No:	2. OP/ IP No:	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment
7. Date of completion:	8. Informant:	9. Reliability:
Name	:	
Age	:	
Gender	:	
OPD/IPD No	:	
Registration No	:	
Date of trial commencement	:	
Date of withdrawal from trial	: Description of adverse	e reaction :
Date:	Signs	ature of principal
investigator	Signa	acure or principal
Signature of guide		

PHARMACOVIGILANCE OF AYURVEDA, SIDDHA, UNANI and HOMOEOPATHY (ASU & H) DRUGS

Reporting Form for Suspected Adverse Reactions

Note:

i.Personal information of the consumers / patients / ADR reporter's will be kept confidential.

ii.All suspected reactions are to be reported with relevant details.

iii.All completed forms are to be submitted to the program coordinator of nearby centre.

	A /II / C / II		
A/U/S/H			
	Ay-NIA/Code of Peripheral		
	Centre/ADR Number/Year		
	Ay-IPGT/Code of Peripheral		
	Centre/ADR Number/Year		
Code	Un-NIUM/Code of Peripheral		
	Centre/ADR Number/Year		
	Si-NIS/Code of Peripheral		
	Centre/ADR Number/Year		
	Ho-NIH/Code of Peripheral		
	Centre/ADR Number/Year		

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

Name			Patient Record
Place of Birth		IPD /	Number (PRN)
	OPD		
Address			Age:
Village / Town			Sex: Male / Female
Post / Via			
District / State			
Diagnosis:		Constitution and Te	emperament:

2. Description of the suspected Adverse Reactions

Date and time of	
initial observation	
Description of	
reaction	

3. Whether the patient is suffering with any chronic disorders?

6. Lis	O previous al t of all ASU onth:	Ü	· ·		·	, ,	1 ,	
Name of the drug	Manufact- urer / Batch no.	Dose	Form / Route of administ- eration	Sta	Date rting	e of Stopped / Continued	Reason for use	Any unwanted occurrences
7. Li	st of other di	rugs use	d by the pa	tien	ıt during	g the period	of one mo	onth:
Name of he drug	Manufacturer / Batch no.	Dose	Form / Rou of administrat		Starting	Oate of Stopped / Continue d	Reason for use	Any unwanted occurrences
								+

Cardiac

Diabetes

Any

Renal

Hepatic

4. Addictions, if any? If yes, please specify:

Others

8. Details of the drug suspected to cause ADR:

b. Manufacturing date and Expiry date (if available):

a. Name of the drug:

- c. Remaining pack / label (if available):
- d. Consumed orally along with (water / milk / honey / or any other)
- e. Whether any dietary precautions have been prescribed? If yes, please specify:
- f. Whether the drug is consumed under medical supervision or used as self medication.
- g. Any other relevant information associated with drug use:

9. Management provided / taken for suspected adverse reaction

10. Please indicate outcome of the suspected adverse reaction (tick appropriate)

Recovered: No		t		Fatal	If Fatal	
	rec	overed:	Unknown:	:	Date of death:	
Severe: Yes /		Reaction	n abated after	r drug stopped or dose reduced:		
No.						
Reaction		reappeared after re administration of drug:				
Was the patie	dmitted	to				
hospital? If yes, give name			9			
and address of hospital						

11. Any abnormal findings of relevant laboratory investigations related to the episode done pre and post episode of ADR:

12. Particulars of ADR Reporter:

Please tick:	Patient / Attenda	nt / Nurse / Doctor / Pharmacist / Health			
worker / Dru	worker / Drug Manufacturer / Any others (please specify)				
Name:					
Address:					
Telephone / E - mail:					

Signature of the reporter:

Date:

Please send the completed form to: The centre from where the form is received or to

The Coordinator, National Pharmacovigilance Centre All India Institute of Ayurveda, SaritaVihar,

New Delhi - 110 076

Email: pharmacovigilanceayush@gmail.com

The ADR Probability Scale

(Program Coordinator has to fill this scale)

