PRE CLINICAL AND CLINICAL EVALUATION OF KARAPPAN NEI (INTERNAL AND EXTERNAL MEDICINE) IN THE TREATMENT OF BALA KARAPPAN IN CHILDREN.

Dissertation submitted to

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For the partial fulfillment of the requirements for the award of the degree of

Doctor of Medicine (Siddha)

Submitted by

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2015-2018

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation work entitled **"Pre Clinical and Clinical evaluation of Karappan Nei (Internal and External Medicine) in the treatment of Bala Karappan in Children"** is a bonafide and genuine research work carried out by me under the guidance of Dr. K. Suresh, M.D.(S)., Ph.D Lecturer, Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed on the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date:
Place: Chennai - 47

Signature of the candidate

(Dr. M.BAKKIYADEVI)

CERTIFICATE

This is to certify that this dissertation work on **"Pre Clinical and Clinical evaluation of Karappan Nei (Internal and External Medicine) in the treatment of Bala Karappan in Children"** has been carried out by **Dr. M. BAKKIYADEVI**, RegNo.321514202 during the year 2015-2018 in the Department of Kuzhanthai Maruthuvam, National Institute of Siddha, Tambaram sanatorium, Chennai under my guidance and supervision in partial fulfilment of regulation laid by The Tamilnadu Dr.M.G.R Medical University, Chennai for the final M.D (Siddha), Branch IV– KUZHANTHAI MARUTHUVAM Examination to be held in OCTOBER - 2018.This dissertation work is not reprinted or reproduced from the previous dissertation work.

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INDEX

1. INTRODUCTION

"**Health is wealth**" of all the wealth man can gain the most precious is being free from disease.

Health is defined by the world health organization as the "State of complete Physical, Mental and Social wall being and not merely the absence of disease and infirmity. Medicine plays a major part in this process. The world is endowed with many system of Medicines like Siddha, Ayurvedha, Unani, Allopathy, Homeopathy etc.,,

The Siddha system is serving the mankind to all of its Physical and Mental, Social and Spiritual components of human being. The advantage and unique feature is the removal of root causes of the disease and perfect for body and mind. Siddha system of medicine was developed by 18Siddhars and hence the name Siddha Medicine. Siddha systemof medicine not only includes medicine, but also Astrology, Yoga, Pranayamam and Varmam in its treatment strategies.

Fundamental principles of Siddha including theories of

- Five Elements (Aimbootham) ஐம்பூதம்
- Three forces / Faults (Mukkuttram) முக்குற்றம்
- Eight fold examination (Envagaithervugal) எண்வகைதேர்வுகள்

FIVE ELEMENTS (AIMBOOTHAM) ஐம்பூதம்

தோல் ஆனது ஐம்பூதங்களில் ஒன்றான உள்ள ஆகாயத்தின் கூறாக உள்ளது. ஆகாய பூதமானது எல்லா உயிர்களுக்கு அடிப்படையாகிய உணவும், பலவகைப்பட்ட மருந்துகளும், மற்ற பூதங்களான மண், நீர், தீ, காற்று ஆகிய அளவிற்கடங்காத எல்லாப் பொருள்களுகம் அடங்குவதற்கும் இடம் தரும். இதைபோல் தோல் எல்லா உறுப்புகளும் தங்குவதற்கு இடமளித்து அவற்றை பாதுகாக்கின்றது.

வளி = விண் + வளி = வாதம்

Three Humors/ Faults (Mukkuttram) முக்குற்றம்

According to Siddhars the Physiological function of the human body is maintained by three vital humour called Vadham, Pitham and Kabham existing in the ratio 1:1/2:1/4 respectively. The equilibrium of this vital humour affected by any external (or) internal factors will result indisease.

"மிகினும் குறையினும் நோய்செய்யும் நூலோர்
வளிமுதலா வெண்ணிய மூன்று"

- திருக்குறள் 941

The learned books count three, with win as first; of these, As any one prevail, or fail; 'twill cause disease.

"வாதமல்லாது மேனி கெடாது"

- தேரையர்

As per the Siddha literature the body get affected mainly due to vitiation of Vadham (vali) humour including dermatological condition.

The Eight Fold Examination (Envagaithervugal) எண்வகை தேர்வுகள்

"நாடி ஸ்பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திர மிவை மருத்துவராயுதம்"

– தேரையர்

Eight fold Examination is a tool in Siddha system of medicine used to determine Diagnosis, Etiology, Treatment and Prognosis of a disease.

Skin is the largest organ in human body. Skin and its derivatives and appendages form the "Integumentary system". Skin derivatives include Nails, Hair and Several types of sweat and sebaceous glands. The skin forms protective covering of the body. The skin develops in the third week of fetal life. The skin at birth covered by vernix caseosa. The whitish greasy coats have bactericidal properties. There are so many skin disease like Vitiligo, Lichen Planus, Psoriasis, Scabies, Pityriasis alba affecting the children. Most common childhood skin disease is eczema.

Eczema is a chronic inflammatory skin disease. It is the most commonest disease affecting the school going children between the age of 3-7 year. It is a worst disease which affect all over the body and also cause mental worries in both children and their parents. The prevalence of eczema about 13% of world population in 2017. In India it is ranged from 0.9% and 23.3%. Recent data shows that its prevalence is still increasing especially in low income countries.

In our classical Siddha literature there are 18 types of Eczema (Karappan) have been described. Signs and symptoms of Eczema is nearly correlated to Bala Karappan mentioned in Siddha system to medicine (Balavagadam). According to the Siddha texts it is characterized by skin Rashes, Papules, Vesicles, Pustules, Fissures, Oozing, Ulceration, Swelling, Itching, Hyperpigmentation lesion.

Siddha system plays a wide ranged role in the field of pediatrics. It ensures the health of the children with its astonishing herbal formulations. Karappan Nei, a poly herb formulation described in the classical Siddha text book pillaipini Maruthuvam Part-2 which is indicated for the treatment for Bala Karappan. It is used both as in internal and External medicine.

Lot of research has been developed in the field of pediatric dermatology. Siddha medicines are more effective for skin disease that's why I have selected one of the skin disease Bala Karappan as my dissertation work.

According to Siddha text skin disease occurs due to derangement of Vadham. Most of the ingredients present in karappan Nei having Kaippu (Bitter) and Kaarppu (Pungent) suvai which are the taste which can neutralize Vaatha humour. Hence I have chosen this trial drug Karappan Nei for my dissertation. All the ingredients of this drug are herbal only. Hence it will be good and safest drug for children.

2. AIM AND OBJECTIVES

Primary Objectives:

To evaluate the efficacy of Karappan Nei as Internal and External Medicine in the treatment of Bala Karappan (Eczema) in children.

Secondary objectives:

- To analyses the study drug Karappan Nei through Physicochemical analysis, Pharmacological activities, Acute toxicity studies, phytochemical analysis.
- To collect and review the ideas mentioned in the ancient Siddha literature about the disease Bala Karappan.
- To Explore the Definition, Etiology, Clinical features, Diagnosis, Investigations and treatment methods of Bala Karappan
- To make a correlative study of the disease with Siddha and Modern concepts.
- To have a clinical trial on the patients with the selected drugs along with proper diet regimen.
- To use Modern diagnostic parameters for studying the progress of the patients.

3. REVIEW OF LITERATURES

3. a. SIDDHA ASPECTS

Bala Karappan is one of the eighteen types of Karappan which affects the children. This skin disease was described by various Siddhars in detail about the general etiology signs and symptoms and prognosis.

கரப்பான்

இயல் (Definition)

உடலில் திமிர், தினவு, சொறி, புண், தடிப்பு, வெடிப்பு, நீர் கசிதல் ஆகிய குறி குணங்கள் உண்டாக்கி உடம்பின் இயற்கை நிறத்தை வேறுபடுத்தும் நோய் கரப்பான் எனப்படும்.

நோய் வரும் பருவம்

தால பருவம் முதல் வருகை பருவம் வரையுள்ள நான்கு பருவங்களிலும் கரப்பான் நோய் குழந்தைகளுக்கு உண்டாகக்கூடும்.

நோய் வரும் வழி (Etiology)

In Text book Balavagadam, it desccibed the etiology of Karappan as,

பெருகுஞ் சோள மிறுகும் பெருங்கம்பு
வரகு காருடன் வாழையின் காயொடு
உரைகொள் பாகற் கெளிற்று மீன் உண்டிடில்
விரிவதாய்க் கரப்பானு மிகுந்ததே.

In take of Fish, Mutton, rhizomes, Tubers of some plants and grains like, Kambu (Pennisetum typhoideum), Solam (Sorghum vulgarel, Varagu (Paspalum Scrobicculatum), Karrasi (Oryza Sativa), Vazhaikkai (Muza Paradisiac), Paakal (Momordica Charantica), Kelirrumean (Osteogeniosus militaris) taken by the mother (By breast feed) or child produces Karappan.

According to siddha literature yugi vaidhya chinthamani:

According to Siddha text book Yugi Vaidhya Chinthamani etiology of Karappan described by eating meat, various types of millet and tubers can cause Karappan.

ஏழான கரப்பானின் உற்பத்திக் கேளாய்
ஏற்றமாய் மாமிசங்கள் புசிக்கையாலும்
கூழான கம்பு தினை வரகு சாமைக்
கொடிதான கிழங்கு வகையருந்த லாலும்

- **யூகி வைத்திய சிந்தாமணி**

According to siddha literature Pararasa Segaram:

According to the Siddha literature Pararasa Segaram etiology of Karappan described as Air born infection, Excessive intake of Jaggery, Plantain, Brinjal, poisonous bites may cause the disease.

வேகக் காற்றதினர் பனை வெல்லத்தால்
பாகமிக்கலான மேதிப் பாவெயிலால்
தாகமானி வருக்க திசார்தலால்
மோக வாழை வழுதலை முள்ளிக்காய்
காயும் பல்விடத் தாற்சுரத் தாற்களில்
எயும் வண்டெலி யால் வருமே துவெளி
குடி நல்லறிவான எருவினார்
யானமான கரப்பன் வகைகளே.

- **பரராச சேகரம்.**

Classification of karappan:

As per the Siddha literature Bala vagadam, Karappan is classified into eighteen types as follows,

“முத்தோட மரியூது சூலை
முன்னுவெடி மண்டை பொரிசட்டை
சற்றேடு கருமையொடு செம்மை

தனிக்கொள்ளி தோடமொடு வாலை

முற்றோல்வ ரட்சியொடு வீங்கல்

மூரிவரும் பதினெட்டு வகையாம்

கொத்தான கரப்பான்க ளென்று

கூறினார் பண்டையோ ராமால்”

“செங்கரப்பான் அனல்கரப்பன் தானும் மண்டைச்

சிரங்கிபபண்ணும் அரிகரப்பான் பொரிக ரப்பான்

அங்கமதி லெழுகரப்பன் தானு மிக்க

அளராம் உதி ரக்கரப்பன் கட்டி யோடு

பொங்கமாய் வீங்கி கரப்பான னுந்தான்

புகலரிய சட்டைதடி வெடிக ரப்பான்

சிங்கமுக எரிகரப்பன் வாத பித்தச்

சேத்துமத்தோ டேகரப்பன் பதினெட் டமெ

எண்வகைக் கரப்பன் இசைந்திடக் கேளு”

Classification of karappan as per the text book of bala vagadam

1. Vatha Karappan (வாத கரப்பான்)
2. Pitha Karappan (பித்த கரப்பான்)
3. Sethuma Karappan (சேத்தும கரப்பான்)
4. Ari Karappan (அரி கரப்பான்)
5. Oothu Karappan (ஊது கரப்பான்)
6. Soolai Karappan (சூலை கரப்பான்)
7. Vedi Karappan (வெடி கரப்பான்)
8. Mandai Karappan (மண்டை கரப்பான்)
9. Pori Karappan (பொரி கரப்பான்)
10. Sattai Karappan (சட்டை கரப்பான்)
11. Oodu Karappan (ஓடு கரப்பான்)
12. Karung Karappan (கரங்கரப்பான்)
13. Seng Karappan (செங்கரப்பான்)
14. Kolli Karappan (கொள்ளி கரப்பான்)

15. Thoda Karappan (தோட கரப்பான்)
16. Vaalai Karappan (பால கரப்பான்)
17. Varal Karappan (வரள் கரப்பான்)
18. Veengu Karappan (வீங்கு கரப்பான்)

1. வாத கரப்பான்:

தெறிக்கும் வீங்குமுட லெங்கு மேதிமிர்க டுப்ப தகியழுந் தேகமேற்
பொறிப் பறந்ததென வேபுண் ணாகியதி லேவெடித் ததிக பொங்கமாய்
முறுக்கி யேசுர தாகி நாவது வறண்டு நோயது முதிர்ந்திடில்
வெறிக் கருங்குழலி மாது வாதகரப் பானெனப் புகல்வர் மேவிடே.

(பால வாகடம் 4ம் பதிப்பு பக்க எண் 385)

- Skin rashes or bumpy rashes
- Papules/ Vesicles/Pustules
- Oozing fromlesion
- Lymphadenopathy
- Itching
- Fever

2. அழற்கரப்பான்:

“கொடுமையான சிரநோயினோடு சொறி கூறு முட்டினமும் வாந்தியும்
கடுமையான சுரமெய்சி வந்திடுதல் கண்பரத் துதொனி முந்தியே
தடைகளாகமல பந்தமாகிவிடில் சார்ந்த பித்தகரப் பானென்றே
விடமு நேரமுத முஞ்சமானவிழி வெண்ண கைத்திரு மருந்திடே”

- Headache
- Itching
- Vomiting
- Fever
- Reddishness in affected skin
- Constipation

3. ஐயக்கரப்பான்:

இசையு நெஞ்சுக ளடைத்து ளேவிரண மாகியேதவை வலித்திடும்
அசையும் வாயதனில் வெந்துமே திரட்சியகி யேகடு கடுத்திடில்
விசையுஞ் சேத்தும கரப்பானென சிகிச்சைமேவு செவ்வரி பரந்து நின்
வசை பொருந்தும் விழி கலைதிரண்டமுக வனிதையே வுடதங்களே"

- Ulcers in the mouth and trunk
- It changes to vesicles
- Chest pain
- Headache

4. அரிகரப்பான்:

"இடைசி றுத்துவன கனிபு ரைத்த மொழி யினியதானவத ரத்தினாய்
துடையி டைக்குள்மிகு விரண மாகியதிற் சூழச லங்ககளுமி குந்துநோய்
புடையு நீள்தசை கரைந்து நட்படவி ருந்து பூதவுடல் வாடினால்
அடைவ சோரி கரப்ப னாமிதைய றிந்து நன்மருந் தாற்றிடே"

- Ulcers in the genital organs and both groins
- Itching and oozing in the inner aspect of the thigh
- Emaciation

5. ஊது கரப்பான்:

கேளாய் குளிர்காய்ச்சல் கேடாங் கருங்கழலை
மூளாவி தான் போல் முயன்றுநிற்கும் - நாள்தோறும்
பூதம்போல் வீங்குவிக்கும் புண்ணாகி மூக்கரிக்கும்
ஊதுகரப் பாந்தோடம் உற்று."

- Fever with rigor
- Tumours in the body
- Generalised oedema and Itching

6. சூலைக் கரப்பான்:

"பிள்ளை முகம்வாடிப் பேதவெடி மேனியெல்லாம்
சள்ளை பொருந்தித் தவிக்குமே – மெள்ளக்கேள்
வள்ளல் முழங் கால்கை மருவியுண்ணக் கூடாது
தள்ளுமென்றே சூலையது தான்."

- Ulcers and pain in the body and general debility
- Difficulty in moving both knees and elbow joints

7. வெடி கரப்பான்:

அரிவை யேயுடலக ளெங்கும் விங்குமசை கீலில் வீங்குமதில் துண்டமாய்
விரிய வீங்கியதி லெவெடித்திடு மிகுந்த வெப்பதுவு மாகவே
திரிகி யேதலை வலித்து மேலும்வெகு தினவு மாகியது வோடினால்
உரிய தாகும்வெடி கரப்ப னாமென வுகந்து பண்டித முணர்த்திடே".

- Swelling in the body
- Pain and swelling all over the joints
- Itching, headache, and fever

8. மண்டைக் கரப்பான்:

"ஓடி மண்டைதனி லேபுண் ணாகியுயர் காதிற் சீவழிந்தறியே
நாடி யேதலைவ லித்து மூக்கினில் நயந்து நிரது ப்ரிந்திடும்
வாடி மெய்யதும் வெப்பமொடு குரல் வளையி னினறினவுமாகவே
கூடில் மண்டைக் கரப்பானெ னப்பரி கார மேலினிக் கூறுவாம்".

- Itching in the scalp
- Ear discharge, headache, and fever
- Loss of weight and pain in the throat

9. பொரிகரப்பான்:

“மாறு மாறென வடிதத வயென வுடற்குளே தடிப்பாகியே

ஏறு மேசிவந் தோடு யேகனத் தெங்கு மேல்வெடித் துள்ளுமே

நீறு போலனல் குளிர்ச்சி யாகியுழ னாவு லர்ந்துநெறி தாழ்த்திடில்

ஆறி டாப்பொறி கரப்ப னாமென வறிந்து பண்டிதந் தொகுத்திடே”.

- Papules in the body and altered sensorium
- Dryness of mouth

10. சட்டைக் கரப்பான்:

“மங்கை கீலில்வலி கள்ளிப் பூவெனம லர்ந்து வாரியிடு மெய்யினிற்

பொங்கு நீர்ப் பனிகள் போல்வி முந்துடலம் வெப்ப மாகிமலஞ் சிக்கியே

துங்க மானசிர நோவு மாகிவளர் தூயவன்னமது துவேடமாம்

தங்கு சட்டை கரப் பானே ணச்சிகிச்சை தானே தற்குவிரித் தோதுவாய்”.

- Pain in all the joints associated with fever
- Yellow colouration of the skin
- Itching and oozing in the lesion
- Loss of appetite

11. ஒடு கரப்பான்:

எண்ணு கின்றதொரு கீலி லேவலிக ளேக மாகியது கட்டியே

வண்ண மெய்நரம் பெங்கு மேயிசிவு குத்த லாகிமல பந்தமாய்

நண்ணி யேதினவு மாய்த்தடித் துடலி னடி வீக்கமு மிகுந்திடிற்

கண்ணி ஒடுகரப் பான்இ தென்றமுறை கண்டு கொள்ளடி கருத்திலே.

- Pain and swelling in all the joints
- Difficul to flexion and extension of joints
- Allergic papules
- Itching
- Constipation

12. கருங்கரப்பான்:

அற்ய கேளய் கரங்கரப்பன் அழமெ குழவி உடல்வெதும்பும்
செறிய முலையும் உண்ணாது தேகநிற்கும் வெவ்வேறாய்க்
கரிய மேனி பசுநரம்பு கதித்தே காட்டும் பரபரத்து
முறுக்கி மிகவுந் துள்ளி விழும் முகமும் பதங்கள் ஊதிடுமே".

- Fever
- Discolouration of the skin
- Oedema in the face and lower limbs

13. செங்கரப்பான்:

"காய்ச்ச லோடுகடுப் பகி யூதிடல் கன்றி மெத்தவு மழன்றுபோய்
மேய்ச்ச லானதின வாகியெங்கணு வியர்க்குருவுகள் மிகுந்துதான்
பாய்ச்ச லானமுக முங்கறுத்துடல் பரிந்து தானது சிவந்திடில்
சூட்ச மாகிவளர் செங்க ரப்பனெனத் தோற்றி யேயவு டதஞ்செயே".

- Low grade Fever
- Macules and papules are present
- Blackish discolouration in the face
- Erythematous lesion present in all over the body

14. கொள்ளிக் கரப்பான்:

கொத்துக் கொள்ளி யின்கரப்பான் குணத்தைக் கேளாய் கோகிலமே
மற்றும் வயிறு தான்வீங்கி மலமு மடைக்கும் இளைப்புண்டாம்
கத்துங் குரலும் அரையுண்டாங் கனத்த விக்கல் உண்டானால்
பத்தும் பதியும் ஒதுவதேன் பாலன் பிழைப்ப தரிதாமே".

- Abdomin swelling
- constipation
- Emaciation
- Hiccough
- Dyspnoea

15. தோடக் கரப்பான்:

உள்ளு மேலுநளிர் காய்ச்ச லாகியுடம் பெங்கும் புண்ணென வழன்றுவாய்
கள்ளு நாறியுடல் தன்னி லேகழலை கண்டு பூதமென வீங்கியே
எள்ளின் மாமலரை யொக்கு மூக்கின் நின்றழுது மேங்கினால்
தள்ளு மான்களின் சாய லாய் கொடியதோ டமானகரப் பானிதே".

- Fever with rigor
- Papules and pustules in the body
- Foul smell in mouth
- Lymphnode enlargement
- Itching innose

16. வாலை(பால) கரப்பான்:

காலது கடுக்குஞ் சந்து கண்டமும் வெடித்துப் புண்ணாய்
ஏலவே கடிவி டம்போல் இருத்துபன் னீர்பேல் பாய்ந்து
கோலமாய் வற்றி நாறும் குழவியு மொடுங்கு மாகில்
மாலருங் குழலாய் வால கரப்பான் செய் வாறு தானே".

- Pain in the lower extremities
- Appearance of vesicles, oozing, bullae, papules
- Foul smelling discharge in the ulcers

17. வரள் கரப்பான்:

உச்சிமுத லுள்ளங்கா லுற்றளவி லெவ்விடமும்
நச்சுச் சிறுசிரங்கு நண்ணியே-நிச்சல்
வெடித்து நீர் மெவு நமை மெவா துறக்கம்
கடிந்தவரட் சிக்கரப்பான் காண்".

- Itching, Oozing, papules in the body
- Bullae present in the whole body
- Insomnia

18. வீங்கு கரப்பான்:

முன்னரே யங்கங்கு மூரிக் கனமுண்டாய்ப்

பின்னரவை புண்ணாய்ப் பெரு.ந்தீயாய்ப-மன்னியெரிந்

தப்பான முத்தணிந்தவற்றி னீர் சொரிதல்

தப்பாவிங் குங்கரப்பான் தான்".

- Swelling in various parts of the body
- Burning sensation in the site of the lesion
- Oozing

Other Siddha Literatures describing the classificationof Karappan

As per the another siddha text book Aathma rakshamirtham yennum vaithiya saarasankiram describes the classification of Karappan in eighteen types as follows

a) ஆத்மா ரத்சாமிர்த்மென்னும் வைத்திய சாரசங்கிரம்

1. வாதக் கரப்பான்
2. பித்த கரப்பான்
3. சிலேத்தும கரப்பான்
4. செங்கரப்பான்
5. கருங்கரப்பான்
6. மண்டை கரப்பான்
7. அரி கரப்பான்
8. பொரி கரப்பான்
9. கிரந்திக் கரப்பான்
10. சூலைக் கரப்பான்
11. வாலைக் கரப்பான்
12. ஊது கரப்பான்
13. செவ்வாப்பு கரப்பான்
14. கொள்ளி கரப்பான்

15. கட்டியொடுவிங்கு கரப்பான்

16. உதிரக் கரப்பான்

17. சட்டைதடிவெடி கரப்பான்

18. சிங்கமுக எரி கரப்பான்

b) யூகி வைத்திய காவியம்

As per thesiddhaliterature yugi vaithiya kaaviyam karappan is classified into 9 types as follows

1. வாதக்கரப்பான்
2. கண்டக்கரப்பான்
3. வறட்சிகரப்பான்
4. பித்தகரப்பான்
5. பித்தவறட்சிக்கரப்பான்
6. கபால கரப்பான்
7. வாதவறட்சிக்கரப்பான்
8. திமிர்வாதக்கரப்பான்
9. செங்கரப்பான்

c) சிகிச்சாரத்ன தீப வைத்திய சிந்தாமணி

As per thesiddhaliterature Sigicha rathna theepam karappan is classified into 7 types as follows

1. வாதக் கரப்பான்
2. திமிர் கரப்பான்
3. கபால கரப்பான்
4. கண்டக் கரப்பான்
5. பித்த கரப்பான்
6. வறட்சி கரப்பான்
7. சிலேத்தும் கரப்பான்

d) குருநாடி சாஸ்திரம்

Other Siddha Literature Guru naadi saasthiram Karappan is classified into eighty five a follows

"படுவன் முப்பத்திரண்டு பருவெரு நாற்பத்தொன்று

முருகிடும் விஷபமாறு முற்றுமொஷசி மூன்றுர்

திருகிடும் பீலி மூன்று சிரசினிற் சிலந்தி சொல்லில்

கடுகிடு மைடம் பத்தாறு கரப்பானு மென்பத்தைந்து

(குருநாடி சாஸ்திரம்)

e) அகத்தியர் 2000

In Agathiyar 2000 classification of Karappan is sixty six in numbers

விளம்பிடு வாதநொவு எண்பத்து நாலுமிக்க

உள்ளங்கள் சன்னி முப்பதோங்குடல் வாயுமெட்டு

கழங்கமு முப்பத்தெழு கரப்பானு மறுப்பத்தாறு

தனங்கொள்ளிப் புருதி நாலு சாற்றுளை குறவை யெட்டே

(அகத்தியர் 2000)

f) அகத்தியர் இரண நூல்

Other siddha literature classification of Karappan is sixty six in numbers

எண்பது கரப்பான் தன்மை யியம்பிடுமாறு கேளீர்

நன்யிடும் வாதம் பித்தம் நலங்கெட்டுத் தாளம்விங்கும்

புண்படுங் கரங்கள் சந்து புலைந்திடல் கருத்து நோகும்

வன்மையுடன் வெடித்துச் சூலை வருவதுரபை தென்வெ

(அகத்தியர் இரண நூல்)

g) யூகி வைத்திய சிந்தாமணி

As per the Siddha literature Yogi Vaithiya Chinthamani Karappan is classified into seven types

ஆமென்ற கரப்பான் தான் ஏழுவித மாகும்

அடங்காத வாதத்தின் கரப்பானோடு

காமென்ற கண்டமாங் கரப்பானாகும்

கருதிய தோர் வறட்சியாங் கரப்பானோடு

தேமென்ற திமிர்வாதக் கரப்பான் றானும்

சிரசினிலே பெருக பாலக் கரப்பான்

போமென்ற பித்தமாங் கரப்பானோடு

பெரிய சேட்டுமக் கரப்பான் பெயர்தானேழே".

(யூகி வைத்திய சிந்தாமணி)

1. Vadha Karappan	(வாத கரப்பான்)
2. Pitha Karappan	(பித்த கரப்பான்)
3. Kabha Karappan	(கப கரப்பான்)
4. Kanda Karappan	(கண்ட கரப்பான்)
5. Varatchi Karappan	(வறட்சி கரப்பான்)
6. Kabala Karappan	(கபால கரப்பான்)
7. Thimir Vatha Karappan	(திமிர்வாத கரப்பான்)

Curable and incurable types of karappn as per siddha text book baavagadam

1. கொள்ளி கரப்பான் - அசாத்தியம் (Incurable)
2. மற்ற 17 வகைகள் - சாத்தியம் (Curable)

முக்குற்ற வேறுபாடுகள் (Pathogenesis)

சித்த மருத்துவத்தில் முக்குற்றங்களின் அடிப்படையில் நோய்கள் வகைப்படுத்தப்பட்டுள்ளன. முக்குற்றறங்களாவது வாத, பித்த, கபம் என்று கூறப்பட்டுள்ளது அவை முறையே

வாதம் - 10

பித்தம் - 5

கபம் - 5

வாதம் / வளி (Vatham)

வடிவத்தன்மை

- நுண்மை (அணுத்துவம்)
- நொய்மை (கடினமின்மை)
- தண்மை (குளிர்ச்சி)
- வெம்மை (உட்டிணம்)

தண்மை, வெம்மை ஆகிய இவ்விரண்டால் வரும் ஒப்புரவின்மை (சருச்சரை) என்பனவாம்.

வளி வாழுமிடம் (Location of Vatham in the body)

அபானம், மலம், இடகலை, உந்தியின் கீழ் மூலம், காமக்கொடி, இடுப்பு எலும்பு, தோல், நரம்புக்கூட்டம், கீல்கல், மயிர்க்கால்கள், ஊன் ஆகிய இடங்களில் வாழ்வதாகும்.

வகைகள்	பணிகள்
1. பிராணன்	• மூச்சு வாங்கல், விடுதல் செய்யும். • புசிக்கும் உணவுகளைச் செரிக்கப் பண்ணும்
2. அபானன் (கீழ்நோக்குகால்)	• மலசத்தைத் தள்ளும் • ஆசனவாயைச் சுருக்கும் • அன்னசாரத்தைச் சேர வேண்டிய இடங்களில் சேர்ப்பிக்கும்
3. வியானன்	• உறுப்புகளை நீட்ட மடக்கச் செய்தல் • பரிசங்களையறிதல் • உண்ணும் உணவின் சாரத்தை அவ்வவ்விடங்களில் நிரப்பித்து உடலைக் காக்கும்
4. உதானன் (மேல் நோக்குக்கால்)	• உணவின் சாரத்தை அங்கங்கே நிறுத்தும். வெளிப்படுத்தியும்/கலக்கியும் வருதல் செய்யும்
5. சமானன் (நடுக்கால்)	• வாயுக்களை மிஞ்சவொட்டாமல் மடக்கிச் சரிபடுத்தி சேர பண்ணும். • தண்ணீர், அன்னம் ஆகியவற்றை சமப்படுத்தி உடலிலெல்லாம் சேரும்படி செய்யும்
6. நாகன்	• அறிவை எழுப்பல். நல்ல பண்களைப் பாடுவிக்கும். • கண்களை திறக்க இமைக்கச் செய்யும் • மயிர்களை சிலிர்க்கப் பண்ணும்
7. கூர்மன்	• இசையை கொட்டுவித்தல்

	• கொட்டாவி விடப்பண்ணல் பலம் உண்டு பண்ணல் • கண்களை திற்க்க/மூட பண்ணல். • உலகப் பொருட்கள் யாவற்றையும் கண்களுக்கு காண்பிக்கும். • கண்களினின்று நீரை விழப் பண்ணும்
8. கிருகரன்	• நாவிற்கசிவு, நாசியிற் கசிவையும் உண்டாக்கல். • பசியை உண்டு பண்ணல் • ஒன்றை நினைத்திருக்கச் செய்தல் • போதற் தொழிலைச் செய்யும் • தும்மயலயம், இருமலையும் உண்டாக்கல்
9. தேவதத்தன்	• சண்டைகொள்ளல் • தர்க்கம்பேசல், மிக்க கோபம்.
10. தனஞ்செயன்	• மூக்கிலிருந்த தடிதது உடம்பு முழுமையும் வீங்கப் பண்ணும். • காதில் கடல் போலிரையும். • காற்றெல்லாம் வெளிப்பட்ட பின்னர் 3வது நாளில் தலை வெடித்த பின் தான் போகும்

பாலக் கரப்பானில் அபானன், உதானன், சமானன், கிருகரன், தேவதத்தன் இவைகள் பொதுவாக பாதிப்பு அடையும்.