Are there previous conclusive reports on the reactions? Did the ADR appear after the suspected drug was administered? Did the ADR improve when the drug was discontinued a specific antagonist was administered? Did the adverse reaction reappear when the drug was re-administered? Are there alternatives causes that could solely have caused the ADR? Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? Did the patient have a similar reaction to the same or similar drugs in any previous exposure? Was the adverse event confirmed by objective evidence? Total Score		Questions	Yes	No	Don't
reactions? Did the ADR appear after the suspected drug was administered? Did the ADR improve when the drug was discontinued a specific antagonist was administered? Did the adverse reaction reappear when the drug was re-administered? Are there alternatives causes that could solely have caused the ADR? Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? Did the patient have a similar reaction to the same or similar drugs in any previous exposure? Was the adverse event confirmed by objective evidence?					Know
Did the ADR appear after the suspected drug was administered? Did the ADR improve when the drug was discontinued a specific antagonist was administered? Did the adverse reaction reappear when the drug was re-administered? Are there alternatives causes that could solely have caused the ADR? Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? Did the patient have a similar reaction to the same or similar drugs in any previous exposure? Was the adverse event confirmed by objective evidence?	1	Are there previous conclusive reports on the	+1	0	0
was administered? Did the ADR improve when the drug was administered? Did the adverse reaction reappear when the drug was re-administered? Are there alternatives causes that could solely have caused the ADR? Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? Did the patient have a similar reaction to the same or similar drugs in any previous exposure? Was the adverse event confirmed by objective evidence?		reactions?			
3 Did the ADR improve when the drug was discontinued a specific antagonist was administered? 4 Did the adverse reaction reappear when the drug was re-administered? 5 Are there alternatives causes that could solely have caused the ADR? 6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?	2	Did the ADR appear after the suspected drug	+2	-1	0
discontinued a specific antagonist was administered? 4 Did the adverse reaction reappear when the drug was re-administered? 5 Are there alternatives causes that could solely have caused the ADR? 6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?		was administered?			
administered? 4 Did the adverse reaction reappear when the drug was re-administered? 5 Are there alternatives causes that could solely have caused the ADR? 6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?	3	Did the ADR improve when the drug was	+1	0	0
4 Did the adverse reaction reappear when the drug was re-administered? 5 Are there alternatives causes that could solely have caused the ADR? 6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?		discontinued a specific antagonist was			
drug was re-administered? 5 Are there alternatives causes that could solely have caused the ADR? 6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?		administered?			
5 Are there alternatives causes that could solely have caused the ADR? 6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?	4	Did the adverse reaction reappear when the	+2	-1	0
have caused the ADR? 6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence? +1 0 0 0 0 0 0 0 0 0 0 0 0 0 0		drug was re-administered?			
6 Was the drug detected in the blood (or other fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?	5	Are there alternatives causes that could solely	-1	+2	0
fluids) in a concentration known to be toxic? 7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence? +1 0 0 0 0 0 0 0 0 0 0 0 0 0 0		have caused the ADR?			
7 Was the reaction more severe when the dose was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?	6	Was the drug detected in the blood (or other	+1	0	0
was increased, or less severe when the dose was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence?		fluids) in a concentration known to be toxic?			
was decreased? 8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence? +1 0 0	7	Was the reaction more severe when the dose	+1	0	0
8 Did the patient have a similar reaction to the same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence? +1 0 0 0 0		was increased, or less severe when the dose			
same or similar drugs in any previous exposure? 9 Was the adverse event confirmed by objective evidence? +1 0 0		was decreased?			
exposure? 9 Was the adverse event confirmed by +1 0 0 objective evidence?	8	Did the patient have a similar reaction to the	+1	0	0
9 Was the adverse event confirmed by +1 0 0 objective evidence?		same or similar drugs in any previous			
objective evidence?		exposure?			
	9	Was the adverse event confirmed by	+1	0	0
Total Score		objective evidence?			
		Total Score			

Score: > 9 = Certain; 5-8 = Probable; 1-4 = Possible; 0 = Unlikely

Signature Program Coordinator



NATIONAL INSTITUTE OF SIDDHA राष्ट्रीय सिद्ध संसथान

Ministry of AYUSH - आयुष मंत्रालय GOVERNMENT OF INDIA-भारत सरकार

TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियम चेन्नई -600 047 गेनराala : 044-22411611 कैक्स\Fax : 22381314 नेत : nischennaisiddha@yahoo.co.in वेब :www.nischennai.org फ़ोन\Tele: 044-22411611 ईमेल: nischennaisiddha@yahoo.co.in

19th JANUARY 2022 Date:

F. No: NIS/4-76/IEC/2020

CERTIFICATE

	l Institute of Siddha, Tambaram Sanatorium, i-600047, Tamil Nadu, India	
Principal Investigator: Dr. N.Archana		
Department of	Kuzhandhai Maruthuvam	
	ed Siddha medication in paediatric population	
(5-12 Years) in rural areas of Virudhun	agar District, Tamil Nadu - A Cross Sectional	
Study		
Documents filed	1) SOP – 6 (Project Submission Application Form) 2) Protocol 3) Data Collection forms 4)	
	Patient Information Sheet 5) Consent form 6) SAE (Pharmacovigilance)	
Clinical Trial Protocol	, , ,	
(others - Specify)	Yes	
nformed consent documents Yes		
Any other documents -		
Date of IEC approval & its number	25/11/2021:NIS/IEC/2021/MP - 1	

We approve the clinical study to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, Review periodically, any SAE occurring in the course of the study, any changes in the protocol and submission of final report.