பித்தம்/அழல (Pitham)

வடிவத்தன்மை

- வெப்பம்
- நெய்ப்பு
- கூர்மை
- நெகிழ்ச்சி

பித்தத்தின் இருப்பிடன்:

பிங்கலை, பிராணவாயு, நீர்ப்பை, மூலாக்கின், இருதயம், தலை ஆகிய இடங்களில் வாழ்வதாகும்.

வகைகள்	பணிகள்
1. அனர்பித்தம்	• உண்ட உணவை செரிக்கும்படி செய்யும்
2. இரஞ்சகம்	• செந்நீரை மிகுதிபடுத்தும். • உணவின் சாற்றுக்கு செந்நிறத்தைக் கொடுக்கும்

3. சாதகப்பித்தம்	• நிறைவேற்றும் பண்புடையது • மனம், புத்தி, பற்று இவற்றைக் கொண்டு விருப்பமான தொழிலைச் செய்து முடிக்கும்
4. ஆலோசகப் பித்தம்	• கண்களுக்கு பொருட்களைத் தெரிவிக்கும் பண்புடையது.
5. பிராசக பித்தம்	• தோலுக்கு ஒளியைக் கொடுத்து ஒளிரச் செய்யும்

பாலக் கரப்பனில் இரஞ்சகம், பிராசகம் இவைகள் பொதுவாக பாதிப்பு அடையும்.

ஐயம்/கபம் (Kabham)

வடிவத்தன்மை

- தன்மை
- மந்தம்
- நெய்ப்பு
- திண்மை
- வழுவழுப்பு
- மென்மை

ஐயம் வாழுமிடம்

சமானவாயு, சுழிமுனை, வெண்ணீர (விந்து), தலை, நாக்கு, உண்ணாக்கு, கொழுப்பு, மச்சை, குருதி, மூக்கு, மார்பு, நரம்பு, எலும்பு, பெருங்குடல், கண், கீல்கள் ஆகிய இடங்களில் வாழ்வதாகும்.

வகைகள்	பணிகள்
1. அவலம்பகம்	• நான்கு ஐயங்கட்கு பற்றுக் கோடாயிருத்தல்
2. கிலேதம்	• உணவுப் பொருள், நீர் இவைகளை ஈரப்படுத்திமெத்தெனச் செய்யும் தொழிலைப் புரியும்.
3. போதகம்	• நாவினின்று உண்ணுகிற சுவைகளை அறிவிக்கும் தொழிலைப் புரியும்
4. தற்பகம்	• தலையினின்று கண்களுக்கு குளிர்ச்சியைத் தரும்.
5. சந்திகம்	• பூட்டுகளில் நின்று இயற்கையாய் எல்லா கீல்களையும் ஒன்றொடொன்று பொருத்தி தளரச் செய்து கொண்டிருக்கும்.

பாலக் கரப்பானில் ஐயம் பொதுவாக பாதிப்பு அடையாது.

Diagnostic Methods (Piniyarimuraimai)

Piniyari Muraimai is the methods of determination of a disease. It is bassed on the following principles

1. Poriyalarithal (Inspection)
2. Pulanal arithal (Palpation)
3. Vinaathal (Interrogation)

Poriyalarithal and pulanal arithal goes hand with the concept of Examining the patient's pori and pulan with that of physician's pori and pulan.

Vinaathal is a method of interrogation about the details of that patients problem from his own words (or) from his parents or neighbours who are taking care of the patients, when the patient is not able to speak (or) patient may be child.

சித்த மருத்துவத்தின் நோய்கணிப்பில் பின்வரும் காரணிகள் முக்கிய பங்கு வகிக்கின்றன.

நோயாளியைச் சார்ந்துத

1. உயிர் தாதுக்கள் (முக்குற்றம்)
2. உடல் தாதுக்கள் (ஏழு உடற்கட்டுகள்)
3. எண்வகைத் தேர்வு

நோயாளியைச் சார்ந்தது

4. பொழுது
   - சிறுபொழுது - வைகறை, விடியல், எற்பாடு, நண்பகல், மாலை, யாமம்
   - பெரும்பொழுது - கார், கூதிர், முன்பனி, பின்பனி, இளவேனில், முதுவேனில்
5. ஐவகை நிலங்கள் - குறிஞ்சி, முல்லை, மருதம், நெய்தல், பாலை.

மேற்கூறிய காரணிகளின் மாறுபாடுகளை ஒன்றுடன் ஒன்று ஒப்பிட்டு நோய் கணிக்கப்படுகிறது.

Ennvagai thervugal (eight fold examination)

Envagai thervugal is a tool and it is described by Siddhar theraiyar as follows

நாடிப் பரிசம் நா நிறம் மொழிவிழி
மலம் மூத்திர மிவைமருத்துவ ராயுதம்

- **தேரன்**

The above concept also supported by another great Siddhar Agasthiyar in Vaidhya Chinthamani Venba – 4000 as follows

"மெய்குறி நிறம் தொனி விழி நா இருமலம் கைக்குறி"

Another Siddha book describe Envagal thervugal as follows

"தேடிய வியாதிக் கெல்லம் தேகத்தில் பரிட்சையுண்டு
கூடியே நிற்குமெட்டு பரிட்சையாங் கூறக்கேளீர்
நாடியே தொட்டாற் தேகம் மூத்திரம் வார்த்தை கண்கள் நாக்கு
பாடியே மலசலங்கள் பல வண்ணம் பார்த்துக் கொள்ளே"

- **சித்த மருத்துவமணிகள்**

மேற்கூறிய பாடலின் மூலம் நாடி, ஸ்பரிசம், நா, நிறம், மொழி,விழி, மலம், மூத்திரம் ஆகியன மருத்துவரின் ஆயுதம் போன்றவை என அறியலாம்.

Hence the diagnosis is made by using the following tools are important in Siddha system of Medicine.

1. Naadi (Pulse reading)
2. Sparisam (Tacfile sensation)
3. Naa (Tongue)
4. Niram (Colour)
5. Mozhi (Speech (or) Voice)
6. Vizhi (Eye)
7. Malam (Stools)
8. Moothiram (Urine)

1. Naadi

"உடலில் உயிர் தரித்திருப்பதற்கு காரணமான சக்தி எதுவோ அதுவே நாடி"

Naadi is the vitiating elements of the body which is Vatham, Pitham, Kabam, Naadi is otherwise called a Uyirthathukkal.

Naadi can be felt by a Physician viz Vatham, Pitham and Kabam with the tips of Index, Middle and Ring fingers respectively at the anterior part of lower end of the radius bone of the patients. It informs the physiological and pathological condition of the body.

The three Uyirthathukkal are formed by the combination of

Edakalai	+	Abanam	=	Vatham
Pinkalai	+	Piranan	=	Pitham
Suzhumunai	+	Samanan	=	Kabam

The ratio between Vatham, Pitham and Kabam is 1:1/2:1/4 respectively.

In Bala Karappan, Vatham naadi generally affected and then other naadi's are also deranged.

2. Sparisam

The following points are elicited through sparisam. Temparature of the skin on any abnormal grounds, Hypersensitiveness and thickness of the skin, swelling and dryness of the skin, ulcers, oedema, obesity, liver and spleen enlargement.

In Bala Karappan, the skin becomes well defined borders, hyperpigmented with central clearing nature.

3. Naa

This is the method of inspection of the tongue, gums, teeth, lips, palate etc.,

4. Niram

Changes in the colour of the skin, teeth, eyes, nail and lips due to Mukkutra derangement are to be noticed Hypo (or) hyperpigmentation is also be noted.

In Bala Karappan skin is hyperpigmented, erythemators, macular, slightly raised margenated with central clearing in nature.

5. Mozhi

Examination of Mozhi includes clarity of speech, crying, low and high piched voice, slurring speech.

No abnormalities were observed in Bala Karappan.

6. Vizhi

Pallor of the conjunctiva, conjunctivitis, cataract (any redness and pterygium etc..)

No abnormality was seen in Bala Karappan.

7. Malam

Semisoild, colour, froth, abnormal consistency, frequency, constipation, foul smell etc.,

In Bala Karappan constipation may be present.

8. Moothiram

Examination of urine for the determination of Neerkuri and Neikuri. It is one of the important diagnostic method.

நீர்க்குறி (Neerkuri)

"வந்த நீர் கரியெடை மணம் நுரை எஞ்சலென்

றைந்தியலுளவை யறைகுது முறையே"

- நோய் நாடல் முதல் பாகம்

நீரில் நிறம், மணம், நுரை, எடை, எஞ்சல், ஆகியவற்றை நோக்க வேண்டும்.

ஆடிக்கலசத் தாவியே காது பெய்

தோருமுகூர்த்தக் கலைக்குட்படு நீரின்

நிறக்குறி நெய்குறி நிருமித்தல் கடனே"

- தேரன்

Prior to the day of urine Examination the patient should have good sleep and instructed to take a balanced diet. After waking up in the morning, the first voiding urine is collected in a clear wide mouthed glass container and is subjected to analysis of "Neerkkuri" within 1½ hours.

Urine has the following general features

- Niram
- Edai
- Manam
- Nurai
- Enjal

நெய்க்குறி (Neikkuri):

குழந்தைகளின் நாடிநடை சரியாக கணிப்பதில் சிரமம் உள்ளதால், நெய்க்குறி பரிசோதனை மூலம் நோயாளர் எக்குற்றத்தால் பாதிக்கப்பட்டுள்ளார் என்பதனை கணிக்கலாம்.

பாலக் கரப்பான் நோயாளியின் சிறுநீரை சோதனை வட்டிலில் ஊற்றி ஒளிமிகுந்த இடத்தில் நீரின் அலையில்லாத போது நல்லெண்ணெயத்துளி விட்டு பார்க்கப்பட்டது சிலரில் அரவென நீண்டும ஆழி போல் (மோதிரம்) பரவியும், சிலரில் முத்து போல் நின்றும் காணப்பட்டது.

அரவென நீண்டின் அ.ஃதே வாதம்

ஆழிபோற் பரவின் அ.ஃதே பித்தம்

முத்தொத்து நிற்கின் மொழிவதென் கபமே

- நோய் நாடல் முதல் பாகம்

“எண்ணெய் விட்டு பார்க்கும் விதி

நிறக்குறி குரைத்த நிருமாண நீரிற்

சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்

னின்றதிவலை போம் நெறிவிழியறிவும்

சென்றது புகழுஞ் செய்தியை யுணரே”

The collected specimen (urine) is kept open in a glass dish or china clay container. It is to be examined under direct sunlight, without any shaking of the vessel. Then add one drop of gingelly oil without disturbing the urinary specimen and the NeiKuri was noted in direct sunlight and conclude the diagnosis as follows

Character of Vathaneer

ஆரவென நீண்டின.ஃதே வாதமே

When the oil drop lengthens like a snake, it is called “Vatha Neer”

Character of Pithaneer

ஆளி போற்பரவின் அ.ஃதே பித்தம்

When the oil drop spreads like a ring, it is called “Pitha Neer”

Character of Kabaneer

முத்தொத்து நிற்கின் மொழிவதென் கபமே"

When the oil drop appears like a pearl, it is called "Kaba Neer"

Character of Thonthaneer

Snake in the ring, ring in the snake, snake in the pearl and ring in the pearl are the characters of "Thontha Neer".

Types of land (Nilam)

Nilam is classified into 5 types depending on the surrounding vegetation, landscape and ecological state study of 5 places is very much necessary as some diseases are common in particular kand.

1. Kurinji – Mountain and its surroundings liver diseases and fluorosis are common.
2. Mullai – Forest and its surroundings pitha noi and liver diseases are common.
3. Marutham – Field and its surroundings.
   The ideal places for healthy living.
4. Neithal – Sea and sseashores.
   Liver disease occurs in combination with other diseases.
5. Paalai - Desert and its surroundings.
   Vatha, Pitha, Kabha, diseases occur. The disease Bala Karappan was predominant in Neithal nilam.

Paruvakalam

Siddhars have classified a year into six seasons each containing two tamil months.

They are,

1. Kaarkalam	-	Avani & Purattasi	(Aug 15	to Oct15)
2. Koothirkalam	-	Ippasi &Karthika	(Oct 15 to	Dec15)
3. Munpanikalam	-	Margazhi &Thai	(Dec 15 to	Feb15)
4. Pinpanikalam	-	Masi &Panguni	(Feb 15 to	Apr15)
5. Elavanilkalam	-	Sithirai&Vaigasi	(Apr15 to	June15)
6. Muthuvenilkalam	-	Aani &Aadi	(June15 to	Aug15)

Udal Vanmai (Body Immunity)

The vanmai is classified into three kinds.

They are,

1. Iyarkai Vanmai
2. Kaala Vanmai
3. SeyarkaiVanmai

1. IyarkaiVanmai

   Natural immunity of the body caused by Mukkutram right from birth onwards.

2. KalaVanmai

   Development of immunity according to age and environment.

3. SeyarkaiVanmai

   Improving the health by intake of nutritients, food materials, exposure to some disease, activities and medicines.

Udal thathukkal (Seven udal kattugal)

Udal thathukkal	General definition of each type
Saram	Gives strength to body and mind
Seneer	Responsibl for knowledge, strength, boldness, healthy complextion.
Oon	Gives structure and shape to body and is responsible for movements of thebody
Kozhuppu	Lubricates the internal organs and helpsthe organs to worksmoothy.
Enbu	Protects the vital organs and act asbasis for movements and maintains bodystructure.

Moolai	Present inside the bones and it givesstrength and maintains the normalcondition of the bone.
Sukilam/Suronitham	Responsible for reproductive function.

Human body is made up of seven udal kattugal which are important for the structure and function of the body. Among theseven udal kattugal (seven physical constituents) saaram and seneer are commonlyaffected in bala karappan.

Management of Bala Karappan in Siddha System

மிகினும்குறையினும் நோய்செய்யும் நூலோர்
வளிமுதலா வெண்ணிய மூன்று

- திருக்குறள் 941

The learned books count three, with win as first; of these, As any one prevail, or fail; ‘twill cause disease.

In Siddha system the main aim of the treatment is to set right the derangement of mukkutram. Treatment is not only for perfect healing but also for prevention and rejuvenation. It is also very much essential to know the disease through its aetiology. The nature and severity of the illness, the seasons and the time of occurance must be observed clearly.

Line of treatment

Line of treatment is asfollows

a. Kaappu (Prevention)
b. Neekam (Treatment)
c. Niraivu (Restoration/Rejuvenation of wellbeing)

1. Kaappu (Prevention of BalaKarappan)

- Use warm water for bath
- Take bath daily and avoid bathing in lake, pond.
- Use green gram powder or “Nalangu Maa” instead of soap for bath.
- Wash in dresses with disinfectant solution and dry in direct sunlight.

- Prevent from Mosquito bite.
- Advised to wear fresh dry and cotton clothes.
- Advised to trim the nails,
- It is a good habit to wash hands after touching other people or animals.

General instructions for Eczema patients

1. The patients should avoid extremes of climate. If it is not possible to change the place of residence, then air conditioning is the answer.
2. The patient should not scratch and keep his nails short.
3. The diet should be light. The exact composition of the diet depends upon the History of the patients, the diet habits and the results of the allergy test.
4. Allergic stuffs should be avoided.
5. Healthy hobbies and playing should be encouraged. They help to divert attention and speed up recover.

Neekam (Treatment)

The aim of Neekam is based on

- To bring the deranged three humours to equilibrium state.
- To treat the patient with
    - Internal Medicine
    - External Medicine
    - Dietrestictions

3. Niraivu (Rejuvenation)

Physical, psychological, social and economic rehabilitation and reassurance of individuals is known asNiraivu.

- Rest
- Positive mental attitude
- Life style modification
- Modification in daily activities

The patients are well motivated. The nature and course of the disease is explained tothem.

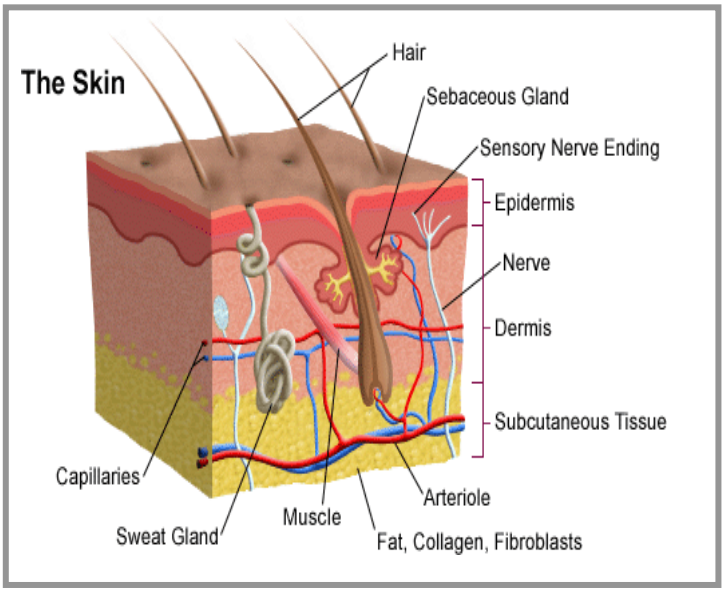
மருத்துவம்

1. வேற்றுநிலை வளர்ச்சியடைந்த வாதத்தினை தன்னிலைப்படுத்தவேண்டும்
2. தன்னிலை வளர்ச்சியடைந்த ஐயத்தினை சமப்படுத்தவேண்டும்
3. பித்தகுற்றத்தால் பாதிப்படைந்துள்ள வாதத்தினையும் சரிப்படுத்தவேண்டும்.
4. வன்மை இழந்த உடற ் கட்டுகளை வன்மை அடையச் செய்யும ் வகையில் மருந்தளிக்கவேண்டும்.

Keeping in mind the need for bringing out an effective therapy for Bala Karappan from Siddha system of Medicine, the author has undergone this dissertation work with Karappan Nei (Internal and Enternal Medicine). The dosage of Medicine all 6 – 12 years (6 – 8 years – 5ml, 9-12 years – 10ml) (bd).

3. b. MODERN ASPECT

Anatomy of the skin:



Cross section of theskin

The skin is a vital organ that covers the entire outside of the body, forming a protective barrier against pathogens and injuries from the environment. The skin is the body's largest organ. The color, thickness and texture of skin vary over the body. There are two general types of skin. Thin and hairy, which is more prevalent on the body and thick and hairless, which is found on parts of the body that are used heavily and endure a large amount of friction, like the palms of the hands or the soles of the feet.

Basically, the skin is comprised of two layers that cover a third fatty layer. These three layers differ in function, thickness and strength. The outer layer is called the epidermis. It is a tough protective layer that contains the melanin–producing melanocytes. The second layer is called the dermis. It contains nerve endings, sweat glands, oil glands, and hair follicles.

Under these two skin layers is a fatty layer of subcutaneous tissue, known as the subcutis or hypodermis.

Parts of the skin:

- Theepidermis
- Dermis
- Hypodermis /subcutaneoustissue

Epidermis:

The epidermis is the most superficial layer of the skin and provides the first barrier of production from the invasion of foreign substances into the body. The principal cell of the epidermis is called akeratinocyte.

Layer of the epidermis:

- Stratum corneum /corneal layer /horney layer
- Stratumlucidum
- Stratum granulosum/granular layer
- Stratum basalis /basal layer
- Malpighian layer

It is the viable part of the epidermis and contains nucleated keratinocytes. It consists of all layers of epidermis except corneal layer.Vitamin Dis synthesized in this layer. Thickness of the viable part is 100 µm.

Stratum corneum/corneal layer / horney layer:

It is the outer most layer and formed by a specialized process, known as keratinization. It is thinnest at eyelid (10-15 µm) and thickest at soles (100 µm). It is made up of piled –up layers of flattened anucleated keratinocytes, known as corneocytes. It appears as a brick wall where the corneocytes are the bricks, and a mixture of lipids and proteins is like that of cement andsands.

Stratum lucidum:

It is an electolucent layer lies between corneal and granular layers. It is most appreciable at palms and soles.

Stratum granulosum/granular layer:

It consists of 1-3 layers of keratinocytes. These cells are having cytoplasmic granules and so name is implied Keratinocytes of this layer contain basophilic granules, known as keratohyaline granules. Keratohyaline granules contain various proteins including involucrin, loricrin and profilaggrin.

Stratum spinosum/spinous layer:

It consists of polygonal kerationcytes and they are interlocked with each other through cytoplasmic processes, appearing as spines and so the name is implied. Cells of upper of spinous layer contain odland bodies or lamellar granules, synthesized by their Golgi apparatous. Odland bodies contain baskets of lipids, polysaccharides and hydrolytic enzymes. These lipi contents contribute to form outer layer of the cornified envelope of corneyocytes. Lipid layer contains ceramids (50 %), cholesterol (35%), and free fatty acids (15%).

Stratum basalis / basal layer:

It consists of single layer of cuboidal or columnar cells which continuously proliferate to replenish the pool of epidermal cells. Basal layer is not straight like corneal layer, it is undulating, having upward and downward projections.

Contents of theepidermis:

- Keratinocyte
- Melanocyte
- Langerhanscell
- Merkelcell
- Epidermal parts of eccrine and apocrineducts
- Epidermal part of pilosebaceous unit.

Dermis:

The dermis is located beneath the epidermis and is the thickest of the three layers of the skin (1.5 to 4 mm thick), making up approximately 90 percent of the thickness of the skin.

The main functions of the dermis are to regulate temperature and to supply the epidermis with nutrient-saturated blood. Much of the body's water supply is stored within the dermis. This layer contains most of the skin specialized cells and structures.

Sweat Gland:

Apocrine glands are specialized sweat glands that can be found only in the axilla, umbilicus, around the anus and genitalia. These glands secrete a milky sweat that encourages the growth of the bacteria responsible for body odor.

Eccrine glands are the true sweat glands. Found over the entire body, these glands regulate body temperature by bringing water via the pores to the surface of the skin.

Sebaceous Gland:

Sebaceous or oil glands, are attached to hair follicles and can be found everywhere on the body except for the palms of the hands and the soles of the feet. These glands secrete oil thathelps keep the skin smooth, suppleand protects against an overgrowth of bacteria and fungi on the skin.

Apocrine and Mammary Gland:

Apocrine glands are similar in structure, but not identical to ecocrine glands. Theyare found in the axillae, anogenital region, as modified glands in the external ear canal, the eyelid, and the breast (mammary glands). They produce odour and do not functionprior to puberty. The mammary gland is considered a modified and highly specialized type of apocrine gland.

Collagen and Elastin:

The dermis is held together by a protein called collagen, made by fibroblasts. Fibroblasts are skin cells that give the skin its strength and resilience. Collagen is a tough, insoluble protein found throughout the body in the connective tissues that hold muscles and organs in place. Elastin a similar protein, is the substance that allows the skin to spring back into place when stretched and keeps the skin flexible.

The dermis layer is made up of two sub layers.

Papillary layer:

The upper papillary layer contains a thin arrangement of collagen fibers. The papillary layer supplies nutrients to the layers of the epidermis and regulates temperature.

Reticular layer:

The lower reticular layer is thicker and made of thick collagen fibers. It strengthens the skin, providing structure and elasticity. It also supports other components of the skin, such as hair follicles, sweat glands and sebaceousglands.

Subcutis:

The subcutis is the innermost layer of the skin, and consists of a network of fat and collagen cells. The functions of this layer is insulator, conserving the body's heat, and as a shock-absorber, protecting the inner organs. It also stores fat as an energy reserve for thebody.

Hair:

Hair is found on almost every part of the body except on the palms, soles. The dorsal surface of the terminal phalanges, inner surface of the labia, inner surface of the prepuse and glans penis. Hairs differ in length, thickness and colour in the differernt parts of the body.

There are three types of hair:

1. Long, medullated and pigmented hair seen on the scalp.
2. Short, fine, non medullated and pigmented ‘lanugo’ hair is seen in women, children and on the faces and trunks of the adults.
3. Thick bristles seen in the nose and theears.

Cutaneous blood supply:

Cutaneous vessels ultimately arise from underlying named source vessels. The cutaneous vessels originate either directly from the source arteries or as terminal branches of muscular vessels. Cutaneous vessels ultimately anastomose with other cutaneous vessels to form a continuous vascular network within the skin.

Lymphatics:

Skin lymphatics parallel the blood supply and function to conserve plasma proteins and scavenge foreign material, antigenic substances, and bacteria. These unvalved superficial dermal vessels drain into valved deep dermal and subdermal plexuses, then coalesce to form larger lymphatic channels which ends in internal jugular vein junctionbilaterally.

Functions:

1. **ProductiveFunction**:

In human beings, the tough, Horney, and keratinized waterproof epidermis, and appendages like hair and nails, provide a sufficently strong barrier against injury, epidermal penetration of harmful substances and bacterial invasions. The skin is to protect against sunlight by synthesis by synthesis of melanin pigment.

2. **Secretory Function**:

Skin secreats sweat through sweat glands and sebum through sebaceous glands. By secreting aweat, skin regulates body temperature and water balance. Sebum keeps the skin smooth andmoist.

3. **Sense Organ:**

The skin is richly supplied with nerves and various types of specialized sensory organs, which provide information regarding environmental changes.

4. **Storage Function ofskin:**

Fat is laid down in fact cells as a permanent store of subcutaneous adipose tissue this provides the reserve stores of body energy.

5. **Thermoregulation:**

Eccrine (sweat) glands and dilated blood vessels (increased superficial perfurtion) aid heat loss, while constricted vessels greatly reduce cutaneous blood flow and conserve heat.

6. Vitaminsynthesis:

In exposure to sunlight skin synthesis 7dehydro cholesterol, the precursor of vit D.

7. Production from UVrays:

Skin protects the body aganits the damaging effects of UV rays of sunlight. Melanin pigment in the skin helps in the production.

8. Immunity:

Sebum secreated from sebaceous glands is acidic and contains microbial agent's clasmatocytes in the skin the cells of mononuclear phagocyte system that trap and kill the organism. Skin is the natural dressing of the body.

9. Contributes to central bloodvolume:

Cutaneous vascular bed accommodates a good quantity of blood volume. Hence Constrictions of blood vessels in the skin contribute to central blood reservoir, from where blood can be diverted to vital organs at the time need.

Embriology:

The whole of the skin-epidermis and dermis-is a unified integrated organ system, but it develops from two different primitive embryonic layers epidermis from the ectoderm and dermis from the mesoderm.

The general ectoderm of the early human embryo, except for the part that specializes as the neural ectoderm, consists of a single layer of cuboidal cells. By the fifth week of intra-uterine life, this becomes double layered. During the third month of foetal life, three layers of cells recognizable, the periderm, the intermediate and the basal layer which is close to the derma. The basal cells multiply rapidly and keep pushing the older cells towards the periderm, and thus, by the fifth month a stratum of these cells (prickle cells) superficial to the basal cells, forms a definite stratum malpighii.

The cells in the zone overlying the stratum malpighii show keratohyalin granules and form the stratum granulosum. As the cells keep moving outwards owing to new cells being added from the basal layer, the most superficial ones culminate in cornification forming the stratum corneum near the surface. Next to the stratum corneum, a thin, clear

zone containing homogeneous semi-fluid eleidin is evident, particularly on the palms and soles, giving rise to the stratum lucidum. The early intermediate layer of cells becomes a part of the stratum germinativum, and the periderm by the end of the fourth month of foetal life is cast off as a part of the vernix caseosa.

The embryonic stratum germinativum, besides giving rise to the surface epidermis, forms the primary epithelial germ which later develops, by downward prolongations into the mesoderm, into the hair, sebaceous glands and apocrine glands and also forms the eccrine sweat glands. Soon after birth, the cells of the stratum germinativum acquire pigment granules from the melanoblasts which migrate from the primitive neural crest and specialize in melanin pigmentformation.

The dermis is mostly derived from the mesenchyme. Untill the end of the second month of intra-uterine life, the dermis consists of closely packed, spindle-shaped mesenchymal cells, and by the third month of intra uterine life, fine reticulam fibres are demonstrable, which later increase in number and thickness and form the collagenous fibres (Maximow and Bloom). The subcutaneous fat is apparent by the end of the third month of the intra-uterine life, but it becomes abundant only during the later months of foetal life.

The nail starts as an epidermal specialization on the dorsum of the tips of the digits by the third month of foetallife.

The earliest hair appears on the eyebrows, upper lip and chin at the end of the second month of intra-uterine life. By the fourth month, hair appears over the general body surface. This hair is fine, silky, downy, tremed lanugo hair and is cast off before birth as a component of the vermixcaseosa.

Most of the sebaceous glands in the body develop in connection with hair follicles during the fifth month of foetal life, as solid epidermal buds, which later become lobulated. In certain regions like the upper eyelids, hairless deeper portion of the vestibule of the nose, prepuce, vulva and the anal region. These glands arise from the general epidermis, independent of the hair follicles.

Most of the eccrine sweat glands develop independently as solid down-growths from the epidermis. They first appear on the finger, lips, palms and the soles during the fourth month of intra-uterine life. By the sixth month of fetal life, they become simple cords, which later coil and acquire lumina.

Atopic Dermatitis

The signs and symptoms of Bala karappan are closely related to signs and symptoms of Atopic Dermatitis (AD). Hence I correlated the Bala Karappan with Atopic Dermatitis occurring inchildren.

Defenition:

Dermatitis literally means inflammation of the skin. When simple dermatitis' boils over" with added oedema, exuadation and crusting, the condition is acute eczema and when dermatitis gets associated with hyperstasia and hyperkeralosis, the condition is chronic eczema. Such changes occur predominantly in the epidermis. Primary lesions inculdes macules, papules, vesicles, edematous patches or plaques. Secondary lesions with oozing, crusting, scaling fissuring and lichenification follow frequently. Dermatology use dermatitis and eczemainterchangeabily.