Member Secretary

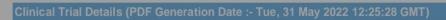
MEMBER SECRETARY INSTITUTIONAL ETHICS COMMITTEE
NATIONAL INSTITUTE OF SIDDMA
EHENNAI -600 047 CHAIRMAN / VICE-CHAIRMAN INSTITUTIONAL ETHICS COMMITTEE NATIONAL INSTITUTE OF SIDDHA CHENNAI - 600 947.

Chairman

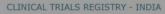








CTRI Number	CTRI/2021/08/035549 [Registered on: 10/08/2021] - Trial Registered Prospective			
Last Modified On	06/08/2021			
Post Graduate Thesis	Yes			
Type of Trial	Interventional			
Type of Study	Drug Siddha			
Study Design	Single Arm Study			
Public Title of Study	Maha analuruva chooranam (internal) and Chennagarapattai ennai (external)for thof Baalavatham(Paresis) in children			
Scientific Title of Study	Clinical evaluation and therapeutic management of Baalavatham(paresis) by mah chooranam (internal) along with Chennagarapattai ennai (external)in children			
Secondary IDs if Any	Secondary ID		Identifier	
	NIL		NIL	
Details of Principal		Details of Princi	pal Investigator	
Investigator or overall Trial Coordinator	Name	DrK KAVITHALAYA		
(multi-center study)	Designation	PG Scholar		
(,	Affiliation	National institute of siddha		
	Address	Room no 9 Department of Kuzhandhai Maruthuva Institute of Siddha Tambaram Sanatorium Kanche TAMILNADU India Room no 9 Department of Kuz Maruthuvam National Institute of Siddha Tambara Kancheepuram TAMILNADU India Kancheepuram TAMIL NADU 600047		
	Phone	6379625508		
	Fax	22381314		
	Email	kavikalai126@gma	il.com	
Details Contact	Details Contact Person (Scientific Query)			
Person (Scientific	Name	DrP ARULMOZHI		
Query)	Designation	Associate Professor		
	Affiliation	National institute of siddha		
	Address	Room no 9 Department of Kuzhandhai Maruthuvar Institute of Siddha Tambaram Sanatorium Kancher TAMILNADU India Room no 9 Department of Kuzh Maruthuvam National Institute of Siddha Tambarar Kancheepuram TAMILNADU India Kancheepuram TAMIL NADU		







PDF of Trial CTRI Website URL

Inclusion Criteria			
Age From	3.00 Year(s)		
Age To	12.00 Year(s)		
Gender	Both		
Details	Monoparesis br/> Diparesis br/> Tetraparesis Quadriparesis br/> Cerebral palsy br/> Difficulty in gravity of both upper and lower limbs both upper and lower limbs br/> Loss of power and muscle br/>		

Exclusion Criteria

	Exclusion Criteria		
Details	Epilepsy Severe aggressive with ADHD Congenital heart disease Autism		
	Any other serious illness		

Method of Generating Random Sequence

Method of Concealment

Blinding/Masking

Primary Outcome

Not Applicable

Not Applicable

Not Applicable

Outcome	Timepoints
To establish the standard treatment methodology	To establish the standard treatm
for the management of Paresis in Siddha system	for the management of Paresis i
muscle tone and reflex gait by Ashworth scale in	of medicine. To assess power s tone and reflex gait by Ashworth and after treatment

Secondary Outcome

Outcome	Timepoints
NIL	NIL
CC - DAI - 2 (7420) - 2 (2 C - 2004 - 2005)	

Target Sample Size

Total Sample Size=30

Sample Size from India=30
Final Enrollment numbers achieved (Total)=Applicable only for Completed/Term Final Enrollment numbers achieved (India)=Applicable only for Completed/Term

Phase of Trial Date of First

Enrollment (India)

Date of First Enrollment (Global)

Estimated Duration of

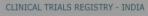
Trial

Phase 3 15/08/2021

No Date Specified

Years=0 Months=1 Days=27

Recruitment Status of Not Applicable







PDF of Trial CTRI Website URL

lusio	

	Inclusion Criteria		
Age From	3.00 Year(s)		
Age To	12.00 Year(s)		
Gender	Both		
Details	Monoparesis br/> Diparesis br/> Quadriparesis Cerebral palsy br/> Difficulty in gravity of both upper and lower limbs both upper and lower limbs both upper and muscle br/> Loss of power and muscle br/>		

Exclusion Criteria

	Exclusion Criteria		
Details	Epilepsy Severe aggressive with ADHD Congenital heart disease Autism Any other serious illness		

Method of Generating Random Sequence

Method of Concealment Blinding/Masking Not Applicable

Not Applicable Not Applicable

Primary Outcome

Outcome	Timepoints
muscle tone and reflex gait by Ashworth scale in	for the management of Paresis of medicine. To assess power s