History:

The term "Atopic dermatitis" was coined in 1933 by Wise and Sulzberger

Etiology:

The causes of eczema are unknown but usually atopic dermatitis is associated with some trigger factors. Effective eczema management requires a combination of prevention and treatment. In addition to preventing eczema flare-ups by minimizing any known triggers, treatment is also an important part of eczema management. Basically, two factors cause dermatitis andeczema.

- Allergic or sensitive skin.
- Exposure to anirritant.

Predisposing factors:

- Genetic factors
- Environment factors
- Allergens
- Age.

Genetic factors: Allergic disorder, asthma, hay fever.

Environment factors: Skin irritants (soap or detergent, cosmetics dust, chemical solvents), Climate.

Allergens: Plant pollen, household dust, mites, molds animal dander, and certain foods.

Age: The risk is greatest for infants and children. 65% of patients develop first year of life, 90% develop symptoms before age 5. Improves in adulthood 50% of those affected in childhood are affected through out life.

Genetic & familial predisposition: There is usually a personal or family history of allergy, like asthma, eczema and hay fever.

General debility: Lowering of resistance of the individual in general debility predisposes to eczema.

Climate: Climate extremes like heat and severe cold.

Immunology:

Immunology deals with the body's response to antigenic challenge. Sensitization develops when a different clone of T-lymphocytes is activated. The sensitized Tlymphocytes yield two sub populations of lymphocytes. Memory cells those are responsible for the persistence of contact allergy. Effector cells that initiate the allergic response when appropriately challenged.

Pathophysiology:

Allergy & hypersensitivity

The body behaves in a particular way when it is exposed to a chemical substance known as, 'Allergen' for the first time, but changes the nature of its reaction when it is exposed for the second and subsequent times. This change is due to proteins known as antibodies. The moment, the allergen IgE combination stimulates the mast cells which unload their chemical contents into the surrounding tissues. These chemical mediators of allergy cause the manifestations of allergy such as erythema, wheal and flare reaction. Flare is due to dilatation of arterioles by local axon reflex and the liberation of vasodilator substances like histamine and its by products like serotonin, bradykinin, acetylcholine from the injured cells like mast cells and basophils etc. The manifestation of hypersensitivity may be immediate (or) delayed type.

Cutaneous Allergy

In the skin two important but different allergic reactions occur.

Dermal reaction

- Dermal reaction is commonly seen in urticaria. Allergic reaction takes place in the dermis. Intra dermal tests (scratch) show reactivity.
- The causative antigen reaches the skin through ingestion, inhalation or injection of protein substances and the reacting antibodies circulate in the serum.
- Epidermal reaction
- It is seen in allergic dermatitis or eczema.
- The causative substance reaches the skin by contact. Intra dermal allergic tests are negative, but patch test shows reactivity
- Allergen + Epidermal protein – Antigen formation (probably in lymph glands)
- Allergen + Antibodies – Eczematous reaction (In epidermis)
- A severe local reaction may result in auto-intoxication & dissemination of eczematous reaction to distant parts.

Status Eczematicus

It is believed that in case of severe allergic states, a state may develop when the patient becomes hypersensitive to even unrelated substances resulting in status eczematicus comparable to status asthmaticus in practice of internal medicine.

Reaction time

It is the time taken by a sensitized individual to manifest a clinical reaction following contact with a known sensitizer. It is usually 12-24 hours but may vary from one hour to 120 hours.

Dissemination reaction

It is a fleeting erythematous macular reaction involving the face and flexures, caused by the escape of lymphokines in the circulation resulting in vasodilatation at distant site.

Clinicalfeatures:

Atopic dermatitis is characterized by superficial inflammatory oedema of the epidermis associated with vesicle formation. Itching varies from mild to severe paroxysms which may even interfere with work and sleep. It can differ in severity, frequency and duration amongindividuals.

Skin areas affected by atopic dermatitis can exhibit a variety of characteristics including:

- Erythema
- Darkening of the area of skin affected by eczema (hyperpigmentation)
- Dryness
- Papules
- Scaling
- Vesiles
- Oozing
- Thickening of the affected (Lichenification) skin due to requents

cratching.

Clinical Evaluvation:

Atopic dermatitis passes in three different phases:

1. **Infantile eczema** (Age: 2 months to 2 years). Affects the cheeks and may extend to the forehead. The lesions are an erythematous, edematous patch covered with vesicles. Eventually, it becomes exudative and crusted. Itching may interface sleep. There is nolichenifiction.

2. **Childhood phase** (Besnier's prurigo- age: 5 to 12 years). The flexure surface of the limbs and neck are affected. The lesions consist of itchy papules and lichenifiedplaques.

3. **Adulthood phases** (dissemination neurodermatitis in adults). The flexures are the most commonly involved sites; the front and side of the neck, and the eyelids may also be affected. Pruritus is severe. The lesions consist of chronic lichenified papules becoming confluent to form poorly defined reddish - brown plaques. There is no oozing (chronic).

Atopic dermatitis in children

Introduction

- Most common chronic paediatric skin disorder, affecting 15% of children.
- Cause unknown but seems to be result of a complex inflammatory process.

- Generally begins during infancy or childhood; Signs and symptoms AD is characterized by pruritus with resultant scratching that leads to excoriations and lichenification.
- The appearance of lesions varies with the patiant's age and background,
    - Infants and toddlers; involvement of the face, trunk and extensor extremities
    - Childhood; Lesions are concentrated in flexural areas, such as the anticubital and popliteal fossae; wrists and ankles.

Children who have atopic dermatitis are susceptible to certain bacterial and viral infections. Increased adherence of Staphylococcus aureus to the skin and reduced production of anti- microbial peptides may explain the high rates of colonisation with and infection due to this bacterium. Altered T-cell function may expain the predisposition of children to develop Molluscum contagiosum, Eczema herpeticum and Eczema vaccinatum.

Prognosis:

The prognosis for children with atopic dermatitis is good; 80% to 90% of infants experience a spontaneous resolution or improvement in symptoms by adolescence.

Other Common types of Dermatitis:

1. Contact Dermatitis

Contact dermatitis is localized to the site of extrinsic stimulation by foreign substance or allergic reaction. Eczema reactions such as reddening and blistering occur at the contact site. There are specific types of contact dermatitis, such as diaper dermatitis and housewive's hand eczema. The causative substances include certain plants, chemical agents, and nickel, mercury and other metals.

Clinical features

Erythema, serous papules, vesicles, erosions and crusts are localized at the contact site of the causative agent. The eczematous lesions are relatively sharply circumscribed and are intensely itchy. Although only localized areas are affected, erosive lesions may become widespread when the causative agent is spread by rubbing and scratching.

If the inflammation spreads over the entire body, systemic symptoms such as fever may arise. When the causative agent is highly stimulative, it may cause necrosis of the skin and ulceration.

Pathogenesis

Allergic contact dermatitis basically occurs as a type IV allergic reaction. The causative agent invades the body percutaneously and is captured by Langerhans cells. It moves to the regional lymph nodes and transmits information about the antigen to thymus derived T cells, and they proliferate in the lymph nodes. If the causative agent reinvades the body after sensitization, the sensitized T cells become activated to release various cytokines, which leads to a prompt inflammatory reaction that causes dermatitis. This reaction is not produced by the first contact, but it is produced in previously sensitized persons even by contact with a minute amount of the antigen.

2. Seborrheic Dermatitis

Seborrheic dermatitis occurs on sites of skin where sebum is actively secreted. It is characterized by erythematous lesions accompanied by yellowish scales. This is one of the most common skin diseases, occurring in infants, adolescents and adults. Pityrosporum fungus resident in the skin is a factor in the occurrence.

Clinical features

Dermatitis appears as follicular eczema on seborrheic sites or intertriginous areas in the head, face, axillary fossa, neck and external genitals. The main features of the lesions are oleaginous scales and erythematous plaques that may be slightly itchy. In infants, yellowish crusts begin to form on the scalp, eyebrows and forehead. In infants, scaly erythematous plaques may also form 2 to 4 weeks after birth. In most cases they resolve 8 to 12 months after birth. In adolescents and adults, pityroid scales increase and scaly erythematous lesions form on the eyebrows and nasolabial groove. Seborrheic dermatitis is chronic and recurrent.

Pathogenesis

Triglycerides in sebum are decomposed by microbes resident in the skin to produce free acid. The free acid reacts to cause seborrheic dermatitis.

3. Nummulareczema

Round, relatively large eczematous plaques are produced. Nummular eczema may occur at any site on the body, and it tends to progress to auto sensitization dermatitis.

Clinical features

Nummular eczema is frequently seen in the winter. Multiple round eczematous lesions occur, mostly on the extremities (particularly on the extensor surface of the lower extremities), trunk, hips and buttocks. At the periphery of the lesions, serous papules aggregate, in the center of which exudative erythema is produced with scales on the surface. Most cases are accompanied by intense itching and multiple scars from rubbing and scratching. As the lesions progress, they may produce dispersal eruption to progress into autosensitization dermatitis.

Pathogenesis

Scratched insect bites may develop urticarial lichens that, when rubbed, progress to nummular eczema, or nummular eczema may result from asteatotic eczema in the elderly, or it may appear as a symptom of atopic dermatitis.

4. AutosensitizationDermatitis

Multiple small papules and erythematous lesions accompanied by itching occur systemically. They are caused by sudden aggravation of a localized lesion. This dermatitis is caused by endogenous allergic reaction.

Clinical features

Reddening, swelling and acute aggravation of exudation occur in the lower extremities as primary lesions of autosensitization dermatitis (in 50% to 60% of cases). Two weeks to several weeks after acute aggravation of reddening, swelling and exudation, dispersed eruptions appear. In most cases, the eruptions are erythema, papules, serous papules, or pustules of 2 to 5 mm in diameter dispersed symmetrically on the extremities, trunk, and face. These are often accompanied by intense itching. Systemic symptoms such as fever and fatigue may occur.

Pathogenesis

Autosensitization dermatitis arises from endogenous allergic reaction. Decayed proteins, bacteria, fungal components, and toxins produced by injured tissues in a primary lesion are considered to be the antigens. These may spread through the entire body such in blood flow from the primary lesion, or they may spread by rubbing or by an accidental dose of the causative substance (orally or intravenously). Autosensitization dermatitis is caused by sensitization against the antigens. The primary lesions can be nummular eczema, stasis dermatitis, contact der-matitis, atopic dermatitis, tinea pedis, or eczematization of aburn.

5. Stasis Dermatitis

Edematous erythema or eczematous plaques form on the lower thighs as a result of varicose veins or congestion in the lower extremities. This disease tends to affect those who work standing, the elderly and obese women. It may progress to autosensitization dermatitis.

Clinical features

Edematous erythema occurs on the lower third of the leg, particularly at the upper ankles. The site gradually presents a dark red, scaly, eczematous plaque, pigmentation or whitish atrophie Blanche. Minor trauma may induce ulceration. Treatments for stasis dermatitis may induce allergic contact dermatitis as a complication, from the application of an antiseptic or a topical agent. Aggregated serous papules often progress to autosensitization dermatitis.

Pathogenesis

Congestion in the cutaneous blood vessels is caused by impairment of venous out flow, which leads to bleeding from the capillary vessel loop in the dermal upper layer. Hemosiderins deposit in tissues, and the skin takes on a blackish-brown appearance. The keratinocytes are injured by further impairment of blood flow. Atrophy and scaling occur in the epidermis and there is tendency of ulceration. The skin looses its function as a barrier and becomes more reactive to extrinsic irritation, leading to eczematous lesions in many cases.

Investigations for eczema

Patch test

Patch tests detect type IV (delayed or cell-mediated) hypersensitivity. It is common practice for a battery of around 20 common antigens, including common sensitizers such as nickel, rubber and fragrance mix to be applied to the skin of the back under aluminium discs for 48 hours. The sites are then examined for a positive reaction 24 hours later and possibly again a further 24 hours later. The positive test is revealed by the development of an eczematous patch with erythema swelling and vesicles at the site of application. Patch test reaction is graded in the followingdegrees,

+ - Only redness

++ - Marked redness and swelling

+++ - Marked redness, swelling and papules

++++ - redness, oedema and vesicles

Specific IgE levels to antigens can be measured in serum by a specific radio allergic sorbent test (RAST). These are occasionally performed to support diagnosis of atopic eczema and to determine specific environmental allergens, eg. Pet dander, horse hair, house dust mite, pollens and foods.

Prick tests

Prick tests are a way of detecting cutaneous type I (immediate) hypersensitivity to various antigens such as pollen, house dust, mite or dander.

Assessment tools

There are two assessment tools used in Morden aspect. These are EASI score

An EASI score is a tool used to measure the severity and extent of atopic eczema (**E**czema **A**rea and **S**everity **I**ndex).

There are four body regions:

1. Head and neck
2. Upper limbs
3. Trunk
4. Lower limbs

Intensity: The intensity of redness, thickness, scratching, lichenification of the eczema is assessed as none (0), mild (1), moderate (2) and severe (3). Half scores are allowed. The four intensity scores are added up for each of the four body regions to give subtotals A1, A2, A3, A4.

Area: The percentage area affected by eczema is evaluated in the four regions of the body. In each region, the area is expressed as nil (0), 1-9% (1), 10-29% (2), 30-49% (3), 50-69% (4), 70-89% (5) or 90-100% (6).

Caculation for area: Each of the body area scores is multiplied by the area affected (C1, C2, C3, C4)

Total score: The EASI score is C1 + C2 + C3 + C4.

The SCORAD index

A = spread.../100

B = intensity.../18

C = subjective symptoms.../20

SCORAD calculation: **A/5 +7 B/2 + C**

1. Extentcriteria

- Headand Neck 9%
- Upper limb each 9%
- Lower limb each 18%
- Anterior Trunk 18%
- Back 18%
- Genitalia 1%

2. Intensity criteria

- Erythema : stage 1 / stage 2 / stage3
- Edema / papulation : stage 1 / stage 2 / stage3
- Oozing / crusting : stage 1 / stage 2 / stage3
- Excoriation : stage 1 / stage 2 / stage3
- Lichenification : stage 1 / stage 2 / stage3

3. Subjective symptoms

The two most representative items concerning the quality of life of patients are:

- Pruritus
- Insomnia

SCORAD index is a clinical tool for evaluating the severity of atopic dermatitis in order to provide better management of patient. So I have chosen SCORAD index method for the assessment of Atopic Dermatitis**.**

3. C. DRUG REVIEW

Ingredients of Karappan Nei (Internal and Enternal Medicine)

- Nilavembu (Andrographis Paniculata)
- Chensanthanam (Pterocarpus Santalinus)
- Kadukkai (Terminalia chebula)
- Muththakaasu (Cuperus Rotundus)
- Thippili (Piper longum)
- Devadharus (Cedrus Deodara)
- Kariveppilai (Murreya Koenigii)
- Thetran vithai (Strychnos Potatorum)
- Manjal (Curcuma langa)
- Pasumpaal (Cow's Milk)
- Pasu Nei (Cow's Ghee)

1. நிலவேம்பு –Andrographis Paniculata

Scientific classification:

Kingdom	:	Plantae
Division	:	Tracheophyta
Order	:	Lamiales
Family	:	Acanthaceal
Genus	:	Andrographis
Species	:	Paniculata

வேறுபெயர்:

சிரட்குச்சி, காண்டகம், கிராதம், கிரியாத்து, கிராகதி, நாட்டு நிலவேம்பு, அனாரியதித்தம், காண்டம், கோகணம்

Organoleptic Characters

Taste	:	Kaippu
Potency	:	Veppam (Heat)
Division	:	Kaarpu (Pungent)

Action

Stomachine

Tonic

Alterative

Stimulant

பொதுகுணம்

வாதசுரம் நீரேற்றம் மாற்றுஞ் சுரதோடே

காதமென ஓடக் கழயுங்காண் - மாதரசே!

பித்த மயக்கறுக்கும் பின்புதெளி வைக்கொடுக்கும்

சுத்தநில வேம்பின் தொழில்.

Chemical constituents:

14 – deoxyandrographolide, 14 – deaxy – 12 – hydroxyan – drographolide, Andrographolide, β – sitosterol, slimasterd, chlorophyll a, 5,2' – dihydorxy – 7, 8 – dimethroxyflavone, β – sitosteryl fatty acid esters, lupeol, triacylglycerols

Medicinal uses:

The whole plant has been used for several intermittent fevers, inflammation, pyrexia and External applications such as Anti-dote for snake-bite, poisonous stings for some insects.

The leaf extract is a remedy for the treatment of infectious disease, colicpain, loss of appetite irregular stools and diarshea.

Decoction of the aerial parts is used to treat hypertension, diabetes, cancer, malaria.

2. செஞ்சந்தனம் –Pterocarpus santatlinus

Scientific classification

Kingdom	:	Plantae
Division	:	Tracheophyta
Order	:	Fabales
Family	:	Fabaceal
Genus	:	Pterocarpus
Species	:	Santalinus

வேறுபெயர்

செஞ்சந்தனம், சிவப்புச்சந்தனம்

Organoleptic Characters

Taste	:	Kaippu, Siru thuvarappu
Potency	:	Thatppam (Cooling), Veppam (Heat)
Division	:	Inippu, Kaarppu

Action

Alternative;
Diuretic
Diaphoretic
Stimulant
Disinfectant
Astringent
Cooling

பொதுகுணம்:

கோதில் சந்தனஞ் சீதோஷ்ணங் கொண்டிருக்கும்

வாதபித்தம் ஐயம் மனப்பிரணம் - ஓதுசுரம்

மேகம் தனித்தாகம் வெப்பு சொறி யும்போக்கும்

ஆகந் தனக்குறுதி யாம்.

Chemical constituents:

Santalin A, Santalin B, Pterocarpol, Pterocarpin, eudesmal (α, β and γ-isomers), Pterocarpin.

Medicinal uses

The wood used in the form of a powder (or) chips is anti inflammatory, astringent and tonic.

A paste of the wood is brewed as a tea in the treatment of chronic dysentery.

The wood paste is applied externally as a cooling application to boils, inflammatory disease of the skin, swollen limbs, ophthalmia, sore eyes and headache.

3. கடுக்காய்– Terminaliachebula

Scientific Classification

Kingdom	:	Plantae
Division	:	Angiosperm
Order	:	Myrtales
Family	:	Combretacea
Genus	:	Terminalia
Species	:	Chebula

வேறுபெயர்

அக்கோடம், அங்கணம், அந்தன், அபரணம், அபையன், அமரிதம், அமலை, அமுதம், அம்மை, அம்ருதா, அரபி, அரிதகி, அயைன், அவ்வியதா, இரேசகி, ரமவதி, ஐயவி, ஹைமவதி, கடு, காயஸ்த்தா, சியிருதம், சிரயஹி, சிரோட்டம், சிவா, சேதகி, சேதநிகா, சேயா, திவ்யா, தேவி, நந்திரி, நெச்சி, பித்தியம், பாரியம், பிஷக்வார, புதனா, புதன், ப்ரபத்யா, ப்ராணதா மேகம், ஜீவ்யா, ஜெயா, வரிக்காய், வனதுர்க்கி, ரோகிணி.

Organoleptic Character

Taste	:	Kaippu
Potency	:	Veppam (Heat)
Division	:	Kaarpu (Pungent)

Action

Stomach Carminative Expectorant Anthelmintic Anti dysentery

பொதுகுணம்

தாடை கமுத்தக்கி தாலு குறியிவிடப்

பாடை சிலிபதமுற் பேதிமுடம் - ஆடையெட்டாத்

தூலமிடி புண்வாத சோணிகா மாலையிரண்

டூலமிடி போம்வரிக்கா யால்.

Chemical Constituents:

Chebulin from flowers. Palmitic, stearic, oleic, linoleic, arachidic and behenic acids from fruit kernels. Fruits contain about 30% of an astringent substance; astringency is due to the charectersitic principle chebulnic acid. Also contain tannic acid 20-40%, gallic acid, resin etc. and a purgative glycoside of anthraquinone derivative. Chebulin exhibited anti spanmodic action on smooth muscle similar to papaverine.

Medicinal Uses:

The fruits are astringent, sweet, acrid, bitter, sour, thermogenic, anodyne, anthelmintic, anti-inflammatory, vulnerary, alterant, stomachic, laxative, purgative, carminative, digestive, cardiotonic, aphrodisiac, antiseptic, diuretic, febrifuge, depurative and tonic. They are useful in vitiated conditions of tridosa, wounds ulcers, inflammations, gastropathy, anorexia, helminthiasis, flatulence, haemorrhoids, jaundice, hepatopathy, splenopathy, pharyngodynia, hiccough, cough, urophathy, versical and renal calculi, cephalalgia, epilepsy, ophthalmopathy, skin diseases, leprosy, intermittent fever, cardiac disorders, stomatitis, neuropathy and general debility.

4. முத்தக்காசு – Cyperus Rotundus

Scientific classification

Kingdom	-	Plantae
Division	-	Angiosperms
Order	-	Poales
Family	-	Cyoeraceal
Genus	-	Cyperus
Species	-	Rotundus

வேறுபெயர்

கோரை

Organoleptic Characters

Taste	:	Kaippu
Potency	:	Thatppam (Cooling)
Division	:	Kaarpu (Pungent)

Action

Astringent

Stimulant

Tonic

Diuretic

Diaphoretic

Demulunt

Emmenagogue

Vermifuge

பொதுகுணம்

சீத சுரந்தீர்க்குஞ் செம்புனல்பித் தம்போகும்

வாத சுரந்தணிக்கும் வையகத்தில் - வேதைசெய்ய

வந்த பிணியையெல்லாம் வாட்டுமுத் தக்காசு

கொந்துலவும் வார்குழலே! கூறு

அதிசாரம் பித்தம் அனற்றாகம் ஐயங்

குதிவாதஞ் சோபங் கொடிய – முதிர்வாந்தி

யுாரைத் தொடர்ந்தாலும் அவ்வவர்க்கெ லாங்குளத்துக்

கோரைக் கிழங்கைக் கொடு.

Chemical Constituants

Cyperene , Cyoerenone, Alpha–Cyperone, Alpha–rotunol, Beta-cyperone, Bela-pinene, Beta-rotunol, Beta-selinene, Calcium, Camphene, Copaene, Isocyperol, Kobusone, Isokobusone, D-gluoose, flavonoids, Linolenic-acid, Magnesium, Manganese, Sitosterol, Stearic-acid, Sugeonol, Oleanolic-acid-3-0-neohesperidoside, Myristic-acid

Medicinal uses

Astringent, diaphoretic, diuretic, analgesic, Antihacterial, Carminative, antitussive, aromatic, litholytic, stimulant, stomachic, vermifuge, tonic, sedative.

5. திப்பிலி – Piper longum

Scientific classification

Kingdom	-	Plantae
Division	-	Magnoliophyta
Order	-	Piperales
Family	-	Piperaceal
Genus	-	Piper
Species	-	Longum

வேறுபெயர்

ஆர்கதி, உண்சரம், உலவைநாசி, காமன், குடாரி,கோலகம், கோலி, கோழையறுக்கி, சரம், சாடி, துளவி, மாகதி, கனை, சௌண்டி, தண்டுலி, கணம், கலினி, பாணம், பிப்பிலி, வைதேகி, அம்பு, ஆதிமருந்து.

Organoleptic Characters

Taste	:	Kaaruppu (Pungent)
Potency	:	Thatppam (Cooling)
Pirivu	:	Inippu (Sweet)

Action

Stimulant

Carminative

பொதுகுணம்

ஈளை யிரும லிரைப்புப் பசப்பிணிகள்

மாள வொழியாமல் வாட்டுமே – யாளுமுறை

பாங்கா யறிந்துசெய்வார் பண்டிதத்தைப் பண்டிதரே

வேங்கைவாய்ப் பான்கணை மெய்.

Chemical Constituents

Alkaloids, Piperine, Pipelongumine, Piperlonguminine, n-hexadecane, n-heptadecane, n-octadecane, α-thiyene, terpinolene, zingiberene, p-cymene, didhydrocarveol, dihydrostigmastend, glycosider, Bracheyamide A, Brachyamide B, Brachystine.

Medicinal uses

Powdered long pepper administered with honey will relieve cough, cold, asthma, hoarsenless and hiccup.

Anti asthamatic, immune suppressant, piles, malcuial fever, romiting, sinusitis.

6. தேவதாரு – Cedrus deodara

Scientific classification

Kingdom	-	Plantae
Division	-	Pinophyta
Order	-	Pinales
Family	-	Pinaceal
Genus	-	Cedrus
Species	-	Deodara

வேறுபெயர்

தேவதாரம், தூண், இருதாரு, தாரு, தாரம், தேவத சுர்மரம், பத்திரதாருகம்

Organoleptic Characters

Taste	:	Siru kaippu
Potency	:	Veppam (heat)
Pirivu	:	Karuppu

Action

Carminative

பொதுகுணம்

தேவதா ரக்குணந்தான் சேர்ந்துவளர் பினிசத்தைக்

காவகத்தி லோட்டுங் கரப்பலவே – மாவலவர்

சொலலும்பு ராண சுரமொடுந் ரேற்றத்தை

வெல்லு மனற்றணிக்கு மெய

Chemical Constituents

Texifolin, Cedeodarin, ampelopsin, cedrin, cedrinoside, deodarin, himachalol, allohimachalol, himadarol, centdarol, dewardiol, isocentdarol, dihydromyricetin.

Medicinal uses

The leaves are bitter, acrid and thernigebic, and are useful in inflammation and tubercular glands.

The heartwood is bitter, acrid thermogenic, emollient, enodyne, anthelmintic, digestive, Carminative, Cardiotonic, galacto-purifier, anti-inflammatory, diuretic, antiseptic, laxative and it useful in inflammations skin diseases, insomnia, epilepsy, hiccough.

7. கறிவேப்பிலை – Murraya Koenigii

Scientific classification

Kingdom	-	Plantae
Division	-	Magnoliapsida
Order	-	Sapindales
Family	-	Rutaceal
Genus	-	Murraya
Species	-	Koenigii

வேறுபெயர்

கறிவேப்பிலை, கருவேப்பிலை, கறியபிலை

Organoleptic Characters

Taste	:	Siru kaippu
Potency	:	Veppam (heat)
Pirivu	:	Karuppu (Pungent)

Action

Tonic

Stomachic

பொதுகுணம்

வாயினருசி வயிற்றுளைச்ச னீடுசுரம்

பாயுகின்ற பித்தமுலமன் பண்ணுங்கான் - தூய

மருவேறு காந்தளங்கை மாதே! ஊலகிற்

கருவேப் பிலையருந்திக் காண்

Chemical Constituents

α-pinene, Sabinene, β-pinene, β-cary ophyllene, limonene, bornyl acetate, terpinen-4-01, γ-terpinene, α-humulene.

Medicinal uses

Fresh leaves, dried leaf powder and essential oil are widely used for flavouring soups, curries, fish and meat dishes, eggs dishes, traditional curry powder blends, seasoning and ready to use other fool preparations.

Whole (or) inparts as antiemetics, antidiarrheal, antifangal, depressant, anti-inflammatory, body aches for kidney pain and vomiting.

8. தேற்றான் விதை – Strychnos Potatorum

Scientific classification

Kingdom	-	Plantae
Division	-	Angiosperms
Order	-	Gentianales
Family	-	Loganiaceac
Genus	-	Strychnos
Species	-	Potatorum

வேறுபெயர்

இல்லம், கதகம், சில்லம், தேறு

Organoleptic Characters

Taste	:	Kaippu
Potency	:	Veppam (heat)
Division	:	Karuppu (Pungent)

Action

Alterative

Tonic

Stomachic

பொதுகுணம்

இல்லம் மலக மிரண்டு மயின்றானோ

யில்லா மலக மிருக்குமே - இல்லாமல்

வாழைக் கனியும் வடையு மிமுதுமுண்பான்

வாழைக் கனியுனடவைத் தவன்

Chemical constituents

Diaboline, Saponin glycoside having oleanolic acid and as aglycone and D-galactose and D-mannose as sugar moieties, chlorogenic acid, oleanolic acid, 3 β-autaxyoleanolic acid, β-Sitosterol, lupenediol, arachidic, lignoceric, palmitic, stearic, linoleic and oleis acid.

Medicinal uses

The seeds are bitter and used as an astringent, demulcent, emetic, diuretic, stomachic and also used to purify water and anti-inflammatory.

They are used in vitiated conditions of vata and kabha, hepatopathy, nephropathy, gonorrhea, leucorrhea, gestropathy, bronchitis, chronic diorrbea, dysentery, ulcers, other eye diseases, scleritis

9. மஞ்சள் – Curcuma longa

Scientific classification

Kingdom	-	Plantae
Division	-	Angiosperms
Order	-	Zingiberales
Family	-	Zingiberaceal
Genus	-	Curcuma
Species	-	Longa

வேறுபெயர்

ஆரிசனம், கான்சனி, நிசி, பூதம்

Organoleptic Characters

Taste	:	Karuppu (Pungent) Kaippu (Bitter)
Potency	:	Veppam (heat)
Pirivu	:	Karuppu (Pungent)

Action

Carminative

Stimulant

Hepatoprotective

பொதுகுணம்

பொன்னிறமாம் மேனி புலானாற்ற மும்போகும்

மன்னு புருட வசியமாம் - பின்னியெழும்

வாந்தியபித்த தோடமையம் வாதம்போந் தீபனமாங்

கூர்ந்தமஞ்ச ளின்கிழங்குக்கு.

Chemical constituents

The rhizome contains he pigment curcumin an essential oil of Sesquiterpenes, Zingiberene, D-phellandrene, turmerone, dehydroturmerone, α-alantolactone, curcumene and cineal.

Medical uses

Aromatic, Stimulant, tonic, Carminative and antholmintic. The rhizome is useful in gastric ulcer, Anti-inflammatory, Anti fungal, anti viral and cholegogic properties.

It is prescribed in the therapy of gastric and duodenal ulcer and also for skin oilments.

10. பசும் பால் – Cow's Milk – LACTUS

வேறுபெயர்

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

பொதுகுணம்

பாலர் கிழவர் பழஞ்சுரத்தோர் புண்ணாளி
சூலையர் மேகத்தோர் துர்பலத்தோர் ஏலுமிவர்
எல்லார்க்கு மாகும் இளைத்தவர்க்குஞ் சாதகமாய்
நல்லாய் பசுவின்பால் நாட்டு

- **புதார்த்த குண சிந்தாமணி**

Composition of Milk

Milk is a translucent white liquid produced by the mammary glands of mammals, a PH ranging from 6.4 to 6.8 making it slightly acidic.

Cow's Milk contains on a average 3.4% protein, 3.6% fat and 4.6% lactose 0.7% minerals and supplies 66 k cal of energy per 100 gms. The largest structure in the fluid protein of the milk is casein protein micelles.

Cow's Milk is a rich source of vitamins including riboflavin, Vitamin E, Vitamin A, folate, thiamin, niacin, vitamin B6, vitamin B12.

Health benefits of cow's Milk

Strengthens bones and teethMilk has often been recommendedas a remedy for everything from goul and acthritis to respiratory distress and burns on the skin

- Weight loss
- Growth and development
- Boosts immunity

11. பசுநெய் – Cow's Ghee

பொதுகுணம்

தாகமுடி லைசுட்கம் வாந்தி பித்தம் வாயுபிர

மேகம் வயிற்றெரிவு விக்ககலழல் - மாகாசங்

குன்மம் வறட்சி குடற்புரட்ட லஸ்திசுட்களஞ்

சொன்மூலம் போக்குநிறைத் துப்பு

- குணப்பாடம் தாது-சிவ வகுப்பு

It has been used in the treatment of Vomiting, Pitha disease, Stomach burning, hic-cough, peptic ulcer, dryness of sjin and irritable bowel syndrome.

Compositions of Ghee

Cows ghee abundant in saturated fatty acids. It contains approximately 8% saturated fatty acids, triglycerides, diglycerides, monoglyverides, phospholipids, beta carotene 600 IV and vitamin E which are known anti oxidants.

4. MATERIALS AND METHODS

Ingredients of Karappan Nei (Internal And External Medicine)

- Nilavembu (Andrographis Paniculata)
- Chensanthanam (Pterocarpus Santalinus)
- Kadukkai (Terminalia chebula)
- Muththakaasu (Cyperus Rotundus)
- Thippili (Piper longum)
- Devadharus (Cedrus Deodara)
- Kariveppilai (Murreya Koenigii)
- Thetranvithai (Strychnos Potatorum)
- Manjal (Curcuma langa)
- Pasumpaal (Cow's Milk)
- PasuNei (Cow's Ghee)

Collection of Raw drugs:

The drugs were purchased from authorized country raw drug store in Chennai.

Identification and Authentication of the drug:

All the plant materials were identified and authenticated by the Botanist National Institute of Siddha, Tambaram sanatorium, Chennai.

சுத்திமுறைகள்

- நிலவேம்பு, கோரைக்கிழங்கு – கடுரவியிலுலர்த்தி எடுத்துக் கொள்க.
- மஞ்சள் - மேல் தோலினைசிவி துண்டுகளாக நறுக்கி இரவியிலுலர்த்தி வைத்துக் கொள்ளவும்.
- தேற்றான் விதை–பசும்பாலில் ஒருநாழிகை ஊறவைத்து நிரில் கழுவி உலர்த்துக.
- தேவதாரு, செஞ்சந்தனம் - வயிரபாகத்தை பொன்வறுவலாக வறுத்து எடுத்துக் கொள்ளவும்.
- கடுக்காய் - மேல் தோலினை எடுத்துக் கொண்டு கொட்டயினை நிக்கிகொள்ளவும்.
- கறிவோப்பிலை–சுத்த வஸ்திரத்தினால் துடைத்து பழுப்பு, அழுகல் முதலியவற்றை நிக்கி எடுத்துக் கொள்ளவும்.
- திப்பிலி– தூசியினை நிக்கி இளவறுப்பாக எடுத்துக் கொள்ளவும்.
- பசுநெய் - அடுப்போற்றி அதிலுள்ள நீர் சுண்ட, நெயினை காந்தாமல் காய்ச்சி வடிகட்டவும்.
- பசுபால் - காய்ச்சி எடுத்துக் கொள்ளவும்.

Preparation Method:

All the ingredients mentioned above will be taken 10 grams each and crushed well. Then added 3.9 litter milk mixes well then add 2.6 litters ghee and boiled it till the mixture reaches Ghee form.

DOSAGE	:	5-10 ml (bd)
ADJUVANT	:	Honey
INDICATIONS	:	Karappan
DURATION	:	48 days
DRUG STROAGE	:	Prepared medicine will be stored in clean and dry glass container

INGREDIENTS OF KARAPPAN NEI

NILAVEMBU

CHENSANTHANAM

KADUKKAI

MUTHTHAKAASU

INGREDIENTS OF KARAPPAN NEI

THIPPILI

MANJAL

DEVADARU

KARIVEPPILLAI

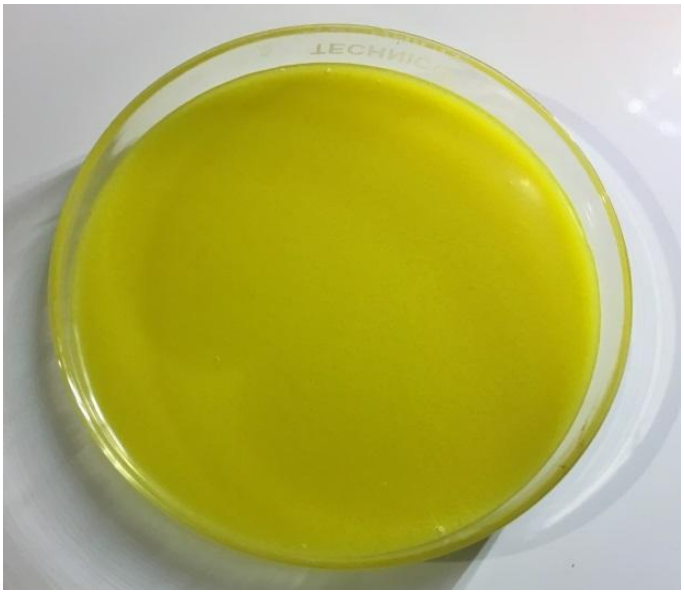
INGREDIENTS OF KARAPPAN NEI

THETTRAN VITHAI

PARU NEI

PASUMPAAL

KARAPPAN NEI



A. Pre-Clinical study

i. Acute toxicity studies
ii. Physico chemical analysis
iii. Phyto chemical analysis
iv. Bio chemical analysis
v. In vitro Anti-inflammatory activity

B. Clinical Study

An open clinical study was carried out in 30 children affected by Bala Karappan aged between 6 – 12 year.

A. PRE CLINICAL STUDY

A i. Acute Toxicity Study

Toxicological Evaluation of Karappan Nei (KN)

The following in vivo toxicity studies were carried out on Karappan Nei (KN) by World Health Organization (WHO) guidelines.

Acute Oral Toxicity study (WHO)

The toxicity study was carried out at National Institute of Siddha. The study was done after getting permission from the Institutional Animal Ethical Committee with IAEC Approval No: NIS/IAEC-IV/03/05012017.

The test animals were obtained from Tamil Nadu Veterinary and Animal Sciences University, Madhavaram. Animals were kept in animal house, National Institute of Siddha, Chennai.

DESCRIPTION OF THE METHOD

Selection of the animals:

Animals were selected as per guidelines. Healthy adult animals of Wistar albino rat, both male and female sex were used for acute oral toxicity study. The female animals used in the studies were nulliparous and non-pregnant.

Housing and feeding conditions:

The temperature in the experimental animal room: 22ºC (± 3ºC)

Humidity: 60 ± 10 %

Lighting: Artificial, the sequence being 12 hours light, 12 hours dark.

The animals were housed in polypropylene cages provided with bedding of husk. The animals had free access to distal water. For feeding, Standard pellet diet (bought from Sai Meera foods pvt. Ltd, Bangalore) was used.

Preparation of animals:

The animals are randomly selected, to permit individual identification by cage number and individual marking on the fur of each animal was made with picric acid. The animals were kept in their cages for 7 days prior to dosing to allow for acclimatization to the laboratory conditions. The principles of laboratory animal care were followed.

Test Substance:

Karappan Nei (KN) is dark yellowish in colour, free flowing- greasy liquid and Slightly pungent.

Route of administration:

Oral route was selected, because it is the normal route of clinical administration.

PROCEDURE:

ACUTE ORAL TOXICITY STUDY

Experimental Animals:

Species and strain	:	Wistar Albino rat
Sex	:	Male and Female
Age, Weight	:	6-8 weeks, 150-175 gm
Test guideline	:	WHO guideline
Groups/treatment	:	Grouped by randomization
Duration of exposure to the Single dose	:	Karappan Nei (KN)
Study duration	:	14 days
Number of animals	:	10 male, 10 female
Route of administration	:	Oral
Number of animals and dose levels	:	1.8 ml

Animals are divided into two groups, each group containing 5 male and 5 female rats. One group as control and the other as test group. Control group is treated with saline and other groups were treated with test drug Karappan Nei (KN) ten times the therapeutic dose (1.8ml).

Groups No. of Rats

Group I Vehicle control (saline)	5 male, 5 female
Group II Test drug –Karappan Nei (1.8ml)	5 male, 5 female

Administration of doses:

The test drug was administered in a single dose by using oral gavage. Animals were fasted prior to drug administration. Following the period of fasting, the animals were weighed and test drug was administered. The control groups received equal volume saline. The test drug was administered at 10 times the therapeutic dose (1.8ml). The food was with held for 3-4 hours after dosing the animal.

Observations:

Observations were made and recorded systematically and continuously observed after the substance administration as per the guidelines.

- ½ hour, 1 hour, 2 hours, 4 hours and up to 24 hours observation
- All rats were observed twice daily for 14 days
- Body weight were Calculated weekly once
- Feed & water intake were Calculated daily

Cage side observation

The animals were monitored for behavioral parameters like Alertness, Aggressiveness, piloerection, Grooming, Gripping, Touch Response, Motor Activity, Tremors, Convulsions, Muscle Spasm, Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmos, Diarrhea, Writhing, Respiration, Mortality.

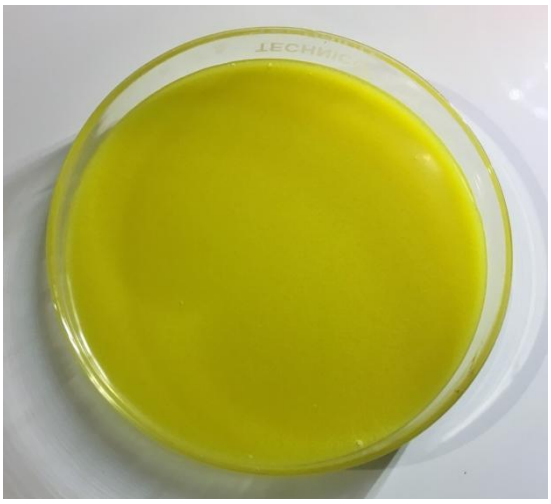
Gross necropsy:

At the end of the 14th day, all the animals were sacrificed by using the injection of Pentothal sodium Gross necropsy includes examinations of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Brain, eye, lungs, heart, spleen, liver, kidneys, adrenals, uterus of all animals were examined.

A.ii) Physicochemical analysis of Karappan Nei (KN)

The Physiochemical analysis of the drug Karppan Nei was done at Noble Research Solutions Tamilnadu Chennai. Since the form of drug is like ghee the parameter such as Description (State, Colour, Odor), Determination of weight/ml, Refractive Index, Viscosity value, Iodine value, Saponification value, Acid value, Peroxide value, TLC/HPTLC, Heavy metal analysis, Sterility test, Test for Specific Pathogen, Test for Pesticides and Aflatoxin assay was done using quality control methods for medicinal plants materials as described in AYUSH protocol.

1. **Sample Description**



State	Liquid
Appearance	Dark Yellowish
Nature	Greasy Viscous
Odor	Pleasant Characteristic

2. **Determination of Weight/MI**

Weight per ml - 0.046 gm. /ml

3. **Determination of Refractive Index**

Determination of RL was carried out using Refract meter.

4. Determination of Weight per ml

Weight per ml was determined using the comparative weight calibration method, in which the weight of 1ml of the base of the formulation was calculated and then weight

of 1 ml of finished formulation were been calculated. The difference between weight variations of the base with respect to finished formulation calculated as an index of weight per ml.

5. Determination of pH

Sample being liquid in nature the direct litmus evaluation method was adopted to check the pH of the sample.

6. Determination of Viscosity value

Viscosity determination were been carried out using Ostwald viscometers. Measurement of viscosity involves the determination of the time required for a given volume of liquid to flow through a capillary. The liquid is added to the viscometer, pulled into the upper reservoir by suction, and then allowed to drain by gravity back into the lower reservoir. The time that it takes for the liquid to pass between two etched marks, one above and one bellow the upper reservoir, is measured.

7. Determination of Iodine value

About 20 gm. of test sample was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this about 25 ml of Wii's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mines and refrigerated for an hour About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

8. Determination of saponification value

About 2 gm of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeat the same procedure without taking the sample for blank titration. Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

9. Acid Value

Accurately 5 g of test sample was weighed and transferred into a 250 mL conical flask. To this, a 50 mL of neutralized alcohol solution was added. This mixture was heated for 10 min by heating mantle. Afterwards, the solution was taken out after 10 min and 1 or 2 drops of phenolphthalein indicator was added. This solution was titrated against KOH solution from the burette. The appearance of pink color indicated the end point. The volume of consumed KOH solution was determined and the titration of test sample was carried out in triplicate and the mean of the successive readings was used to calculate the acid-value of the respective sample by following expression.

Acid value = Titter Value X 0.00561X 1000 / Wt of test sample (g)

10. Peroxide value

5 g of the substance being examined, accurately weighed, into a 250-ml glass-stoppered conical flask, add 30 ml of a mixture of 3 volumes of glacial acetic acid and 2 volumes of chloroform, swirl until dissolved and add 0.5ml volumes of saturated potassium iodide solution. Allow to stand for exactly 1 minute, with occasional shaking, add 30 ml of water and titrate gradually, with continuous and vigorous shaking, with 0.01M sodium thiosulphate until the yellow colour almost disappears. Add 0.5 ml of starch solution and continue the titration, shaking vigorously until the blue color just disappears (a ml). Repeat the operation omitting the substance being examined (b ml). The volume of 0.01M sodium thiosulphate in the blank determination must not exceed 0.1 ml.

Peroxide value = 10 (a-b)/w

11. TLC/HPTLC

1. TLC Analysis

Test sample was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Toulene: Ethyl Acetate: Acetic Acid (1.5:1:0.5) After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm

Reference

Lukasz Komsta, Monika Waksmundzka-Hajnos, Joseph Sherma. Thin Layer Chromatography in Drug Analysis. CRC Press, Taylor and Francis.

2. High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analyzed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

Reference

1. Wagner H. Plant Drug Analysis. A thin Layer chromatography Atlas.2nd ed. Heidelberg: Springer-Verlag Belgium; 2002:305, 227.

12. Heavy metal analysis

Standard: Hg, As, Pb and Cd – Sigma

Methodology

Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample KN was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test sample KN.

Sample Digestion

Test sample KN digested with 1mol/L HCl for determination of arsenic and mercury. Similarly for the determination of lead and cadmium the sample were digested with 1mol/L of HNO3.

Standard reparation

As & Hg- 100 ppm sample in 1mol/L HCl

Cd &Pb- 100 ppm sample in 1mol/L HNO3

13. Sterility test by pour plate method

Objective

The pour plate techniques were adopted to determine the sterility of the product. Contaminated / un sterile sample (formulation) when come in contact with the nutrition rich medium it promotes the growth of the organism and after stipulated period of incubation the growth of the organism was identified by characteristic pattern of colonies. The colonies are referred to as Colony Forming Units (CFUs).

Methodology

About 1ml of the test sample was inoculated in sterile petri dish to which about 15 ml of molten agar 45^{o}C were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (About 10 minutes). Plates were then inverted and incubated at 37^{o} C for 24-48 hours. Grown colonies of organism was then counted and calculated for CFU.

14. Test for Specific Pathogen

Methodology

0.5 ml of the test sample was directly inoculated in to the specific pathogen medium (EMB, DCC, Mannitol, Cetrimide) by pour plate method. The plates were incubated at 37^{o}C for 24 – 72 hrs for observation. Presence of specific pathogen identified by their characteristic color with respect to pattern of colony formation in each differential media.

Abbreviation

Organism	Abbreviation
E-coli	*EC*
Salmonella	*SA*
Staphylococcus Aureus	*ST*
Pseudomonas Aeruginosa	*PS*

15. Test for Pesticides

1. Organochloorine Pesticides
2. Organophosphorus Pesticides
3. Phyrethroids

Extraction

About 10 g of test substance were extracted with 100 ml of acetone and followed byhomogenization for brief period. Further filtration was allowed and subsequent addition of acetone to the test mixture. Heating of test sample was performed using a rotary evaporator at a temperature not exceeding 40ºC until the solvent has almost completely evaporated. To the residue add a few milliliters of toluene R and heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered through membrane filter.

Reference

1. WHO guideline for assessing the quality of herbal medicines with reference to contaminants and residues. WHO Geneva. 2007.

2. Lohar. D.R.Protocol for testing of ASU medicines. Pharmacopoeial Laboratory for Indian Medicines. Ministry of AYUSH. 2007.

16. Aflatoxin Assay

Standard

Aflatoxin B1

Aflatoxin B2

Aflatoxin G1

Aflatoxin G2

Solvent

Standard samples was dissolved in a mixture of chloroform and acetonitrile (9.8 : 0.2) to obtain asolution having concentrations of 0.5 µg per ml each of aflatoxin B1 and aflatoxin G1 and 0.1 µg per mleach of aflatoxin B2 and aflatoxin G2.

Test solution: Concentration 1 µg per ml

Procedure

Standard aflatoxin was applied on to the surface to pre coated TLC plate in the volume of 2.5 µL, 5µL, 7.5 µL and 10 µL. Similarly the test sample was placed and Allow the spots to dry and develop thechromatogram in an unsaturated chamber containing a solvent system consisting of a mixture ofchloroform, acetone and isopropyl alcohol (85 : 10 : 5) until the solvent front has moved not less than 15 cmfrom the origin. Remove the plate from the developing chamber, mark the solvent from and allow the plateto air-dry. Locate the spots on the plate by examination under UV light at 365 nm.

Reference

Luciana de CASTRO. Determining Aflatoxins B1, B2, G1 And G2 In Maize Using Florisil Clean Up WithThin Layer Chromatography And Visual And Densitometric Quantification. Ciênc. Tecnol. Aliment.vol.21no.1 Campinas. 2001.

A.iii. Phytochemical analysis of Karappan Nei

Preparation of Extract:

Sample Extraction were carried out with Ethyl acetate solvent and the resulting extract was utilized for the phytochemical analysis.

1. **Test for alkaloids:**

Mayer's Test: To the test sample, 2ml of mayer's reagent was added.

2. **Test for coumarins:**

To the test sample, 1 ml of 10% sodium hydroxide was added.

3. **Test for saponins:**

To the test sample, 5 ml of water was added and the tube was shaken vigorously.

4. **Test for tannins:**

To the test sample, ferric chloride was added.

5. **Test for glycosides- Borntrager's Test**

Test drug is hydrolyzed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolyte is subjected to the following tests. To 2 ml of filtered hydrolyte, 3 ml of chloroform is added and shaken, chloroform layer is separated and 10% ammonia solution is added to it.

6. **Test for flavonoids:**

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid.

7. **Test for phenols:**

Lead acetate test: To the test sample; 3 ml of 10% lead acetate solution was added.

8. **Test for steroids:**

To the test sample, 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence.

9. **Triterpenoids (Noller's test)**

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentratedsulphuric acid was added from the sides of the test tube.

10. Test for Cyanins

A. Aanthocyanin:

To the test sample, 1 ml of 2N sodiumhydroxide was added and heated for 5 min at 100^0C.

11. Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic'sreagent is added. The mixture is heated on a boiling water bath for 2 minutes.

12. Proteins (Biuret Test)

To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide.

Reference :

Brain KR, Turner TD. The Practical Evaluation of Phyto pharmaceuticals. Bristol: Wright Scientechnica; 1975:36-45

A.iv. Biochemical analysis of karappan Nei

Biochemical Analysis of Karappan Nei was done at the Biochemistry lab at National Institute of Siddha, Chennai by the method of Kolkate..

Preparation of Extract:

5ml of sample was taken in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and biochemical constituents in it.

Procedure:

Test for Silicate

A 2ml of the sample was shaken well with distilled water.

Action of Heat:

A 2ml of the sample was taken in a dry test tube and heated gently at first and then strong.

Action of Heat:

A 2ml of the sample was taken in a dry test tube and heated gently at first and then strong.

Ash Test:

A filter paper was soaked into a mixture of extract and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited.

I. Test for Acid Radicals

Test for Sulphate:

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

Test for chloride:

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

Test for Phosphate:

2ml of the extract were treated with 2ml of dil.ammonium molybdate solution and 2ml of con. HNo3.

Test for carbonate:

2ml of the extract was treated with 2ml of dil. magnesium sulphate solution.

Test for Nitrate:

1gm of the extract was heated with copper turning and concentrated H_2So_4 and viewed the test tube vertically down.

II.Test for Basic radicals

Test for lead:

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

Test for copper:

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

Test for Aluminium:

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

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.

Test for Zinc:

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

Test for Calcium:

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

Test for Magnesium:

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

Test for Ammonium:

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

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.

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.

Test for Mercury:

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

Test for Arsenic:

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

III. Miscellaneous

Test for Starch:

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

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 colourchanges are noted.

Test for the Alkaloids:

a) 2ml of the extract was treated with 2ml of dil.potassium Iodide solution.

b) 2ml of the extract was treated with 2ml of dil.picric acid.

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

Test for Tannic Acid:

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

Test for Unsaturated Compound:

To the 2ml of extract 2ml of dil.Potassium permanganate solution was added**.**

Test for Amino Acid:

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

Test for Type of Compound:

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

A. v.In vitro Anti-inflammatoryactivity

In-vitro Anti-Inflammatory Activity by Protein (Albumin) denaturation Assay

Albumin Denaturation Assay Procedure

In-vitro anti-inflammatory activity KN was studied using albumin denaturation technique. The reaction mixture consisted of bovine serum albumin (5% aqueous solution) and test sample KN at varying concentration ranges from 100 to 500 µg/ml and standard Diclofenac sodium at the concentration of100 µg /ml of final volume. pH was adjusted by using a small amount of 1N Hydrochloric acid.

The samples were incubated at 37°C for 20 min and then heated at 57°C for 3 min. After cooling the sample, 2.5 ml of phosphate buffer solution was added into each test tube. Turbidity developed was measured spectrophotometrically at 660 nm, for control distilled water was used instead of test sample while product control tests lacked bovine serum albumin. The experiment was performed in triplicate.

The Percentage protection from denaturation is calculated by using the formulae

$$\left[\frac{(A)_{\text{control}} - (A)_{\text{sample}}}{(A)_{\text{control}}}\right] \times 100.$$

Statistical analysis

Results are expressed as Mean ± SD. The difference between experimental groups was compared by One-Way Analysis Of Variance (ANOVA) followed by Dunnet Multiple comparison test.

Reference

1. G.Leelaprakash, S.MohanDass. In-vitro anti-inflammatory activity of methanol extract of enicostemmaaxillare. Int. J. Drug Dev. & Res., 2011, 3 (3): 189-196.
2. M.V.Anoop, A.R.Bindu. In-vitro Anti-inflammatory Activity Studies on Syzygiumzeylanicum (L.) DC Leaves. International Journal of Pharma Research & Review, August 2015; 4(8):18-27.

B. CLINICAL STUDIES:

Clinical studies CTRI/2017/05/008722.REF/2017/04/014108

A Protocol was prepared andsubmittedforIEC of National Institute of Siddha.The IEC approval number is No:NIS/IEC/2016/11-18/14.10.2016. The trial registed in Clinical trial Registry of India with Reg.No.CTRI/2017/05/008722. After obtaining approval from the committee, the clinical study on *bala karappan (*Eczema*)* in children with the drug of choice *KARAPPAN NEI (INTERNAL AND EXTERNAL MEDICINE)* was carried outas per the protocol.

The trial drug KarappanNei 5-10 Ml (bd) is given for 48 days. For OP patients the clinical assessment was be done on 0 st ,16 th,32 th,48 th day and prognosis was noted . Laboratory investigations were done on 0^{th} day & 48^{th} day of the trial. After the end of the treatment, the patients were advised to visit the OPD for another 1 months for follow-up.

Study Enrollment

In this study, patients reporting at the NIS OPD with the three or more clinical symptoms of papules, vesicles, pustules, fissures, oozing, ulceration, oozing or dryness with foul smell, Pain in lower extremities, hyperpigmentation, was be examined clinically for enrolling in this study based on the inclusion and exclusioncriteria.

- ❖ The patients who were enrolled was informed about the study, experimental medicine, 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 was obtained in writing from them in the consent form.
- ❖ All these patients were given unique registration card in which patients Registration number of the study, Address, Phone number and Doctors phone number etc. were given, so as to report easily communication for the sake of thepatient.
- ❖ Complete clinical history, complaints and duration, examination findings-- all wererecorded in the prescribed Proforma in the history and clinical assessment forms separately.
- ❖ Patients were advised to take the trial drug and appropriate dietary advice given according to the patient's perfectunderstanding.

Population and Sample:

- ❖ The population consists of pediatric patients attending the OPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai-47.
- ❖ The sample consists of 6-12 years age group fulfilling all the inclusion criteria and the exclusion ncriteria.

Sample size: 30 Patients

Study place: Department of Kuzanthai Maruthuvam,
Ayothidoss Pandithar hospital,
National Institute of Siddha, Ch-47

Inclusion criteria:

Age 6 to 12 years
Both sex- male & female children

Symptoms of,

- Pain in lower extremities
- Itching
- Papules
- Vesicles
- Pustules
- Ulcer formation with oozing
- Hyper pigmentation
- Sleep disturbances

Exclusion criteria:

H/o Scabies

H/o Photo dermatitis

H/o jaundice

H/o Any other serious illness

Withdrawal criteria:

- Exacerbation of symptoms
- Occurrence of any adverse effect
- Patients turning unwilling to continue the study during the course of trial period.

Studydesign : An Open clinicaltrial.

Studyduration : 24Months

Dosageof drugs : 6-12 years (5 -10 ml) (bd)

For 6 – 8 years 5 ml

For 9 – 12 years 10 ml

Adjuvant : Honey

Dose calculation for pediatric group is based on Age, formula mentioned in the GunapadamThathuvagupputext.

Assessments:

i. Clinical assessment by SCORAD index

ii. Routine investigations

iii. Siddha method of assessment

i. Clinical assesment

The SCORAD index

A = spread.../100

B = intensity.../18

C = subjective symptoms.../20

SCORAD calculation: A/5 +7 B/2 + C

ii. Routineinvestigation

Blood - HB, Total WBC, Total RBC, DC, AEC

iii. Siddha method of assessment

- Nilam
- Kaalam
- Uyir thathukkal
- Udal thaathukkal
- Envagai thervugal

Out Come

Primary outcome

Number and screening of clinical symptoms are slightly reduced such as Papules, Vesicles, Pustules, Oozing from lesion, Itching by using SCORAD index.

Secondary outcome

Clinical Efficacy of the trail drug and its side effects if any…

The experimental drug may have good efficacy and safety in clinical study.

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 recording and completeness will be monitored by statistician (Sr.Research Officer (Statistics). All forms will be further scrutinized in presence of Investigators by Sr.Research Officer (Statistics) for logical errors and incompleteness of data before entering onto computer to avoid any bias.

No modification in the results is permitted for unbiased 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 retrospectively all collected data will be entered using MS access software onto computer. Investigators will be trained to enter the patient data and cross checked by SRO.

Adverse Effect/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 National Institute of Siddha and the same will be reported to regional pharmacovigilance center.

Ethical Issues

- To prevent any infection, with proper sterilization of lab equipment were used.
- No other external or internal medicines wereused.
- The data collected from the patient's informant was recorded. The patient's informant was informed about the diagnosis, treatment andfollow-up.
- After the consent of the patient's informant (through consent form), patient was enrolled in thestudy.
- Informed consent was obtained from the patient's informant explaining in the understandable language to the patient'sinformant.
- Treatment was provided free ofcost.
- In conditions of treatment failure, adverse reactions, patients were given alternative treatment at the National Institute of Siddha with fullcare.

Data Collection Forms

Form I	Screening & Selection Performa
Form II	Consent Form
Form III	Assent Form
FormIV	Case Report Form
FormV	Drug compliance
FormVI	Information sheet
FormVII	Dietary advice form
FormVIII	Adverse reaction form
FormIX	Pharmaco vigilance
FormX	Withdraw form

5. RESULTS AND OBSERVATION

A. Pre Clinical studies

i. Acute Toxicity Study

ii. Physicochemical analysis

iii. Phytochemical analysis

iv. Bio chemical analysis

v. In vitro Anti inflammatory activity

A. i. Acute Toxicity Study

Results

Behavioral Signs of Acute Toxicity Study of Karappan Nei

Parameters	30 mints		4 hrs		24 hrs		1st week		2nd week	
	C	E	C	E	C	E	C	E	C	E
Skin & Fur	N	N	N	N	N	N	N	N	N	N
Mucous Membrane	N	N	N	N	N	N	N	N	N	N
Respiratory rate	N	N	N	N	N	N	N	N	N	N
Heart rate	N	N	N	N	N	N	N	N	N	N
Salivation & Lacrimation	N	N	N	N	N	N	N	N	N	N
Lethargy	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
Piloerection	N	N	N	N	N	N	N	N	N	N
Urinary incontinence	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
Defecation	N	N	N	N	N	N	N	N	N	N
Sleep & Gait	N	N	N	N	N	N	N	N	N	N
Tremors &Convulsion	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL
Mortality	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL	NIL

N – Normal, C – control, E – Experimental

All the data were summarized in the form of (table-7) revealed that there was no abnormal signs and behavioral changes in all animals at the dose level of 1.8ml is administered orally, during the study period.