Secondary Outcome

Outcome	Timepoints		
NIL	NIL		

Target Sample Size

Total Sample Size=30 Sample Size from India=30

Final Enrollment numbers achieved (Total)=Applicable only for Completed/Term Final Enrollment numbers achieved (India)=Applicable only for Completed/Term

Phase of Trial Date of First **Enrollment (India)**

Date of First Enrollment (Global)

No Date Specified

Estimated Duration of

Years=0 Months=1 Days=27

Phase 3

15/08/2021

Trial

drug analysis pdf



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Sample Name #	:Maha Analurva Choorna	ım			
Supplied By #	:NA		Report Date :16-03-2022		
Manufactured B #	y :NA		Report No. :ICA-2203160079		
Submitted By	:K. Kavithalaya		Booking Code :A01-2203050035		
Mfg. Lic. No. #	:NA		Booking Date :05-03-2022		
Party Ref. No. #	:28-02-2022				
Address	ddress :K. Kavithalaya-National Institute of Siddha, Tambaram, sanatorium, Chennai				
Batch No. #	:NA	Batch Size #:	Party Ref. Date # :28-02-2022		
D/M #	:10.02.2022	D/E# :-	Sample Qty. #:100 gm		

	C: TEST RESULTS				
Desc	ription				
Desc	ription	Brown Coloure	d Powder.		
S.N o.	Test Paramet er	Inst. Used	Method	Requiremen t	Result
Test	Details :	<u> </u>			
1.	General Parameters				
a.	Odour	NA	Organoleptic		Characteristic
b.	Colour	Visual	Visual		Brown
2.	Chemical Parameters				***
a.	Total ash	Muffle Furnace	API		4.60%
b.	Acid insoluble ash (%w/w)	Chemically	API		1.87%
C.	Alcohol soluble extractives(%w/w)	Chemically	API		9.93%
d.	Water soluble extractives	Chemically	API		9.88%
e.	pH Value	pH Meter	API		5.12
f.	Foreign matter(% by mass)	Visual	API		Absent
g.	Loss on drying	Hot air oven	API		5.34%
h.	Tap Density(gm/ml)	-	API		0.3862
i.	Microscopic	Microscope	API		Sample was observed under

19-03-2022

Interstellar Testing Centre Pvt. Ltd. 86, Industrial Area, Phase-1, Panchkula-134109 (Haryana) Panchkula-134109 (Haryana) Phone: (O) 1072-2561543, 2565825 Email: customersupport@itclabs.com Visit us :www.itclabs.com



Drowning Khandelwal [Authorized

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Interstellar Testing Centre Pvt. 1 4 4

Rashmi Srivastava 19-03 -2022 Reviewer

19-03-2022 Roopak Kumar [Authorized Signatory]



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Page 2 of 3

j.	Bulk density (Untapped)(gm/ml)	-	API		0.2896
k.	Total acidity(% by mass)	Chemically	API		0.86%
I.	Particle size, % through 100 mesh	SIEVE	API		42.85% (Passing material on 100 mesh sieve)
m.	Identification(Fingerprint)	HPTLC	In house method		Data Submitted to Customer
3.	Microbiological Tests				
a.	Total viable aerobic count,cfu/gm	Microbiologica I	API	Max100000	30500
b.	Total fungal count, cfu/gm	Microbiologica I	API	Max1000	380
C.	E.coli/gm	Microbiologica I	API	Absent	Absent
d.	Salmonella/gm	Microbiologica I	API	Absent	Absent
e.	S.aureus/gm	Microbiologica I	API	Absent	Absent
f.	P.aeruginosa/gm	Microbiologica I	API	Absent	Absent
4.	Heavy metals				
a.	Lead (as Pb) (ppm)	ICPOES	ITC/STP/F/INST/ 0 08	NMT-10	BLQ(LOQ:0.5)
b.	Arsenic (as As) (ppm)	ICPOES	ITC/STP/F/INST/ 0 08	NMT-3	BLQ(LOQ:0.5)
c.	Mercury (as Hg) (ppm)	ICPOES	ITC/STP/F/INST/ 0 08	NMT-1	BLQ(LOQ:0.5)
d.	Cadmium (as Cd) (ppm)	ICPOES	ITC/STP/F/INST/ 0 08	NMT-0.300	BLQ(LOQ:0.25)
5.	Aflatoxins				
a.	B1 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.5	BLQ (LOQ:0.0005)
b.	B2 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.1	BLQ (LOQ:0.0005)
c.	G1 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.5	BLQ (LOQ:0.0005)
d.	G2 (ppm)	HPLC	STP/ITC/AY/003	NMT 0.1	BLQ (LOQ:0.0005)

^{&#}x27;#' represents Customer Defined Fields

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Interstellar Testing Centre Pvt.



19-03-2022 Roopak Kumar [Authorized Signatory]

10:50 AM



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NOTE:

Party has asked for the above tests only.API

*****End Of Report****



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