There was no mortality observed after dosing of Karappan Nei upto 1.8ml during the study period of 14 days. This indicates that the LD50 of Karappan Nei is more than 1.8ml

There were no changes in skin and fur, eyes and mucous membranes of all animals. The eating, drinking habit, sleep pattern, locomotion were normal in all animals and no changes in body weight as compared to control group.

At the end of the 14 the day, necropsy was performed and there was no abnormality seen in test groups as compared to control group during the examination.

A. ii. Physicochemical analysis of Karappan Nei

Analytical Report

S.No	Parameter	Karappan Nei
1	**Specific Gravity**	1.0190
2	**Viscosity at 50^{o}C (Pa s)**	28.28
3	**Refractive index**	1.38
4	**Weight per ml (gm/ml)**	
5	**Iodoine value (mg I2/g)**	142.24
6	**Saponification Value (mg of KOH to saponify 1gm of fat)**	287.82
7	**Ph**	5
8	**Weight per ml**	0.046 gm/ml
9	**Acid Value mg KOH/g**	0.617
10	**Peroxidase Value mEq/kg**	7.429

Interpretation

Since specific gravity of Karappan Nei is 1.0190 an viscosity at 50 c (Pa s) is 28.28. High value of saponification is 287.82. This value indicate to bio active molecules may present in karappan Nei. Its having ph 5.

A. iii. Phytochemical analysis of Karappan Nei

S.No	Parameter	Observation	Result
1.	Test for alkaloids	Dull white precipitate revealed	Present
2.	Test for Coumarins	Formation of Yellow color	Present
3.	Test for Saponins	Copious lather formation	Absent
4.	Test for tannis	Dark blue or greenish black color	Present
5.	Test for glycoside	Pink color	Present
6.	Test for flavonoids	Yellow color	Present
7.	Test for Phenols	Bulky white precipitate	Present
8.	Test for steroids	The layer showed yellow with green flurorescence	Present
9.	Triterpenoids	Appearance of red ring	Present
10.	Test for Cyanins	Formation of bluish green colour	Absent
11.	Test for Carbonhydrates	Characteristic colour precipitate	Absent
12.	Proteins	Violet purple colour	Absent

Interpretation

Phytochemical analysis shows the presence of Alkaloids, Coumarins, Tannis, Glycosides, Flavonoids, Phenols, Steroids, Triterpenoids, and absence of Cyanins, Carbohydrates, Protenis, Saponin.

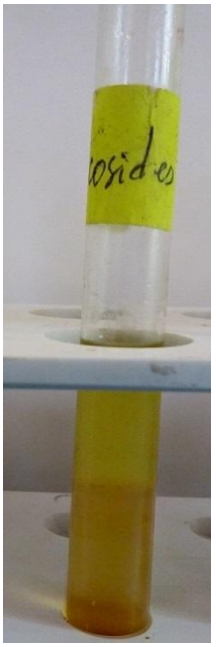
RESULTS

Test for Alkaloids

Test for Flavonoids

Test for Steroids

Test for Glycoside

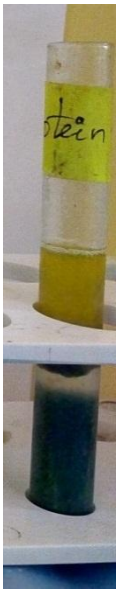


Test for Triterpenoids

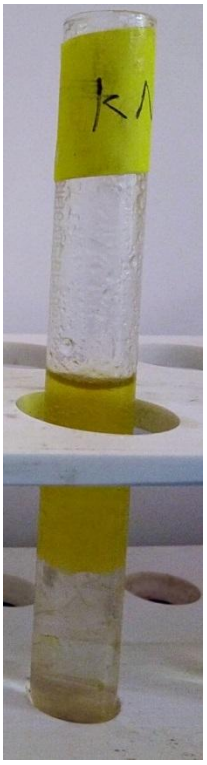
Test for Phenols

Test for Tanins

Test for Proteins

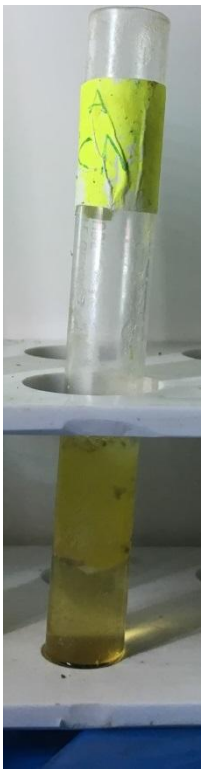


Test for Saponins



Test for Carbohydrates

Test for Beta cyanins



A. iv. Biochemical Analysis of Karappan Nei

Results of Acid radicals studies

S.No	Parameter	Observation	Result
1	Test for Sulphate	Cloudy appearance present	Absent
2	Test for Chloride	No Cloudy appearance present	Absent
3	Test For Phosphate	Cloudy yellow appearance present	Absent
4	Test For Carbonate	Cloudy appearance present	Present
5	Test For Nitrate	-	Absent
6	Test for Sulphide	-	Absent
7	Test For Fluoride & oxalate	-	Absent
8	Test For Nitrite	-	Absent
9	Test For Borax	-	Absent

Interpretation

The acidic radicals test shows the presence of Carbonate.

Results of basic radicals studies

S.NO	Parameter	Observation	Result
1	Test for Lead	-	Absent
2	Test for Copper	-	Absent
3	Test For Aluminium.	-	Absent
4	Test For Iron.	Blood red colour Appeared	Present
5	Test For Zinc	-	Absent
6	Test for Calcium	Cloudy appearance and white precipitate present	Absent
7	Test For Magnesium	White precipitate Obtained	Absent
8	Test For Ammonium	Mild brown colour appears	Absent
9	Test For Potassium	-	Absent
10	Test For Sodium	-	Absent
11	Test For Mercury	-	Absent
12	Test For Arsenic	-	Absent

Interpretation

The basic radical test shows the presence of Iron, and absence of heavy metals such as lead, arsenic and mercury etc .

Miscellaneous

S.No	Parameter	Observation	Result
1	Test for Starch	-	Present
2	Test for Reducing sugars	-	Absent
3	Test For Alkaloids.	Yellow colour developed	Present
4	Test For Tannic acid	Blue-black precipitate obtained	Absent
5	Test for unsaturated compounds	-	Absent
6	Test for Type of compounds	Green and Red colour present	Absent

Interpretation

The Miscellaneous test shows presence of Starch, Alkaloids, absence of Reducing sugar, Tannic acid, Unsaturated Compounds and types of component.

A. v. In-Vitro anti – inflammatory activity of Karappan Nei was studied using albumin denaturation technique.

The results obtained was tabulated below

FINAL RESULT

Concentration in µg/ml	Absorbance
Control	0.92 ± 0.07
KN 100	0.76 ± 0.02
KN 200	0.63 ± 0.064
KN 300	0.52 ± 0.02
KN 400	0.43 ± 0.51
KN 500	0.34 ± 0.6
Diclofenac sodium (100 µg)	0.010 ± 0.08

Each value represents the mean ± SD. N=3

Concentration in µg/ml	Percentage Inhibition of Protein Denaturation
KN 100	10.46 ± 3.36
KN 200	24.5 ± 3.30
KN 300	35.65 ± 3.91
KN 400	45.4 ± 2.20
KN 500	55.83 ± 3.26
Diclofenac sodium (100 µg)	91.45 ± 1.41

Each value represents the mean ± SD. N=3

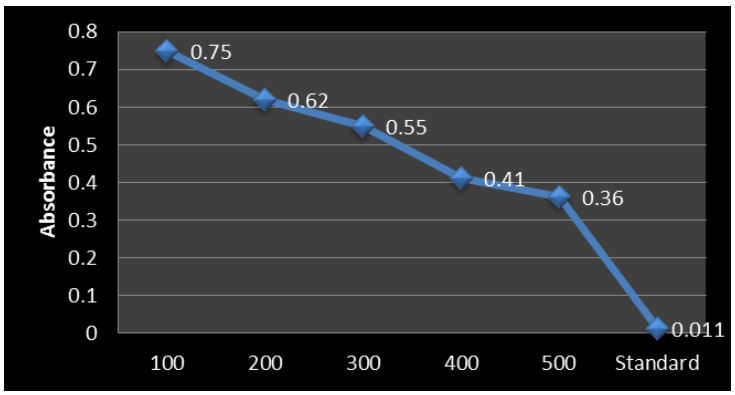
Result Analysis

The result obtained from the present clearly indicates that the test drug KN was effective in inhibiting heat induced albumin denaturation. Maximum percentage inhibition of about 55.83 % was observed at 500 µg/ml when compare to that of the Diclofenac sodium, a standard anti-inflammatory agent with the maximum inhibition 91.45 % at the concentration of 100 µg/ml.

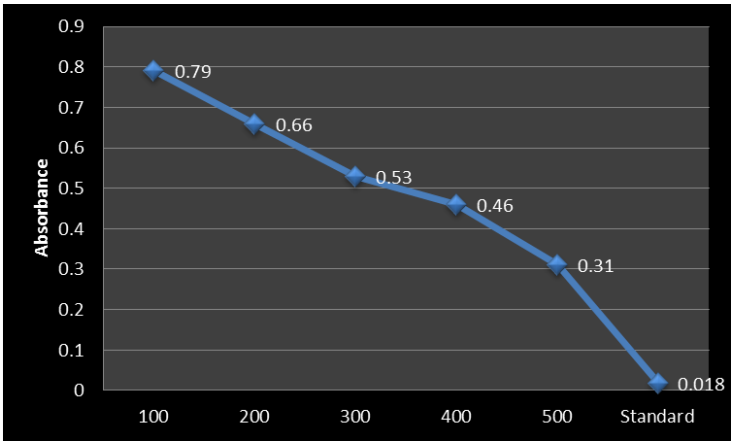
Conclusion

From the result of the study it was concluded that the test drug KN possess promising anti-inflammatory property in protein denaturation assay.

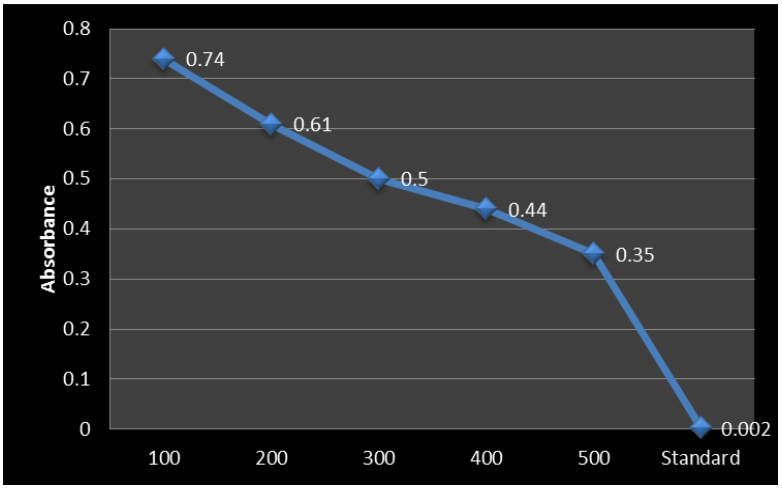
Absorbance Range of test and standard at Trial 1



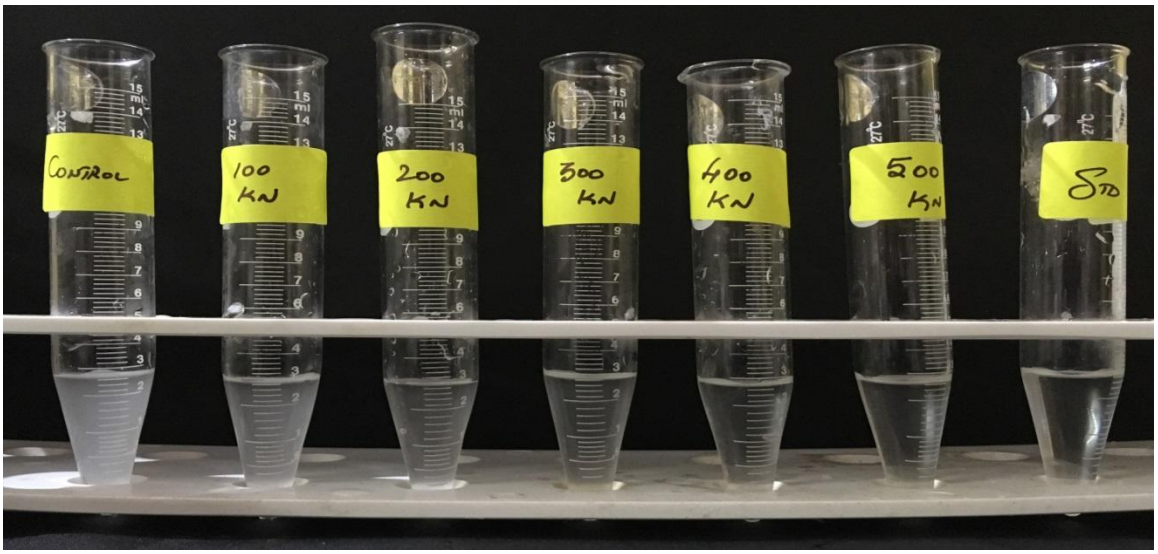
Absorbance Range of test and standard at Trial 2



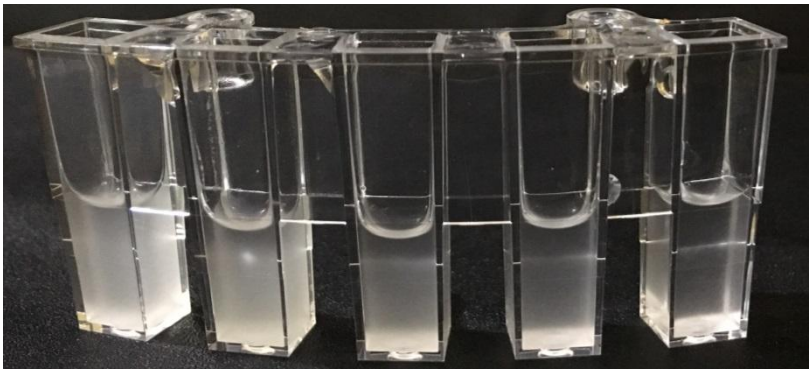
Absorbance Range of test and standard at Trial 3



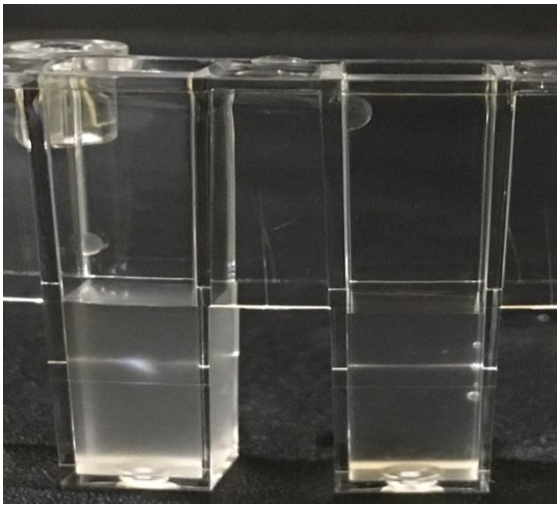
Preparation of Test and control



Absorbance of reaction mixture – Test Sample



Absorbance of reaction mixture – Control and Standard



B. Clinical Studies

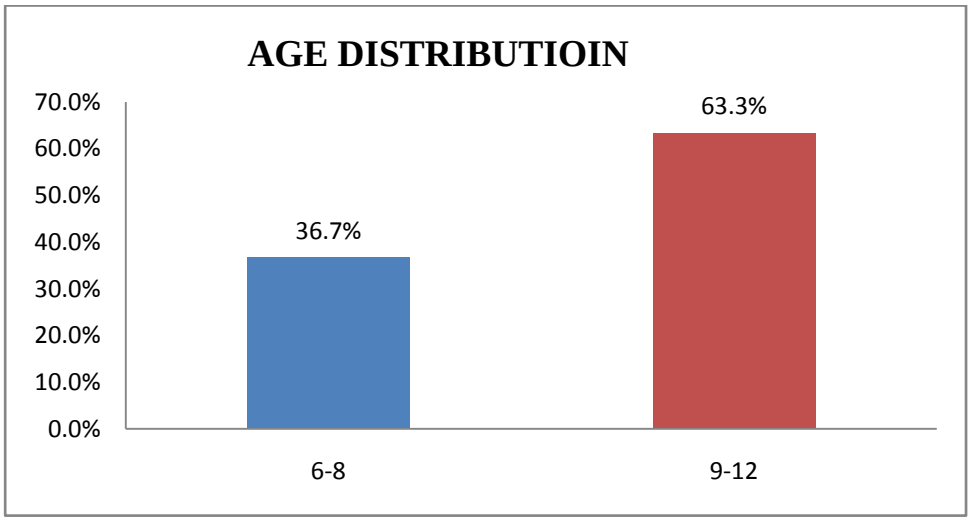
30 Children aged 6 -12 Years with confirmed diagnosis of *BALA KARAPPAN* with satisfying the inclusion criteria were enrolled in this study after obtaining written informed consent and were to receive *KARAPPAN NEI (Internal And External Medicine)* with dosage of 5-10 ml BD for 48 days.

Results were observed with respect to the following criteria

1. Age
2. Sex
3. Religion
4. Parent's Socio Economic Status
5. Diet habits
6. Allergic history
7. Family history
8. Duration of illness
9. Site of lesion
10. Nilam
11. Paruva kaalam
12. Uyir thathukkal
    - Vatham
    - Pithan
    - Kabham
13. Pori / pulangal
14. Kanmenthiriyangal
15. Ezhu udalkattugal
16. Envagai thervugal
17. Clinical symptoms
18. Haemotological Profile

TABLE 1: Distributions of Children with Bala karappan according to Age

SL.NO	AGE IN YEARS	NO OF CASES	PERCENTAGE
1	6-8	11	36.7%
2	9-12	19	63.3%
TOTAL		30	100.0%

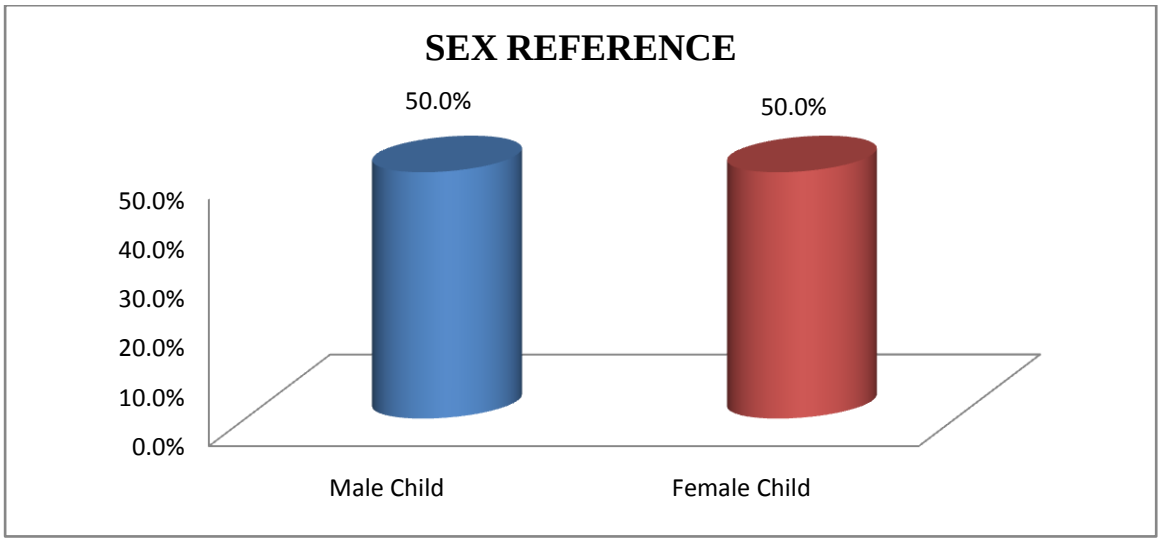


Inference

Among the 30 patients selected for this study, maximum numbers of patients 63.3% were in the age group of 9 to 12 years, 36.7% were in the age group of 6 to 8 years.

TABLE 2: Distributions of Children with Bala karappan according to Sex

SL.NO	SEX	NO OF CASES	PERCENTAGE
1	Male Child	15	50.0%
2	Female Child	15	50.0%
TOTAL		30	100.0%

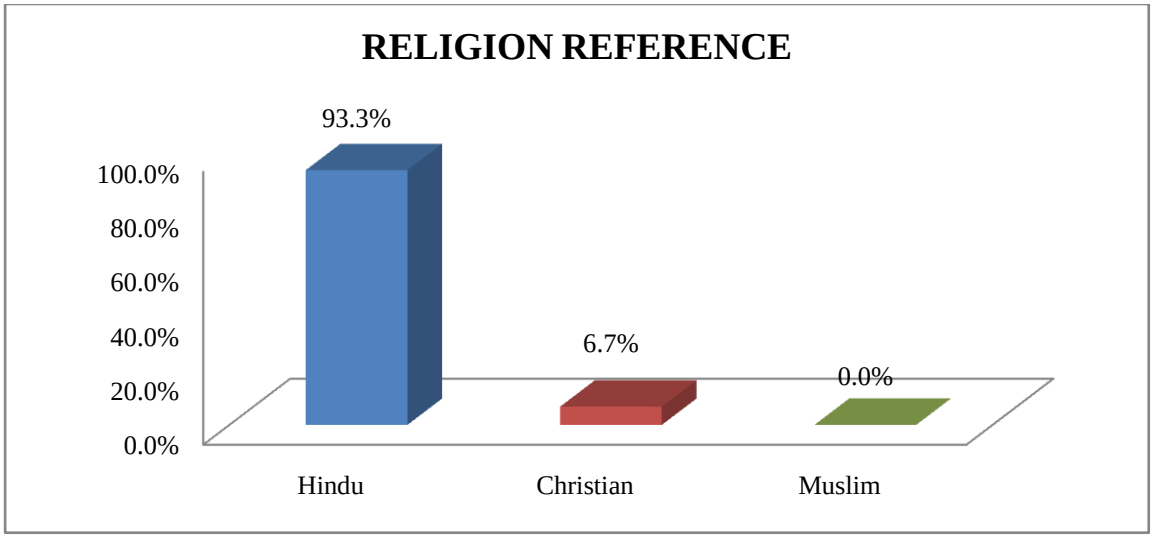


Inference:

Among the 30 children included in this study, 50.0% were male and female 50%.

TABLE 3: Distributions of Children with Bala karappan according to Religion

SL.NO	RELIGION	NO OF CASES	PERCENTAGE
1	Hindu	28	93.3%
2	Christian	2	6.7%
3	Muslim	0	0.0%
	TOTAL	30	100.0%

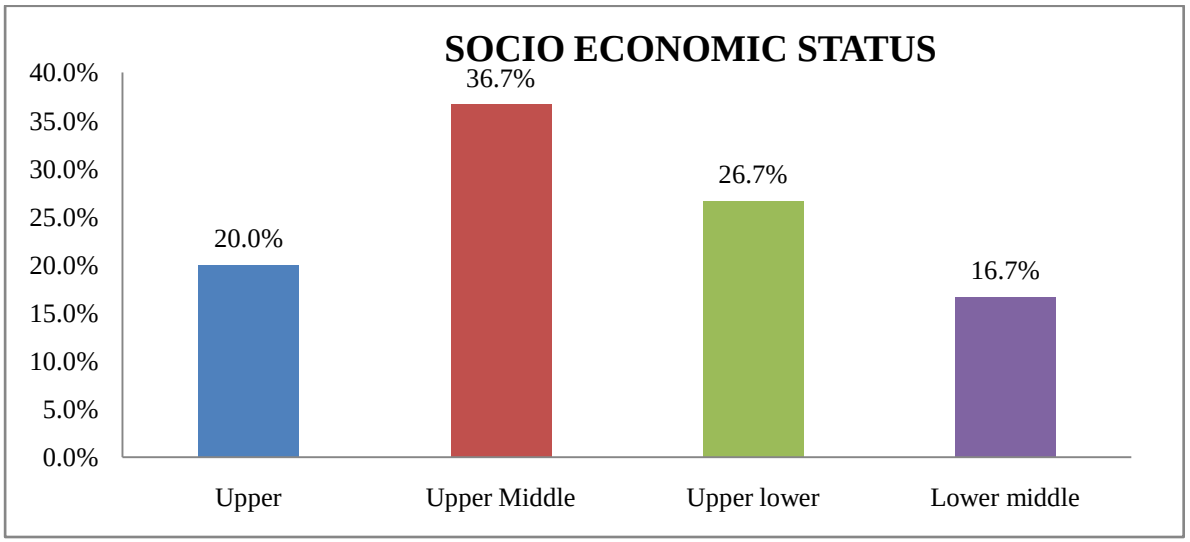


Inference

High incidence of karappan was noted 93.3% in Hindus, And 6.7% in Christian people. No cases were reported from Muslim community in this study period.

TABLE 4: Distribution of children with Bala Karappan according to parent's Socio economic status:

SL.NO	SOCIOECONOMIC STATUS	NO OF CASES	PERCENTAGE
1	Upper	6	20.0%
2	Upper Middle	11	36.7%
3	Upper lower	8	26.7%
4	Lower middle	5	16.7%
TOTAL		30	100.0%

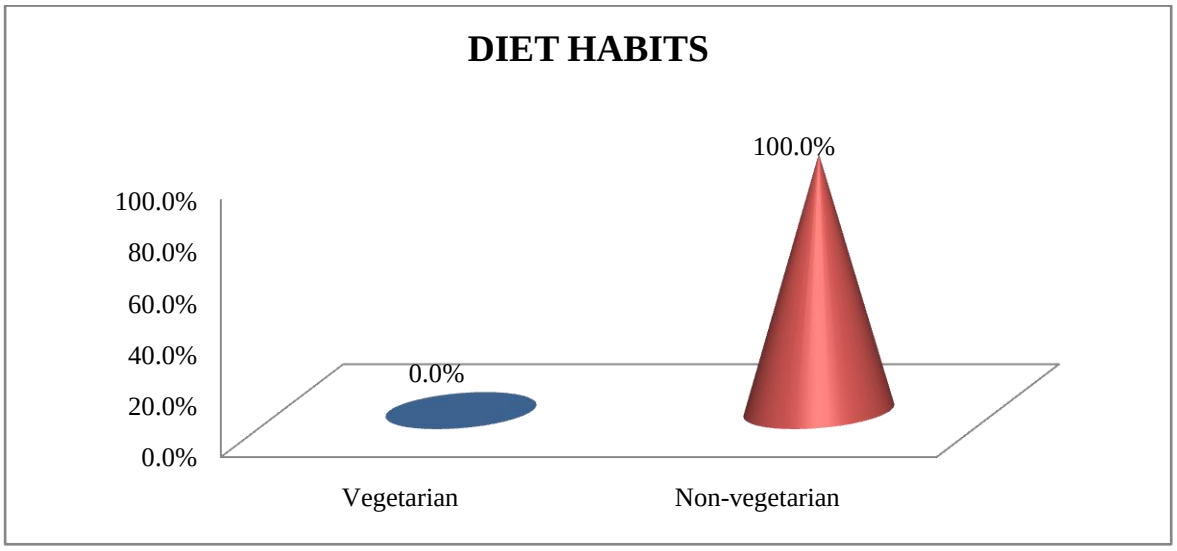


Inference

Out of 30 patients, 20.0% of the patients were from Upper income group, 36.7% patients were from Upper middle income group, 26.7% patients were from Upper Lower and the remaining 16.7% patients were under Lower Middle income group.

TABLE 5: Distribution of children with Bala Karappan according to Diet:

SL.NO	FOOD HABITS	NO OF CASES	PERCENTAGE
1	Vegetarian	0	0.0%
2	Non-vegetarian	30	100.0%
TOTAL		30	100.0%

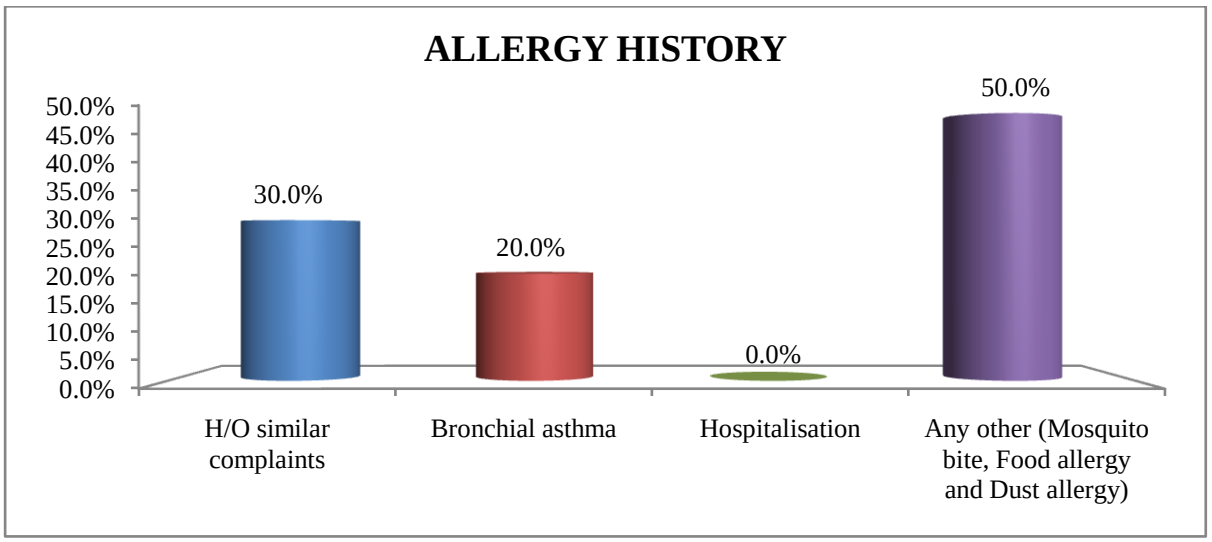


Inference

All the cases involved in this study were non-vegetarians 100%.

TABLE 6: Distribution of children with Bala Karappan according to Allergic history:

SL.NO	ALLERGY H/O	NO OF CASES	PERCENTAGE
1	H/O similar complaints	3	30.0%
2	Bronchial asthma	2	20.0%
3	Hospitalization	0	0.0%
4	Any other (Mosquito bite, Food allergy and Dust allergy)	5	50.0%
TOTAL		10	100.0%

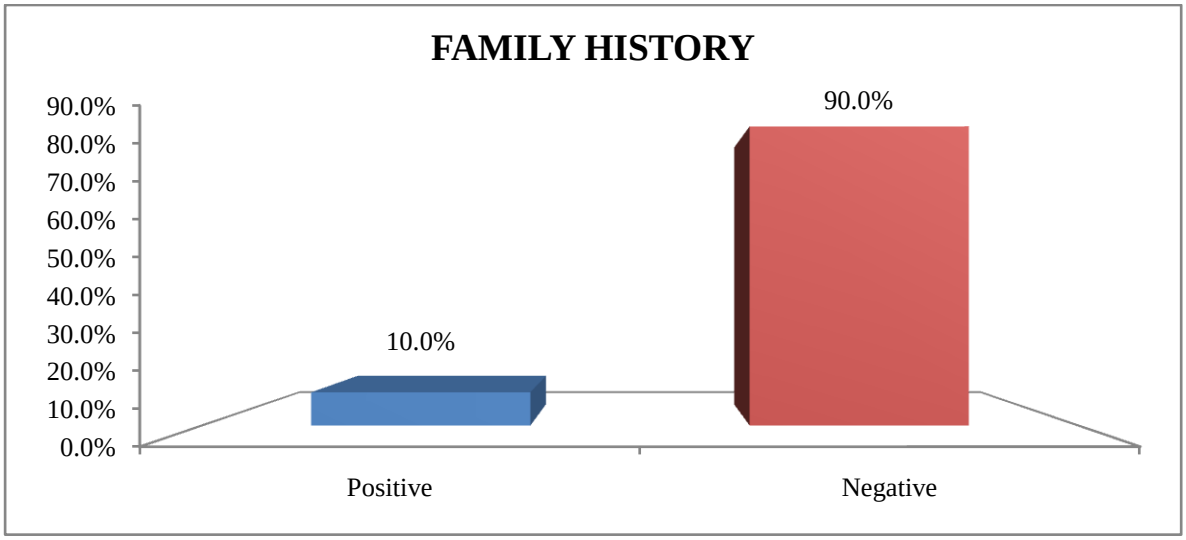


Inference

Out of 30 patients, 30% of the patients showed past H/O similar complaints, 20% had Bronchial Asthma, and 50% had history like Mosquito bite, Food Allergy, Dust Allergy. No patients having history of hospitalization.

TABLE 7: Distribution of children with Bala Karappan according to Family history:

SL.NO	FAMILY HISTORY	NO OF CASES	PERCENTAGE
1	Positive	3	10.0%
2	Negative	27	90.0%
TOTAL		30	100.0%

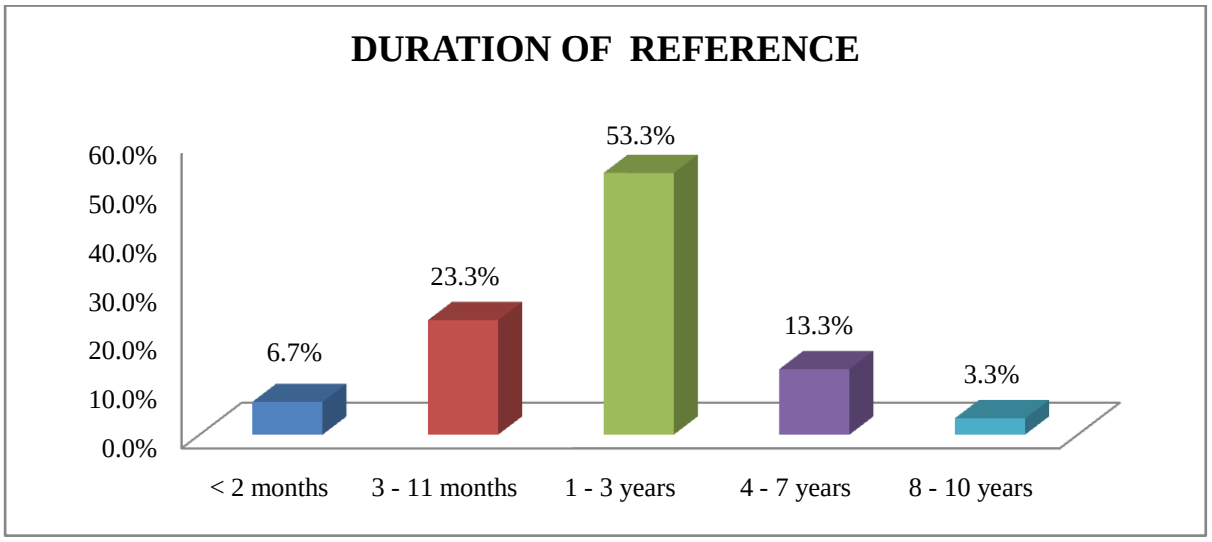


Inference

Among 30 patients, 90% of the patients showed no family history related with this disease 10% showed positive family history.

TABLE 8: Distribution of children with Bala Karappan according to Duration of Illness

SL.NO	DURATION	NO OF CASES	PERCENTAGE
1	< 2 months	2	6.7%
2	3 - 11 months	7	23.3%
3	1 - 3 years	16	53.3%
4	4 - 7 years	4	13.3%
5	8 - 10 years	1	3.3%
TOTAL		30	100.0%

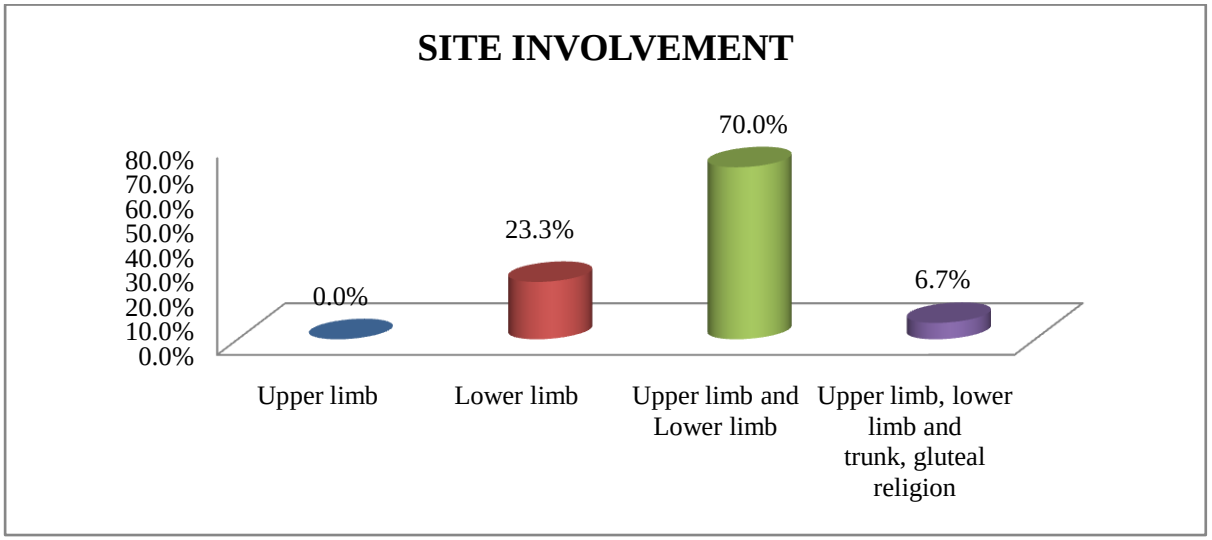


Inference

Among the 30 patients the maximum number of patients (53.3%) had the duration of illness between 1 to 3 years, (23.3%) of them had between 3 to 11 months, (13.3%) were below 4 to 7 years, (6.7%) were between < 2 months and (3.3%) were 8-10 years.

TABLE 9: Distribution of children with Bala Karappan according to Site of involvement

SL.NO	SITE	NO OF CASES	PERCENTAGE
1	Upper limb	0	0.0%
2	Lower limb	7	23.3%
3	Upper limb and Lower limb	21	70.0%
4	Upper limb, lower limb and trunk, gluteal religion	2	6.7%

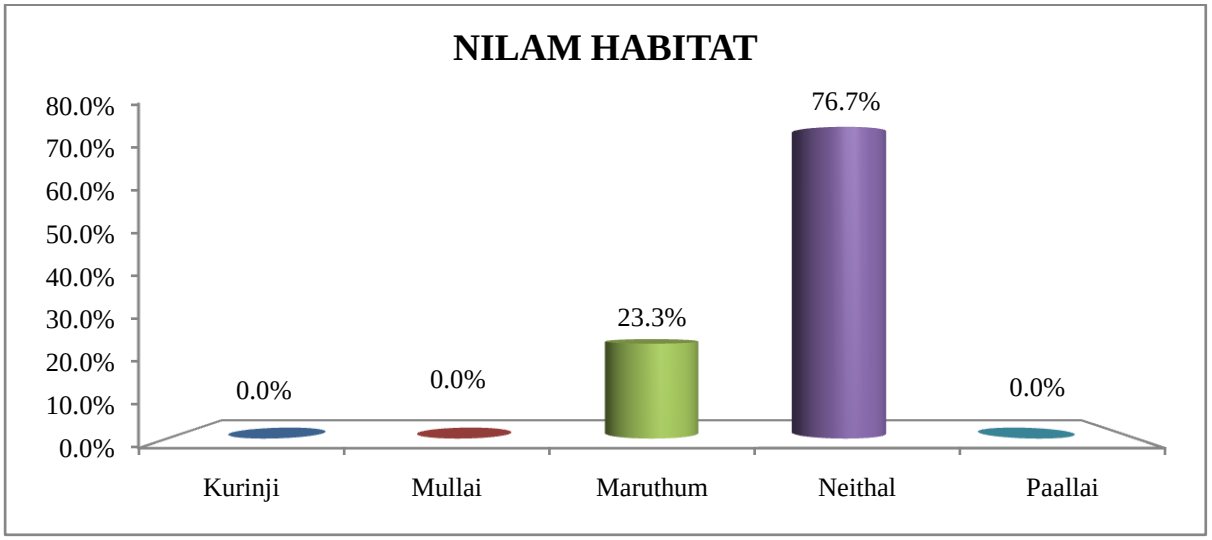


Inference

Among 30 patients 70.0% had the lesion in both upper and lower limbs, 23.3% had lesion only in the lower limbs, and 6.7% had lesion only in upper limbs and lower limb, trunk. gluteal region.

TABLE 10: Distribution of children with Bala Karappan according to Nilam Habitat

SL.NO	NILAM	NO OF CASES	PERCENTAGE
1	Kurinji	0	0.0%
2	Mullai	0	0.0%
3	Maruthum	7	23.3%
4	Neithal	23	76.7%
5	Paallai	0	0.0%

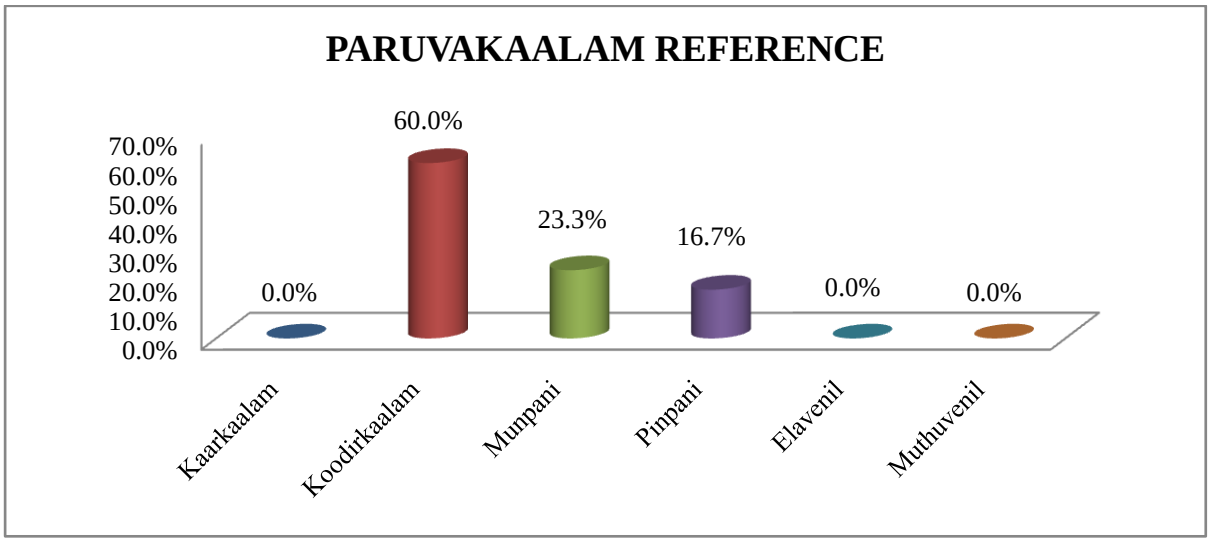


Inference

Among the 30 patients 77% of the patients were from Neithal (Coastal Area), 23% are from Marutham (Fertile Land), 0 % were reported from Kurinji (Hill area), Paalai (Dessert area) and Mullai (Forest Land).

TABLE 11: Distribution of children with Bala Karappan according to Paruvakaalam:

SL.NO	PARUVA KAALAM	NO OF CASES	PERCENTAGE
1	Kaarkaalam	0	0.0%
2	Koodirkaalam	18	60.0%
3	Munpani	7	23.3%
4	Pinpani	5	16.7%
5	Elavenil	0	0.0%
6	Muthuvenil	0	0.0%



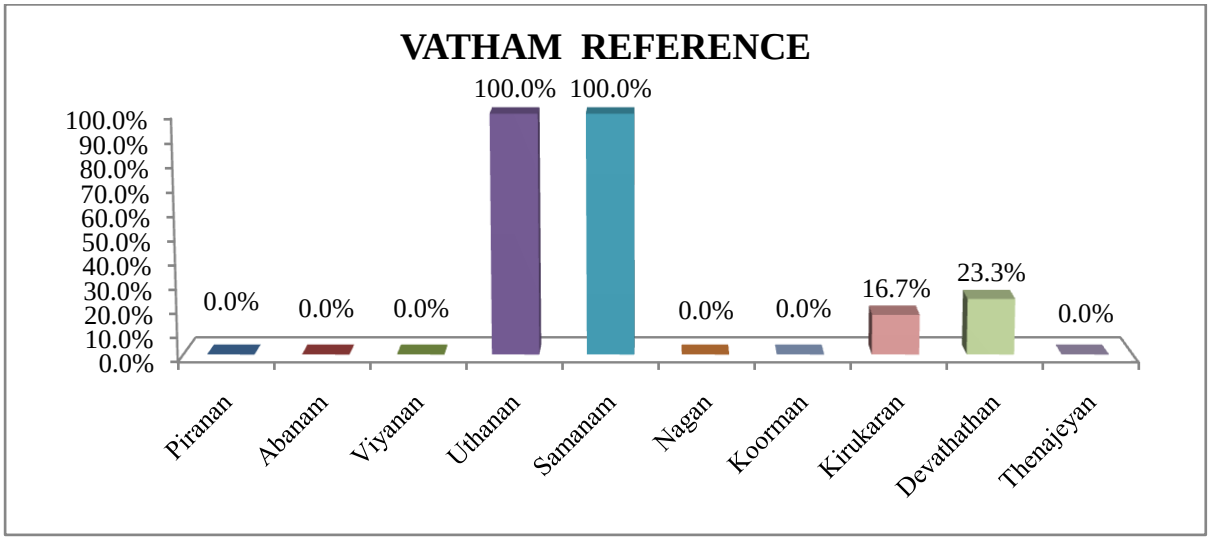
Inference

Among the 30 patients admitted for this study, the highest number of patients (60.0%) reported in Koothir Kaalam and 23.3% were reported in Muthuvenil Kaalam, 16.7% were reported in pinpani kalam.

Table 12: Distribution of children with Bala Karappan according to Uyir thathugal:

12. a: VAATHAM

SL.NO	VAATHAM CLASSIFICAION	NO OF CASES	PERCENTAGE
1	Piranan	0	0.0%
2	Abanam	0	0.0%
3	Viyanan	0	0.0%
4	Uthanan	30	100.0%
5	Samanam	30	100.0%
6	Nagan	0	0.0%
7	Koorman	0	0.0%
8	Kirukaran	5	16.7%
9	Devathathan	7	23.3%
10	Thenajeyan	0	0.0%

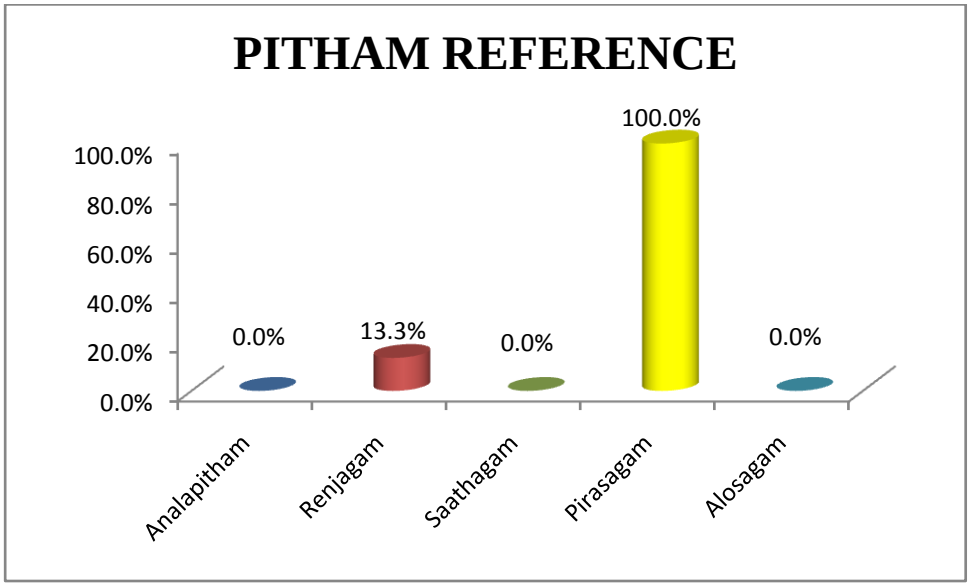


Inference

Samanan and Uthanan (Papules , Pustules, Vesicles) was found to be affected in all the 30 patients and devathathan (sleep disturbances) was affected in 23.3% of patients, Kirukaran was affected in 16.7% of patients (Cold, Cough).

TABLE 12.b: PITHAM

SL.NO	PITHAM CLASSIFICAION	NO OF CASES	PERCENTAGE
1	Analapitham	0	0.0%
2	Renjagam	4	13.3%
3	Saathagam	0	0.0%
4	Pirasagam	30	100.0%
5	Alosagam	0	0.0%

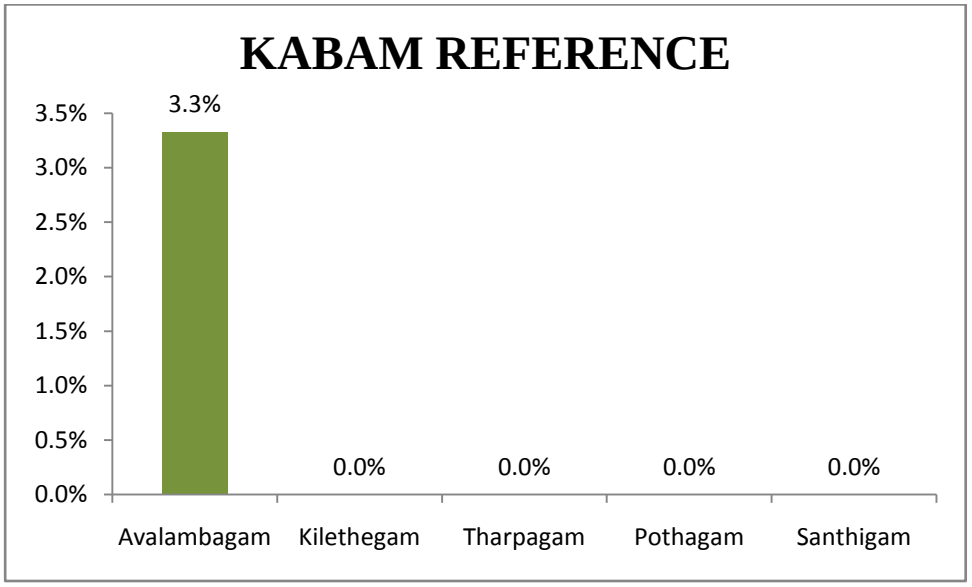


Inference

Prasakam (skin) was affected in all the cases 100% and Ranjagam (anaemia) was affected in 13.3% of patients.

TABLE 12 (C): KABAM

SL.NO	KABAM CLASSIFICAION	NO OF CASES	PERCENTAGE
1	Avalambagam	1	3.3%
2	Kilethegam	0	0.0%
3	Tharpagam	0	0.0%
4	Pothagam	0	0.0%
5	Santhigam	0	0.0%

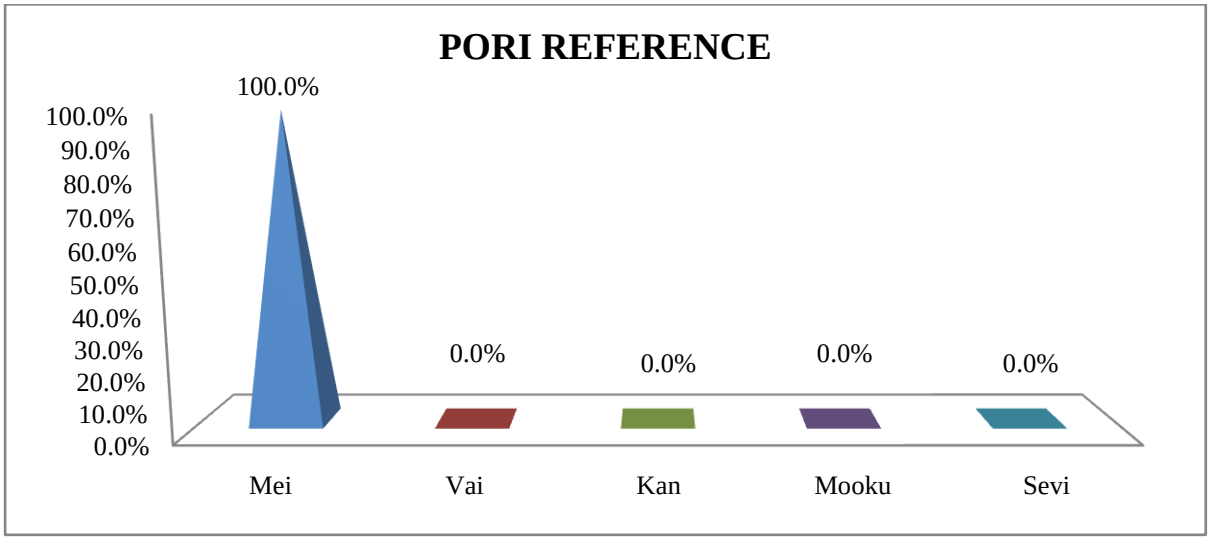


Inference

In 3.3% of the patients avalambagam (indigestion) was found to be affected.

TABLE 13: Distribution of children with Bala Karappan according to Pori / pulangal:

SL.NO	PORI	NO OF CASES	PERCENTAGE
1	Mei	30	100.0%
2	Vai	0	0.0%
3	Kan	0	0.0%
4	Mooku	0	0.0%
5	Sevi	0	0.0%

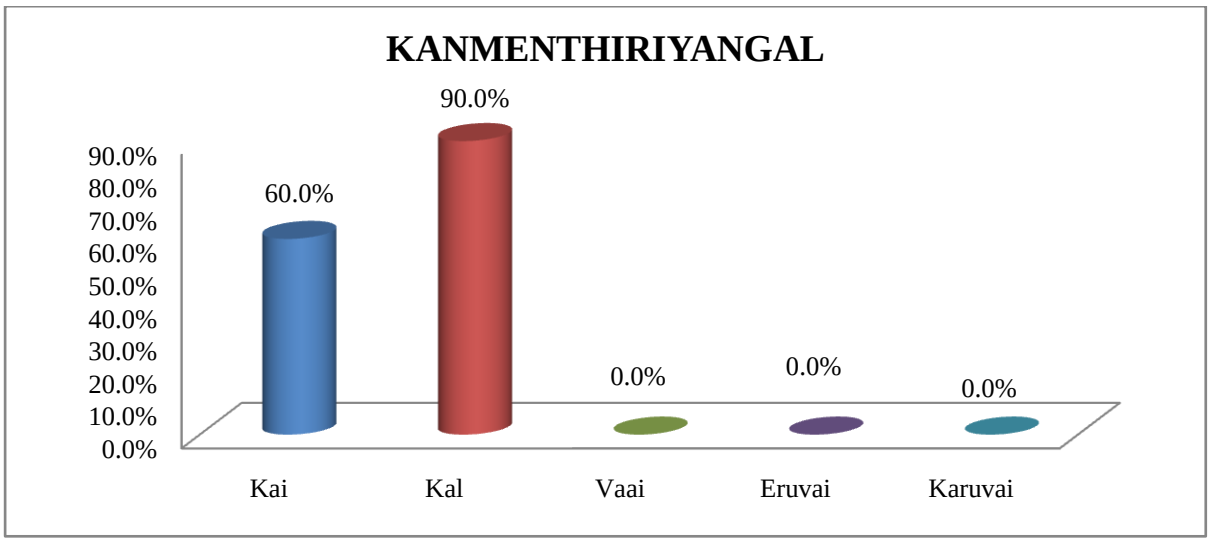


Inference

Mei was affected in 30 patients (100%) of cases.

TABLE 14: Distribution of children with Bala Karappan according to Kanmenthiriyangal:

SL.NO	KANMENTHIRIYANGAL	NO OF CASES	PERCENTAGE
1	Kai	18	60.0%
2	Kal	27	90.0%
3	Vaai	0	0.0%
4	Eruvai	0	0.0%
5	Karuvai	0	0.0%

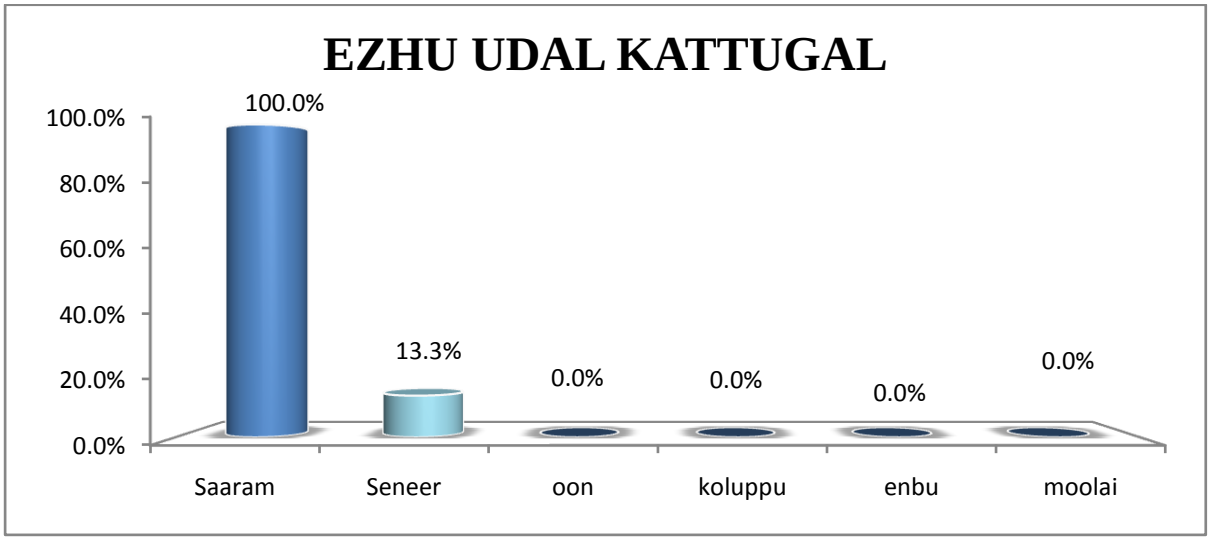


Inference

Among 30 patients, Kai was affected in 60.0 %, Kaal was affected in 90 %.

TABLE 15: Distribution of children with Bala Karappan according to Ezhu udal katugal:

SL.NO	EZHU UDAL KATTUGAL	NO OF CASES	PERCENTAGE
1	Saaram	30	100.0%
2	Seneer	4	13.3%
3	Oon	0	0.0%
4	Koluppu	0	0.0%
5	Enbu	0	0.0%
6	Moolai	0	0.0%
7	Sukkilam/suronitham	0	0.0%

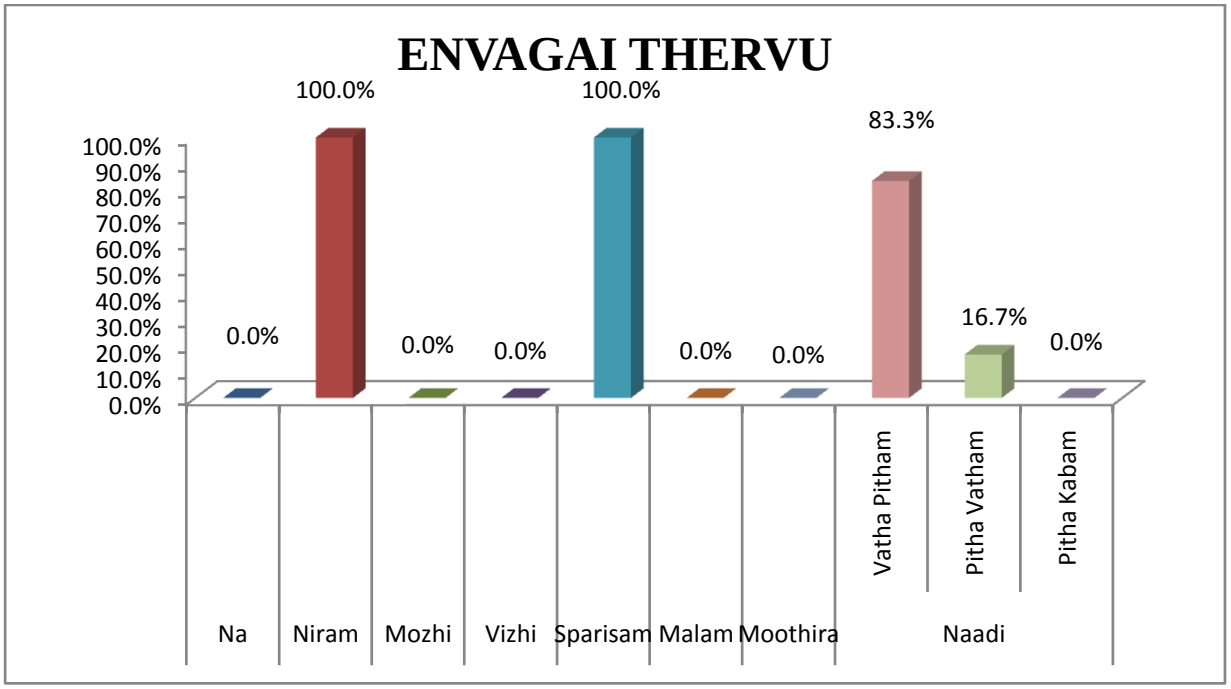


Inference:

In Bala karappan Saram was affected 100 %, Senneer was affected 13.3%.

TABLE 16: Distribution of children with Bala Karappan according to Envagai thervu:

SL.NO	EN VAGAI THERVUGAL		NO OF CASES	PERCENTAGE
1	Na		0	0.0%
2	Niram		30	100.0%
3	Mozhi		0	0.0%
4	Vizhi		0	0.0%
5	Sparisam		30	100.0%
6	Malam		0	0.0%
7	Moothiram		0	0.0%
8	Naadi	VathaPitham	25	83.3%
		PithaVatham	5	16.7%
		PithaKabam	0	0.0%



Inference:

In bala karappan Niram affected 100%, Sparisam affected 100%,

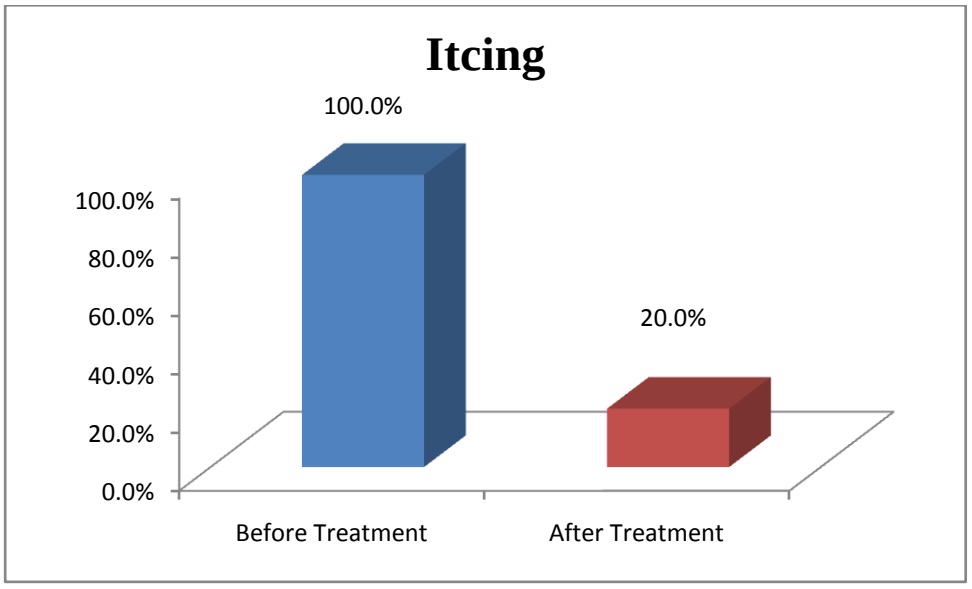
And Nadi, vatha pitham affected 83.3%, pitha vatham 16.7% affected.

Table 17: Results of Clinical Symptoms

SL. NO	SYMTOMS	NO OF CASES	BEFORE TREATMENT		AFTER TREATMENT		IMPROVEMENT PERCENTAGE
			NO OF CASES	PERCENTAGE	NO OF CASES	PERCENTAGE	
1	Itcing	30	30	100.0%	6	20.0%	80.0%
2	Presence of blislers, papules, pustules, vesicles	30	30	100.0%	1	3.3%	96.7%
3	Pain in lower extrimitis	30	14	46.7%	0	0.0%	46.7%
4	Ulcer formation with oozing	30	25	83.3%	6	20.0%	63.3%
5	Sleep disturbance	30	30	100.0%	2	6.7%	93.3%
6	Hyperpigmentation	30	30	100.0%	21	70.0%	30.0%

CLINICAL FEATURES-BEFORE TREATMENT AND AFTER TREATMENT

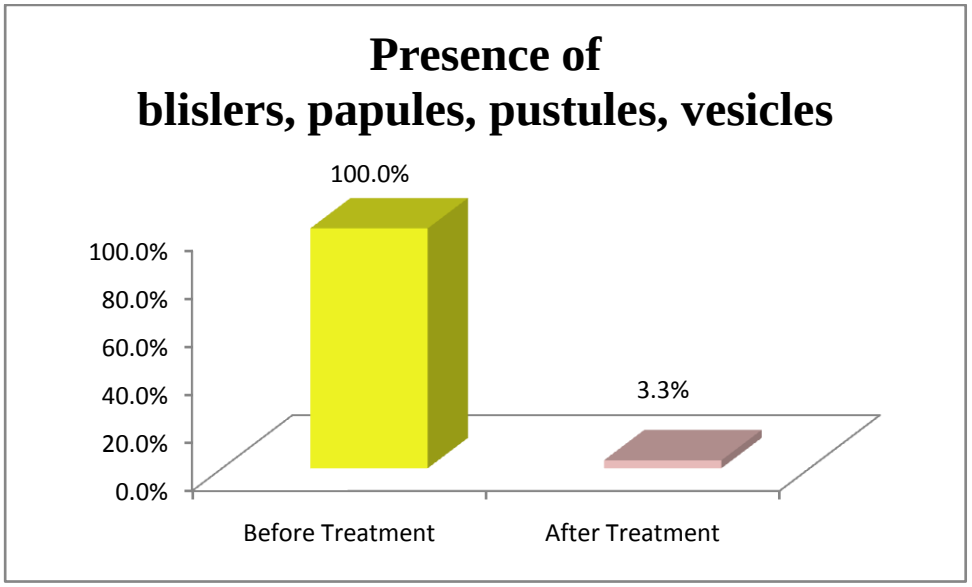
1. **Itching – before And after treatment:**



Inference

Among 30 cases (100%) only 6 cases (20.0%) reporting with itching symptoms.

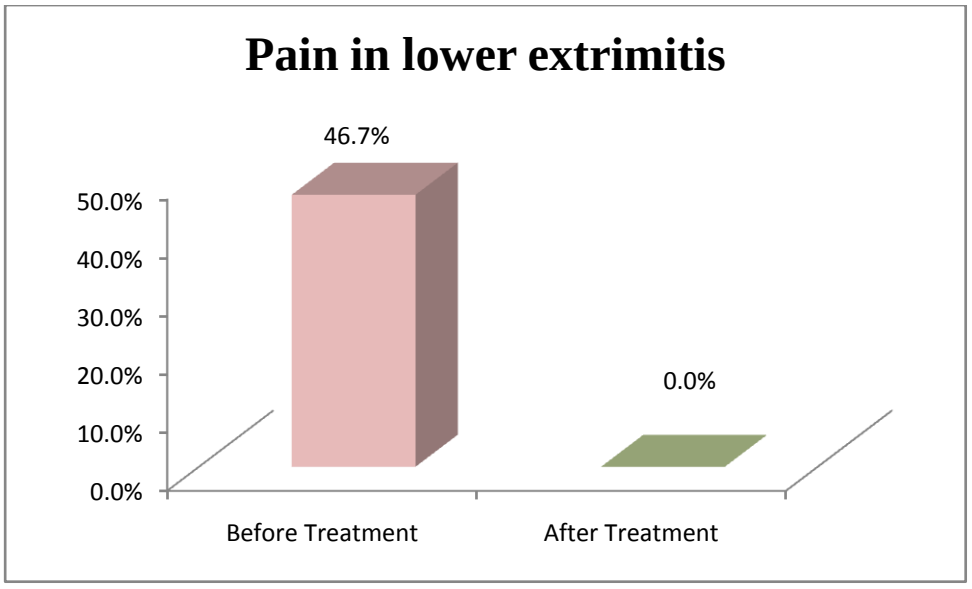
2. **Presence of Blisters, Papules, Pustules, Vesicles - before And after treatment**



Inference

Among 30 cases (100%) only 1 cases (3.3%) reporting with presence of Blisters, Papules.

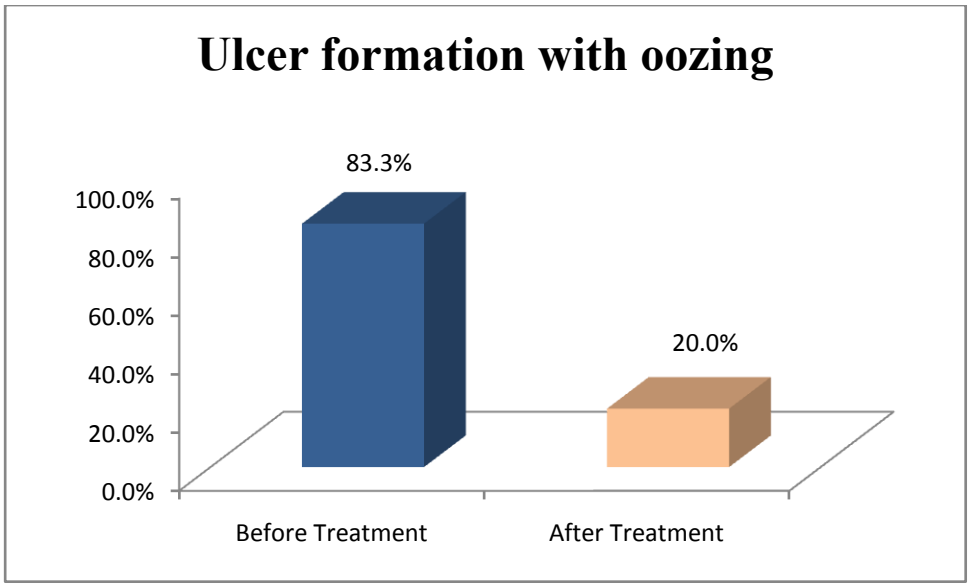
3. **Pain in lower extremities - before And after treatment**



Inference

Among 30 cases (100%) No cases reporting with symptom of pain in lower extremities.

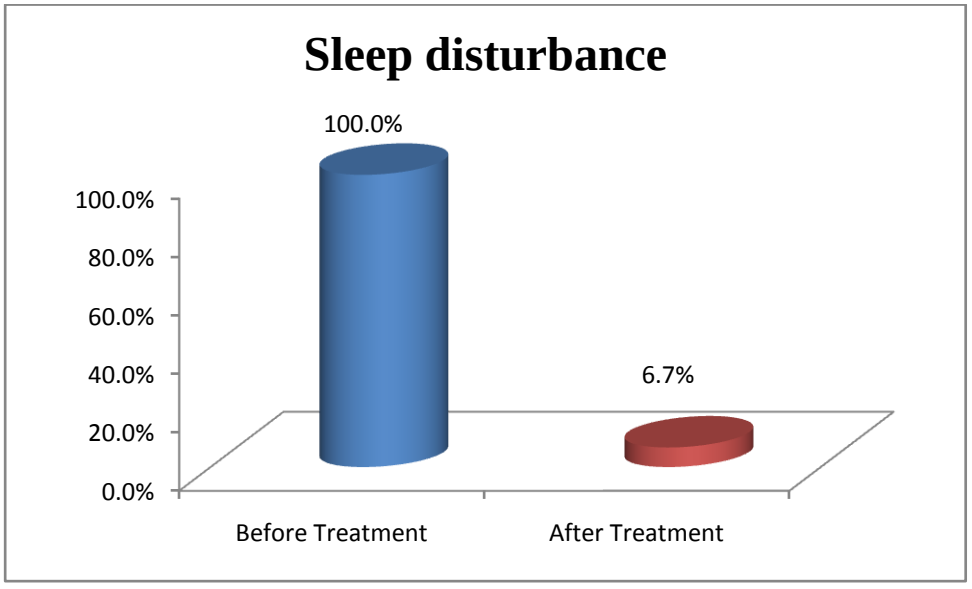
4. **Ulcer formation with oozing - before and after treatment**



Inference

Among 30 cases (100%) Only 6 cases (20.0%) reporting with ulcer formation with oozing.

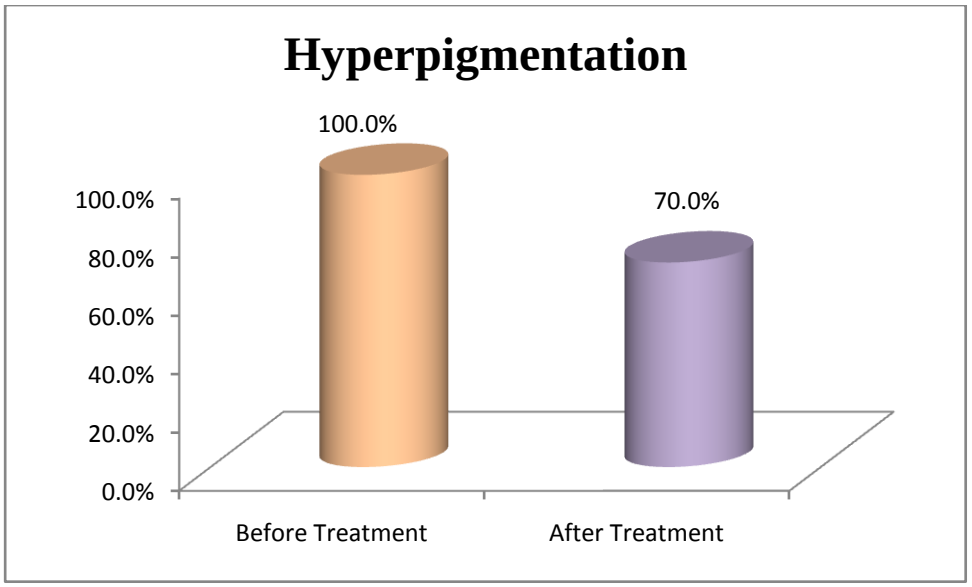
5. Sleep disturbance - Before And After treatment



Inference

Among 30 cases (100%) Only 2 cases (6.7%) reporting with sleep disturbance.

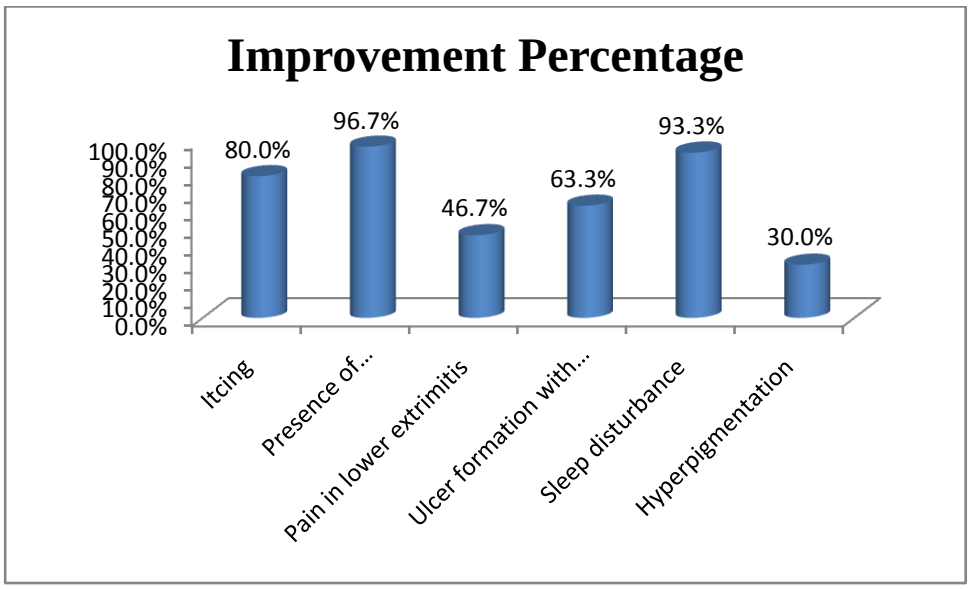
6. Hyperpigmentation - Before And After treatment



Inference

Among 30 cases (100%) only 21 cases (70.0%) reporting with hyperpigmentation.

CLINICAL IMPROVEMENT IN PERCENTAGE



Inference

In this study among 30 children's, 80.0% Itching, 96.7% Papules, Vesicles, Blisters, Pustules, 46.7% had Pain in lower extremities, 63.3% had Ulcer formation with oozing, 93.3% sleep disturbances, 30.0% hyper pigmentation were cured.

18) RESULTS OF SCORADCALCULATION

S.No	Op No	Name	Age /Sex	Before treatment	After treatment	Difference	Percentage
1.	J76040	Baby.S. Keerthi	11 / FCH	50.9	5.9	45	88.40
2.	J80924	Baby. Vishalisharmitha	9 / FCH	55.5	1.4	54.1	97.47
3.	J69345	Mast. E. Sathish Kumar	10 / MCH	53.9	5.5	48.4	89.79
4.	J81265	Mast. S. P. Tamil Selvan	6 / MCH	49.9	0.8	49.1	98.39
5.	D65176	Baby. N. Varshini	7 / FCH	49.1	7.4	41.7	84.92
6.	I49712	Mast. N. Naveen Kumar	10 / MCH	56.6	5.7	50.9	89.92
7.	J13039	Mast. G. HariPrabu	9 / MCH	41.6	4.1	37.5	90.14
8.	J53646	Mast. G. Vijay	10 / MCH	74.5	9.6	64.9	87.11
9.	J81699	Mast. P. Thirukumaran	11 / MCH	55.1	4.3	50.8	92.19
10.	J50305	Baby. N. Vishnupriya	11 / FCH	50.8	1.2	49.6	90.63
11.	J83239	Baby. S. Bakkiyashree	12 / FCH	57.7	5.7	52	90.12
12.	H89794	Baby. M. Panimalar	9 / FCH	46.1	5.5	40.6	88.06
13.	J84052	Baby. M. Sujitha	10 / FCH	50.8	4.5	46.3	91.14
14.	J29851	Baby. S. Saiharini	6 / FCH	55.3	11.5	43.8	79.20
15.	J85012	Baby. A. Preethi	9 / FCH	39.6	4.1	35.5	89.64
16.	J75070	Mast. T. Yokesh	8 / MCH	38	4.3	33.7	88.68
17.	H43096	Baby. S. Monika	7 / FCH	64.5	10	54.5	84.49
18.	J84247	Mast. T. Varun	9 / MCH	35.1	0.2	34.9	99.43
19.	J82049	Baby. T. Meera	12 / FCH	34.6	0.2	34.4	99.42

20.	G27954	Mast. S. Logeshwaran	11 / MCH	55.6	7.6	48	86.33
21.	I71990	Mast. S. LigneshKarthick	8 / MCH	38.6	4.5	34.1	88.34
22.	J39198	Mast. B. Monish	7 / MCH	46.4	4.3	42.1	90.73
23.	J88484	Baby. I. K. Durgashree	6 / FCH	40.9	4.1	36.8	89.97
24.	J84638	Baby. R. Elakkiya	12 / FCH	43.5	4.1	39.4	90.57
25.	I83253	Mast. P. Vishnu Vardhan	7 / MCH	64.2	10.8	53.4	83.17
26.	J86891	Mast. M. Depak	12 / MCH	41.9	0	41.9	100
27.	J90700	Baby. M. Nisha	10 / MCH	39.8	1	38.8	97.48
28.	I17135	Mast. M. Nithish Kumar	8 / MCH	54.9	7	47.9	87.24
29.	J42189	Baby. S. Pravishika	12 / FCH	55.5	0	55.0	99.09
30.	J86724	Baby. S. Sri Ishwarya	7 / FCH	67.9	11	56.9	83.79

19) HAEMATOLOGICALPROFILE:

Haematological values were plotted before and after treatment

S.No	Op No	Hbgms%		TC cells/cu.mm		RBC 10^6 cells/cu.mm		ESR ½ hr/1hr		AEC	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	J76040	11.5	11.5	8600	9200	4	4.2	2/4	2/4	346	252
2	J80924	12.4	12.4	5000	5500	4.3	4.3	2/4	2/4	165	152
3	J69345	12.4	12.4	10000	11200	4.5	4.6	4/10	2/4	286	352
4	J81265	12.8	12.8	8800	9600	5.4	5.5	4/10	2/8	502	364
5	D65176	13.1	13.1	11200	11400	5.2	5.1	2/4	2/8	176	256
6	I49712	11.8	11.8	8900	9100	5	4.8	2/4	2/8	348	278
7	J13039	11.6	11.8	18100	10100	4.5	4.5	4/10	2/6	682	381
8	J53646	12.9	12.9	7100	9100	4.5	4.4	2/4	2/4	251	202
9	J81699	11.9	12.1	5500	7200	4.3	4.4	4/10	2/8	165	252
10	J50305	12.2	12.3	7100	9100	4.3	4.6	4/12	12/8	193	278
11	J83239	13.7	13.8	7100	8900	5.2	5.2	2/4	2/8	369	252
12	H89794	11.5	11.6	9200	6100	4.2	4.1	4/12	2/4	489	208
13	J84052	12.4	12.4	9500	11100	4.3	4.2	2/6	2/8	546	442
14	J29851	12.7	12.7	9200	8900	4.6	4.8	2/4	2/4	411	366
15	J85012	11.5	11.6	5900	7200	4.2	4.4	2/10	2/4	212	308
16	J75070	11	11.2	8200	9100	4.3	4.4	4/10	2/10	223	312
17	H43096	13.4	13.2	11400	10900	4.5	4.4	4/16	2/10	282	151
18	J84247	11.9	11.9	6700	5800	4.2	4.3	4/12	2/10	362	312
19	J82049	12.6	12.6	8100	6300	4.2	4.2	4/10	2/8	556	308
20	G27954	12.1	12	11500	12300	4.5	4.2	2/10	2/6	428	367
21	I71990	11.6	12	8500	7200	4.3	4.5	2/6	2/4	109	145
22	J39198	12.7	14.2	7300	5400	5	4.9	2/4	10/14	167	239
23	J88484	12.5	14.1	7500	5200	4.8	4.7	2/4	2/6	142	168
24	J84638	12.3	12.4	6200	6500	4.3	4.3	4/16	6/8	191	258
25	I83253	12.4	16.1	5400	9000	4.3	5.4	2/8	2/4	210	161
26	J86891	13.6	14.2	9100	6200	5.1	5	2/4	12/8	252	252
27	J90700	13.2	12,4	6400	6800	4.9	4.5	2/6	2/4	105	254
28	I17135	12.3	12.7	5400	11000	4.2	4.3	4/10	4/10	153	220
29	J42189	12.3	12.7	11300	11400	4.4	4.1	10/24	10/20	502	380
30	J86724	13	13.6	9900	11900	5.6	6	10/26	18/38	454	366

Differential Count Profile of WBC

S.no	Op.no	Polymorphs		Lymphocytes		Monocytes		Eosiniphils		Basophils	
		BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	J76040	52	54	40	48	7	3	6	2	-	-
2	J80924	42	42	52	52	7	5	6	3	-	-
3	J69345	55	56	39	44	6	2	4	1	-	-
4	J81265	32	44	60	58	8	6	5	2	-	-
5	D65176	64	62	32	48	4	4	6	3	-	-
6	I49712	38	42	56	54	6	4	4	0	-	-
7	J13039	62	56	30	44	8	6	7	0	-	-
8	J53646	53	52	42	48	5	8	0	0	-	-
9	J81699	46	52	48	50	6	4	6	2	-	-
10	J50305	38	43	56	52	6	4	0	0	-	-
11	J83239	51	56	39	44	10	6	0	0	-	-
12	H89794	50	49	43	36	2	2	7	0	-	-
13	J84052	50	52	48	52	8	6	0	0	-	-
14	J29851	45	48	48	52	7	6	2	0	-	-
15	J85012	45	48	48	52	7	6	4	0	-	-
16	J75070	48	52	57	56	5	2	0	0	-	-
17	H43096	59	54	36	42	5	2	3	2	-	-
18	J84247	38	52	56	52	2	2	4	4	-	-
19	J82049	53	49	38	46	22	7	1	0	-	-
20	G27954	43	47	51	53	22	4	4	0	-	-
21	I71990	62	65	34	28	4	1	0	0	-	-
22	J39198	58	53	37	39	5	1	0	0	-	-
23	J88484	44	63	52	31	4	6	0	0	-	-
24	J84638	55	51	42	42	7	-	3	0	-	-
25	I83253	40	65	57	30	9	5	1	0	-	-
26	J86891	54	56	40	40	6	5	3	2	-	-
27	J90700	36	56	59	40	5	5	0	0	-	-
28	I17135	57	75	38	20	5	5	0	0	-	-
29	J42189	53	60	37	32	10	8	6	1	-	-
30	J86724	58	54	34	39	8	7	6	2	-	-

Distribution of Children's with Bala Karappan according treatment results obtained:

S.No	SCORAD %	No. of Cases	Percentage
1	SCORAD 0%	0	0
2	SCORAD>25%	0	0
3	SCORAD 25% -50%	0	0
4	SCORAD 50% - 75%	0	0
5	SCORAD 75% - 100%	30	100%

Inference:

Out of the 30 cases, the signs and symptoms were reduced markedly in 30 cases were reduced the clinical symptoms by SCORAD value is 75% -100%, No cases had SCORAD 0%, >25, 25% - 50%, 50% -75%. These results were based on the clinical improvements observed by author.

For clinical studies

All collected data were entered into MS Excel software using different columns as variables and rows as patients. STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. Bar diagram, Pie charts were used to describe the value of different variables for pictorial representation. The quantity variables were expressed as Mean and standard deviation and qualitative data as percentage. A probability value of less than 0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

Statistical Analysis

A. Summary of statistics at SCORAD scale

Treatment	No of Cases	Mean ± Std. Dev	Minimum	Maximum
Before Treatment	30	50.29±9.92	34.6	74.5
After Treatment	30	4.87±3.41	0	11.5

Observation:

The mean + S.D before and after treatment on SCORAD reveals that there is reduction after treatment i.e 90% reduction.

B. Statistical significance of treatment

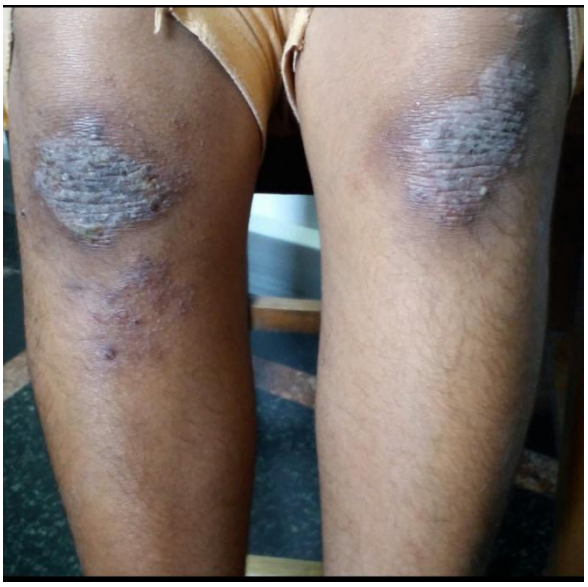
SCORAD	Mean ± Std. Dev	't' value	'P' value
Before Treatment	50.2933±9.9232	31.0072	P<0.001
After Treatment	4.8766±3.4176		

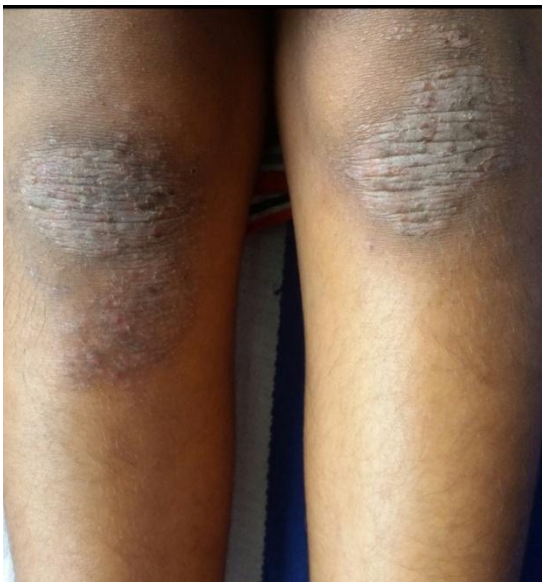
Observation:

There is statistically highly significant reduction of eczema from–SCORAD scoring after the treatment.

1. **J 83239**

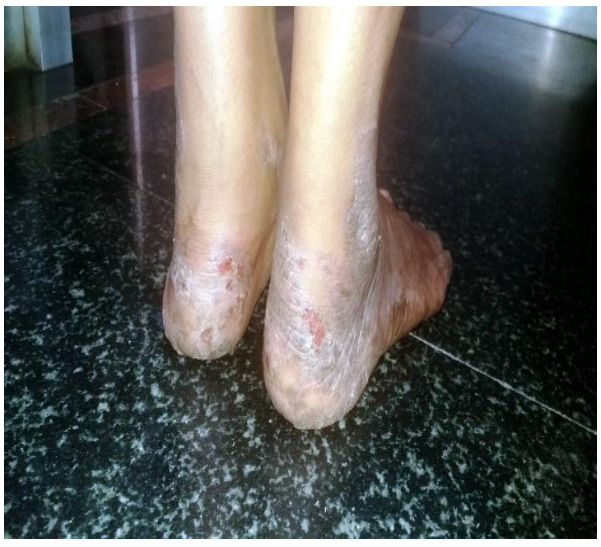
BEFORE **AFTER**





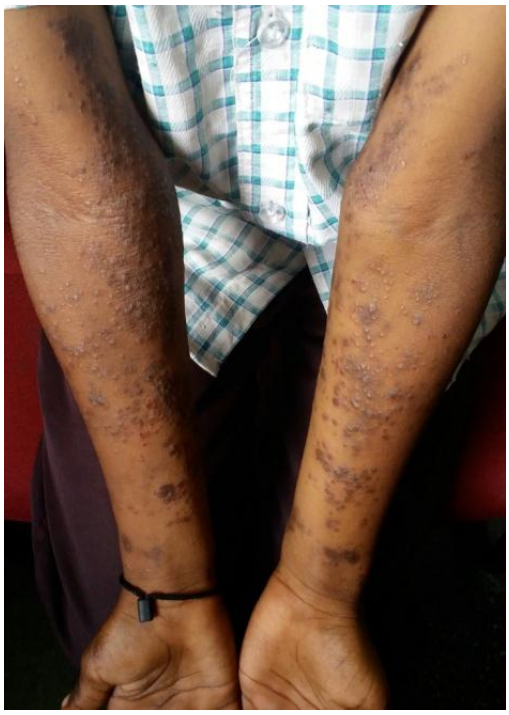
2. **J 42189**

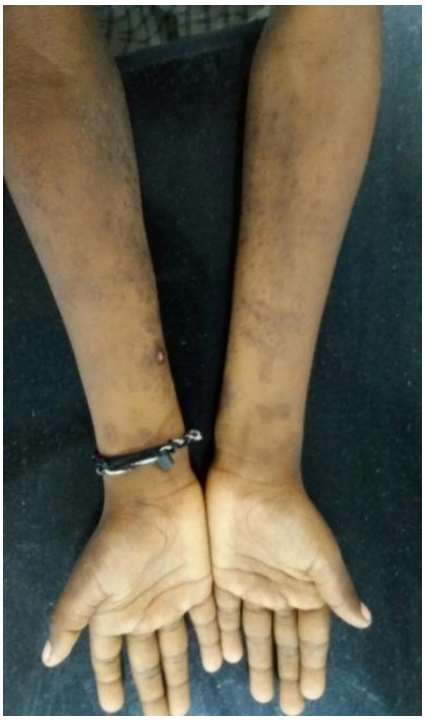
BEFORE **AFTER**



3. J 53646

BEFORE **AFTER**





7. DISCUSSION

Bala Karappan is a skin disease characterized by blisters, papules, vesicles, pustules, itching, pain present in lower extremities, ulcer formation with oozing, sleep disturbance, hyperpigmentation. The clinical signs and symptoms of Bala karappan is nearly correlated with Atopic Dermatitis in modern science. In this present study, 30 cases were treated in the outpatient department of Kuzhanthai Maruthuvam, according to clinical features mentioned in textbook of Bala vagadam. The diagnosis was made based on clinical symptoms. The chosen drug ***Karappan Nei*** **(External and External)** indicated for Bala karappan has been given to all the participants with the dosage of 5-10 ml/ bd. This clinical study was conducted after the proposal was screened by the Screening committee of National Institute of Siddha. The Clinical study has been approved by IEC of NIS, approval No: NIS/IEC/2016/11-18/14.10.2016. The trial registered in Clinical trial Registry of India (CTRI) with Reg.No.CTRI/2017/05/008722. The Authentication of ingredients of the trial drug was obtained from Medicinal Botanist, National Institute of Siddha, Chennai.

The trial drugs were prepared by the author in the Gunapadam practical laboratory of National Institute of Siddha with supervision of lab in charge and the Guide. The trial drug was prepared as per the standard operating procedure as mentioned in the protocol.

There is statistically highly significant reduction of eczema from–SCORAD scoring after the treatment.

The Physicochemical analysis and phytochemical analysis of the trial drug Karappan Nei was done at Noble Research Solutions, Chennai. Since the form of the drug was like ghee the parameters such as Determination of Weight/ml, Refractive Index, Ph, Viscosity value, Iodine value, Saponification value, Acid value, Peroxide value was done using Quality control methods as per the AYUSH protocol for medicinal plants materials.

The Bio chemical analysis revealed the presence of Iron.

In clinical studies, the patients were recruited for the trial based on inclusion and exclusion criteria and after getting the informed consent from the patient. 30 patients were included in this study. All 30 patients were treated in Kuzhandhai Maruthuvam OPD of Ayothidoss Pandithar Hospital of National Institute of Siddha. Separate

proforma was maintained for every patient. Progress chart was also maintained by using SCORAD index to monitor the clinical signs and symptoms of the disease. The treatment was aimed at normalizing the deranged thodams and providing relief from symptoms. Before treatment, the patients were advised to adapt lifestyle modifications such as oil bath weekly once and to follow good dietary regimen.

The patients were treated with trial drug Karappan Nei for 48 days. Patients were instructed to take the medicines regularly and advised to follow pathiyam and to avoid exposure to allergic substances if any. Patients were asked to visit the hospital on 8^{th} day and 16^{th} day, 32^{th} day and 48^{th} day. After completion of the study; the patients were advised to visit the OPD for one month for further follow-up. The results observed during the study period were discussed as below.

Age

Among the 30 patients selected for this study, maximum numbers of patients 63.3% were in the age group of 9 to 12 years, 36.7% were in the age group of 6 to 8 years.

Sex

By the results of the clinical study, Among the 30 children included in this study 50% were male children and 50% female children.

Religion

High incidence of karappan was noted 93.3% in Hindus, And 6.7 % in Christian people. No cases were reported from Muslim community in this study period.

Socio-economic status

Out of 30 patients, 20.0% of the patients were from Upper income group, 36.7% patients were from Upper middle income group, 26.7% patients were from Upper Lower and the remaining 16.7% patients were under Lower Middle income group.

Diet

In this study all the cases involved in this study were non-vegetarians 100%.

Allergic history

Out of 30 patients, 30% of the patients showed past H/O similar complaints, 20% had Bronchial Asthma and 50% had history like Mosquito bite, Food Allergy, Dust Allergy. No patients having history of hospitalization.

Family history

Among 30 patients, 90%of the patients showed no family history related with this disease 10% showed positive family history.

Duration of illness

Among the 30 patients the maximum number of patients (53.3%) had the duration of illness between 1 to 3 years, (23.3%) of them had between 3 to 11 months, (13.3%) were below 4 to 7 years, (6.7%) were between < 2 months and (3.3%) were 8-10 years.

Site of involvement

Among 30 patients 70.0% had the lesion in both upper and lower limbs, 23.3% had lesion only in the lower limbs, and 6.7% had lesion only in upper limbs and lower limb, trunk. gluteal region.

Nilam Habitat

Among the 30 patients 77% of the patients were from Neithal (Coastal Area), 23% are from Marutham (Fertile Land), 0 % were reported from Kurinji (Hill area), Paalai (Desert area) and Mullai (Forest Land).

Paruvakaalam

Among the 30 patients admitted for this study, the highest number of patients (60.0%) reported in Koothir Kaalam and 23.3% were reported in Muthuvenil Kaalam, 16.7% were reported in pinpani kalam.

Mukkutram

Vali (Vatham)

Due to the derangement of different vatha the following symptoms occur. Samanan and Uthanan (Papules , Pustules, Vesicles) were found to be affected in all the 30 patients and devathathan (sleep disturbances) was affected in 23.3% of patients, Kirukaran was affected in 16.7% of patients (Cold, Cough).

Azhal (Pitham)

Prasakam (skin) was affected in all the cases 100% and Ranjagam (anaemia) was affected in 13.3% of patients.

Iyyam (Kabam)

In 3.3% of the patients avalambagam (indigestion) was found to be affected.

Pori

Mei was affected in 30 patients (100%) of cases.

Kanmenthiriyam

Among 30 patients Kai, was affected in 60.0 %, Kaal was affected in 90 %.

Ezhu UdalKattukal

In Bala karappan Saram was affected 100 %, Senneer was affected 13.3%.

Envagai Thervukal

In bala karappan Niram affected 100%, Sparisam affected 100%.

And the Nadi, vathapitham observed in 83.3%, pithavatham observed in 16.7%.

Lab Investigation:

Laboratory investigation of blood was done for all 30 cases in before and after treatment.

Clinical Features of Bala Karappan

The clinical feature was recorded in this study among 30 children's. Among them 100% of patients had Itching, 100% had Papules, Blisters, Pustules, Vesicles, 46.7% had Pain in lower extremities, 83.3% had Ulcer formation with oozing, 100% had sleep disturbances, 100% had Hyperpigmentation before treatment . The patients showed a good prognosis after treatment with reduced percentage of clinical features as said above (20.0%), (3.3%), (0%), (20.0%), (6.7%) and (70.0%) respectively. Out of the 30 cases, the signs and symptoms were reduced markedly in 30 cases by SCORAD value of 75% -100%,No cases had SCORAD 0%, >25, 25% - 50%,50% - 75%. These results were based on the clinical improvements observed by SCORAD scoring.

The trial medicine chosen for treatment of *Bala Karappan* is *Karappan Nei.* The ingredients of this drug have the properties (Anti inflammatory, Anti Oxidant, Wound Healing) of controlling the symptoms *Bala Karappan*. The pharmacological studies already reported on the individual drugs also favour of its effect in this disease of inflammatory condition.

The mean and standard deviation of clinical symptoms of SCORAD index value for all the 30 patients before and after treatment is 50.293 ±9.923 and 4.876 ±3.417 respectively. The mean + S.D before and after treatment on SCORAD reveals that there is reduction of symptoms in after treatment i.e 90% reduction. It is statistically highly significant in reduction of eczema.

The results of the study suggest that the treatment with **KARAPPAN NEI (Internal And External)** has given significant improvement in patients of ***Bala Karappan***.

7. SUMMARY

The disease Bala Karappan was taken for the clinical study with the trial drug Karappan Nei (Internal And External Medicine) after scrutinizing by the Screening committee of National Institute of Siddha.

Clinical studies were carried out after obtaining proper approval from IEC of National Institute of Siddha and the trial was registered in Clinical trial registry of India. The medicines were prepared after obtaining proper authentication of ingredients from Medicinal Botanist of National Institute of Siddha. Acute toxicity study, Physiochemical analysis, Phytochemical analysis and Pharmacological activity (anti – inflammatory) for the trial medicine was performed.

All the 30 patients were treated in OPD of Kuzhandhai Maruthuvam department at Ayothidoss Pandithar Hospital of National Institute of Siddha. The patients with Bala Karappan were recruited for this study based on Inclusion and Exclusion criteria and a detailed clinical study was done. Separate proforma was maintained for each patient along with SCORAD index chart on 0, 16^{th}, 32^{th}, 48^{th} day to monitor the prognosis.

From the clinical study, it was inferred that Bala Karappan was affecting in the school going children (6-12 years) and the incidence was chronic in maximum number of patients. The trial drug was given two times in a day for 48 days. All the patients were advised to follow the strict diet regimen during the treatment.

The Bio chemical analysis of drug showed presence of Carbonate, Iron, Starch. The physicochemical analysis showed that the trial drug was in appropriate in consistency for this study. The phytochemical analysis of drug showed presence of Alkaloids, Flavonoids, Glycosides, Steroids, Triterpenoids, Coumarins, Phenol, Tannins. The patients have not complained of any adverse effects or difficulties during the course of treatment. Thus the drug compliance was good with the patients of Bala Karappan. The clinical efficacy of the trial drugs in children was analyzed statistically with all the symptoms mentioned in the assessment criteria and also through SCROAD index value.

The result were observed as follows,

Among 30 children, the symptoms of Bala karappan like 80.0% Itching, 96.7% Papules, Vesicles, Blisters, Pustules, 46.7% Pain in lower extremities, 63.3% Ulcer formation with oozing, 93.3% sleep disturbances, 30.0% hyper pigmentation were improved clinically.

The signs and symptoms were reduced markedly in 30 cases by SCORAD value range of 75% -100%, and No cases have been identified the by SCORAD value range of 0%, <25% and 25% -50%, 50%-75%.

The mean and standard deviation of clinical symptoms of SCORAD index value for all the 30 patients before and after treatment is 50.293 ±9.923 and 4.876 ±3.417 respectively. The mean + S.D before and after treatment on SCORAD reveals that there is reduction of symptoms in after treatment i.e 90% reduction. It is statistically highly significant in reduction of eczema.

The observation made during the study both clinically and statistically explores that the trail drug Karappan Nei was effective in the management of Bala Karappan in children.

8. CONCLUSION

All the 30 patients clinically diagnosed as Bala Karappan were treated with Karappan Nei with the of dose for 5-10 ml Internally and also used as External medicine for two times a day for 48 days.

The efficacy of the trial drug for the management of Bala Karappan was significantly effective by means of SCORAD value. The reduction of clinical symptoms was highly significant ($p < 0.001$). The reduction in the clinical symptoms was 90% after treatment.

Pharmacological activity of Karappan Nei was showed that, the drug was having potent anti-inflammatory activity by In-vitro studies.

Hence the author strongly recommends that this trial drug Karappan Nei may be given to children without any hesitations for the management of Bala Karappan. The ingredients of the trial drug also cost effective. Further research works may be carried out in the large group of patients to explore this novel drug more scientifically.

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NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Preclinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine) in the treatment of BALA KARAPPAN(Eczema) in children.

Form I- SCREENING AND SELECTION FORM

1. S.I. No: 2. OP/ IP No: 3. Name:

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

7. Informant: 8. Reliability:

INCLUSION CRETERIA	YES	NO
Age: between 6-12 years	☐	☐
Itching	☐	☐
Presence of Blisters/Papules/ Vesicles/ Pustules	☐	☐
Pain in lower extremities	☐	☐
	☐	☐
Ulcer formation with oozing		
Sleep disturbances	☐	☐
Hyper pigmentation	☐	☐
Patients willing to give biological samples	☐	☐
Willing to attend OPD once in 7 days	☐	☐
EXCLUSION CRITERIA:		
Scabies	☐	☐
Photo dermatitis	☐	☐
Jaundice	☐	☐
Patients with any other serious illness	☐	☐
Admitted to the trial	Yes ☐	No ☐
If yes	OP No:	IP No:

Place: Signature of Investigator

Date: Signature of Guide

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600047

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Pre Clinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine) a Siddha drug for BALA KARAPPAN (Eczema) in children.

II CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms readily understood by the parent/guardian

Signature _____

Name _____

Date _____

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 body functions.

I am aware of my right 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 of **'KARAPPAN NEI'** for the treatment of **' BALA KARAPPAN'**.

Date : Signature _____

Place: Name _____

Signature of witness _____

Name _____

தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாச பண்டிதர் மருத்துவமனை சென்னை-47
குழந்தை மருத்துவத்துறை

கரப்பான் நெய் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு

ஒப்புதல் படிவம் II-A

ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த மருத்துவ ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளியின் பெற்றோருக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதி அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறைப் பற்றியும், இந்த மருத்துவத்தை தொடர்ந்து எனது குழந்தையின் உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனை பாதுகாக்க பயன்படும் மருத்துவ ஆய்வுக்கூடப் பரிசோதனைகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது. நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்போது வேண்டுமானாலும் என் குழந்தையை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு **பால**கரப்பான் நோய்க்கான **கரப்பான் நெய் (உள் மருந்து மற்றும் வெளி மருந்து) சித்த மருந்திற்கான** பரிகரிப்புத் திறனை கண்டறியும் மருத்துவ ஆய்வுக்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெற்றோர் பெயர்:

கையொப்பம்:

சாட்சிக்காரர் பெயர்:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600047

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Preclinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine) in the treatment of BALA KARAPPAN (Eczema) in children.

FORM III CASE REPORT FORM

Sl.No :	OP/IP No.	Visit Date : (__/__/____)
Name :		
Age :		
Gender Male ☐ Female ☐		
Father/ Mother /Guardian Name :		
Fathers Occupation :		
Fathers Monthly Income :		
Religion :		
Socioeconomic Status :		
Informant :		

Postal Address & Contact No:

COMPLAINTS AND DURATION:

H/O PRESENT ILLNESS:

Past History /Symptoms/Signs	**Yes**	**No**	**If, Yes Details**
Any Similar Complains	☐	☐	_____
Bronchial Asthma	☐	☐	_____
Dust Allergy	☐	☐	_____
Hospitalization	☐	☐	_____
Any other	☐	☐	_____

Family History

Any Hereditary/ Familial Disease ☐ Yes ☐ No

If Yes, Details--------

Immunisation History

Proper Immunization give Yes ☐ No ☐

Food habits:

1. Veg ☐ 2. Non-Veg ☐

General assessment

	YES	**NO**
1. Picca	☐	☐
2. Nail biting	☐	☐
3. Bowel movements	☐	☐

General Examination:

1. Pallor	YES ☐	NO ☐
2. Jaundice	YES ☐	NO ☐
3. Cyanosis	YES ☐	NO ☐
4. Clubbing	YES ☐	NO ☐
5. Pedal oedema	YES ☐	NO ☐
6. Lymph adenopathy	YES ☐	NO ☐

Vital signs:-

1. Pulse rate / mint
2. Heart rate / mint
3. Respiratory Rate / mint
4. Temperature-F

Anthropometry:-

Height

Weight

SYSTEMIC EXAMINATION:

EXAMINATION OF THE SKIN:

1. Affected site:

2. Colour: Normal ☐ Reddish ☐ Black ☐ Greyish ☐

3. Itching: No ☐ Mild ☐ Moderate ☐ Severe ☐

4. Scaling: No ☐ Mild ☐ Moderate ☐ Severe ☐

	YES	NO
5. Oozing:	☐	☐
6. Ulcération :	☐	☐
7. Macule :	☐	☐
8. Papule:	☐	☐
9. Pustule:	☐	☐
10. Blister:	☐	☐
11. Vésicles :	☐	☐
12. Sleep disturbances	☐	☐
13. Erythema:	☐	☐

14. Pigmentation: Normal ☐ Hypo ☐ Hyper ☐

CLINICAL ASSESSMENT:

S.NO	CLINICAL SYMPTOMS	0 th DAY	16 th DAY	32 th DAY	48 th DAY
1.	Itching				
2.	Presence of Blisters/Papules/ Vesicles/Pustules				
3.	Pain in lower extremities				
4.	Ulcer formation with oozing				
5.	Sleep disturbances				
6.	Hyper pigmentation				
7.	**SCORAD SCALE**				

EXAMINATION OF OTHER SYSTEMS:

	Normal	Affected
Cardio vascular system:	☐	☐
Gastro intestinal system:	☐	☐
Musculo skeletal system:	☐	☐
Central nervous system:	☐	☐
Endocrine system:	☐	☐
Respiratory systems:	☐	☐

Nilam:-

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Paalai ☐

Kaala Iyalbu:-

Kaarkalam ☐	Koothirkaalam ☐	Munpanikaalam ☐
Pinpanikaalam ☐	Illavenirkaalam ☐	Muthuvenirkaalam ☐

Yaakai

Vatham ☐	Vatha Pitham ☐	Vatha Kabam ☐
Pitham ☐	Pitha vatham ☐	Pitha Kabam ☐
Kabam ☐	Kaba Vatham ☐	Kaba Pitham ☐

Gunam

Sathuvam ☐ Rasatham ☐ Thamasam ☐

Pori / Pulangal

	Normal	Affected	Normal	Affected	Remarks
Mei / unarvu	☐	☐	☐	☐	
Vaai / suvai	☐	☐	☐	☐	
Kan / parvai	☐	☐	☐	☐	
Mooku / natram	☐	☐	☐	☐	
Sevi / olli	☐	☐	☐	☐	

Kanmendhirium / Kanmavidayam

	Normal	Affected	Normal	Affected	Remarks
Kai / dhanam	☐	☐	☐	☐	
Kaal / ghamanam	☐	☐	☐	☐	
Vaai / vaku	☐	☐	☐	☐	
Eruvai / visarkam	☐	☐	☐	☐	
Karuvai / anantham	☐	☐	☐	☐	

Uyir Thathukkal:

Vatham:	Normal	Affected	Remarks
Pranan	☐	☐	
Abanan	☐	☐	
Viyanan	☐	☐	
Uthanan	☐	☐	
Samanan	☐	☐	
Nagan	☐	☐	
Koorman	☐	☐	
Kirukaran	☐	☐	
Devathathan	☐	☐	
Dhanajeyan	☐	☐	

Pitham	Normal	Affected	Remarks
Analam	☐	☐	
Ranjagam	☐	☐	
Saathagam	☐	☐	
Alosagam	☐	☐	
Prasagam	☐	☐	

Kabam	Normal	Affected	Remarks
Avalambagam	☐	☐	
Kilethagam	☐	☐	
Pothagam	☐	☐	
Tharpagam	☐	☐	
Samthigam	☐	☐	

Udalthathukkal	Normal	Affected	Remarks
Saaram	☐	☐	
Senneer	☐	☐	
Oon	☐	☐	
Kozhuppu	☐	☐	
Enbu	☐	☐	
Moolai	☐	☐	
Sukilam / Suronitham	☐	☐	

Envagai Thervugal	Normal	Affected	Remarks
Naa			
Niram	☐	☐	
Thanmai	☐	☐	
Suvai	☐	☐	
Niram	☐	☐	
Mozhi	☐	☐	

Vizhi

Niram ☐ ☐

Thanmai ☐ ☐

Parvai ☐ ☐

Sparisam ☐ ☐

Malam

Niram Normal ☐ Affected ☐

Nurai Normal ☐ Affected ☐

Elagal Normal ☐ Affected ☐

Erugal Normal ☐ Affected ☐

Moothiram

Neerkuri: Niram Normal ☐ Affected ☐

Edai Normal ☐ Affected ☐

Nurai Normal ☐ Affected ☐

Manam Normal ☐ Affected ☐

Enjal Neikuri Normal ☐ Affected ☐

Neikuri:

Vatham ☐

Pitham ☐

Kabam ☐

Others ☐

LABORATORY INVESTIGATIONS

ROUTINE BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TMT Date:	AFTER TMT Date:
Hb (gms%)		11.5 – 14.5		
T.RBC (milli /cu.mm)		4-4.9		
ESR (mm)	½ hr.	0- 4		
	1 hr.	0-13		
T.WBC (milli /cu.mm)		5000-14500		
DIFFERENTIAL COUNT (%)	Polymorphs	40-75		
	Lymphocytes	28-48		
	Monocytes	3-6		
	Eosinophils	0-3		
	Basophils	0-1		
ABSOLUTE EOSINOPHIL COUNT	440 cells/cu m.m			

Urine Investigation	Before TMT Date:	After TMT Date:
Albumin		
Sugar		
Deposits		

Naadi:

ThaniNadi

Vadham ☐ Pitham ☐ Kabam ☐

ThonthaNadi

Vathapitham ☐ Pitha vatham ☐ Pitha kabam ☐ Kabapitham ☐

ThodaNadi

Vatha kabam ☐ Kaba vatham ☐

Admitted to trial: Yes ☐ No ☐

If yes, S. No: IP ☐ OP ☐

Diagnosis:

DRUGS ISSUED: _____

Date : _____

Station: _____

Date: _____ Signature of investigator:

Signature of Guide: Date:

Place:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Preclinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine)in the treatment of BALA KARAPPAN(Eczema) in children.

FORM IV DRUG COMPLIANCE

1. S.I. No:	2. OP/ IP No:	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment:
7. Informant:	8. Reliability:	

NAME OF THE DRUG : KARAPPAN NEI

FORM OF THE DRUG : LIQUID

ADMINISTRATION : PER ORAL

DOSE AND DURATION : 5 ml (BD) FOR 48 DAYS

ADJUVANT : Honey

Days	Date of Drug Intake	Morning	Evening
1.			
2.			
3.			
4.			
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44.			
45.			
46.			
47.			
48.			

Date:

Station: Signature of principal Investigator:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Preclinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine)in the treatment of BALA KARAPPAN (Eczema) in children.

FORM IV DRUG COMPLIANCE

1. S.I. No:	2. OP/ IP No:	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment:
7. Informant:	8. Reliability:	

NAME OF THE DRUG : KARAPPAN NEI

FORM OF THE DRUG : LIQUID

ADMINISTRATION : PER ORAL

DOSE AND DURATION : 10 ml (BD) FOR 48 DAYS

ADJUVANT : Honey

Days	Date of Drug Intake	Morning	Evening
1.			
2.			
3.			
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48.			

Date:

Station: Signature of Principal Investigator:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Pre Clinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine) Siddha drug for BALA KARAPPAN (Eczema) in children.

FORM V – 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. Reliablity:

Registration No :

Date of trial commencement :

Date of withdrawal from trial :

Description of adverse reaction :

Signature of Guide:

Date: Signature of Investigator:

Place:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Pre Clinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine) Siddha drug for BALA KARAPPAN (Eczema) in children.

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. Reliablity:

FORM VI WITHDRAWAL

Date of trial commencement :

Date of withdrawal from trial :

Reason(s) for withdrawal:

Long absence at reporting : Yes/ No

Irregular treatment : Yes/ No

Shift of locality : Yes/ No

Complication adverse reactions if any : Yes/ No

Exacerbation of symptoms : Yes/ No

Patient not willing to continue : Yes/ No

Signature of Guide:

Date: Signature of Investigator:

Palace:

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை-47

பட்டமேற்படிப்பு குழந்தை மருத்துவத்துறை

கரப்பான் நோய்க்கு கரப்பான் நெய் பரிகரப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு

ஒப்புதல் படிவம் II-B குழந்தைக்கானது

----------ஆகிய நான் தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்டமேற்படிப்பு குழந்தை மருத்துவத்துறையில் பயிலும் மரு.மு.பாக்கியதேவி அவர்களால் நடத்தப்படும் கரப்பான் நோய்க்கு கரப்பான் நெயின் பரிகரப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்வில் பங்கேற்பதற்கு எனது பெற்றோர்/காப்பாளர் திரு/திருமதி ---------- சம்மதம் தெரிவித்திருப்பதை நன்கு அறிவேன்.

எனக்கு இந்த ஆராய்ச்சி பற்றி புரியும் வகையில் எடுத்துரைக்கப்பட்டுள்ளது. எவ்வாராய்ச்சில் இருந்து எப்போது வேண்டுமானாலும் விலக எனக்கு உரிமை இருக்கின்றது என்பதை பற்றியும் நன்கு தெரிந்து கொண்டு எந்த ஆராய்ச்சியில் பங்கேற்க்க சம்மதிக்கிறேன்.

தேதி:

இடம்:

குழந்தையின் கையெப்பம்:

பெயர்:

பெற்றோர் கையெப்பம்:

பெயர்:

சாட்சிக்காரர் கையெப்பம்:

பெயர்:

சாட்சிக்காரர் உறவு முறை:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI-47

FORM VII – PATIENT INFORMATION SHEET

Name of investigator: Dr. M. Bakkiyadevi

I Dr. M. Bakkiyadevi Studying as PG Scholar in kuzhandhai maruthuvam department at National Institute of Siddha, Tambaram Sanatorium is doing a open clinical study on "**BALA KARAPPAN" (Eczema**). Eczema is a most common disease. The symptoms are pain in lower extremities, itching, blisters, papules, vesicles, pustules, ulcer formation with oozing, hyper pigmentation. In this regard, I am in a 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.

You have the liberty in choosing to take part in the study or not to take part. You can choose not to answer a specific question. You may be benefited if you take part in this study. Moreover, taking part in the study may be of benefit to the community, as it may help us to understand the disease elaborately and its potential solution problem of defaulters and potential solutions. All the medicine and other relevant investigation procedures will be provide with free of cost.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the medicine "KARAPPAN NEI INTERNAL AND EXTERNAL MEDICINE**.** The information I am collecting in this study will remain between you and the investigator (myself). I will ask you few questions through a questionnaire. The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions for study related contact me (Dr. M. Bakkiyadevi) through my mobile number 9994627411. 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.

Name: Date:

Signature:

தகவல் படிவம்

பாலகரப்பான் நோய்க்கான சித்த மருந்துகளின் **கரப்பான் நெய் (உள் மருந்து மற்றும் வெளி மருந்து) சித்த மருந்திற்கான** பரிகரிப்பு திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஆராய்ச்சியாளர் பெயர் **Dr. மு.பாக்கியதேவி**

நிறுவனத்தின் பெயர் **அயோத்திதாச பண்டிதர் மருத்துவமனை**

தேசிய சித்த மருத்துவ நிறுவனம்

தாம்பரம் சனட்டோரியம் சென்னை-47.

தேசிய சித்த மருத்துவ நிறுவனத்தி **ன் குழந்தை மருத்துவ துறையில்** பட்ட மேற்படிப்பு பயின்று வரும் நான் **பால**கரப்பான் என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுளேன் . **பால**கரப்பான் என்னும் சித்த மருத்துவத்தில் சொல்லப்படும் நோயானது **திமிர்**, **தினவு**, **சொறி**, **புண்**, **தடிப்பு**, **வெடிப்பு**, **நீர் கசிதல்** ,**உடல் இளைத்து அழகிழந்து போதல்** முதலிய குறிகுணங்கள் காணப்படும் தன்மையுடையது.

இந்த ஆராய்ச்சி சம்மந்தமாக சில கேள்விகள் கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்கு தங்களது குழந்தையை உட்படுத்தவும் உள்ளேன்.

இது சம்மந்தமான தங்களது குழந்தையின் அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன். இதில் பயணப்படி முதலிய எந்த உதவி தொகையும் வழங்கப்பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது தங்களது குழந்தையின் உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க சிசிச்சை அளிக்கப்படும்.

இந்த ஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் குழந்தையை உட்படுத்தும் பட்சத்தில் **உள் மருந்து மற்றும் வெளி மருந்தாக கரப்பான் நெய் 48** நாட்கள் எடுக்க வேண்டும்.இந்த ஆராய்ச்சியில் நோயின**ராக** சேர்ந்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் தங்களது குழந்தையை விலக்கிக் கொள்ளலாம்.

இந்த ஆராய்ச்சி சம்மந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மை பற்றியும் அறிவதற்கும் ஆராய்ச்சியாளரான **Dr. மு.பாக்கியதேவி** (பட்ட மேற்படிப்பாளர் குழந்தை மருத்துவ பிரிவு) கைபேசி எண். **99946 27411** எப்போதும் தொடர்பு கொள்ளலாம்.

மேலும் இந்த ஆராய்ச்சிக்கு **IEC** (நிறுவன நீதிநெறிகுழு) சான்று பெறப்பட்டுள்ளது.

இந்த **மருந்து** சிறப்பாக **பால**கரப்பான் நோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது . ஏற்கனவே உபயோகத்தில் உள்ளது . இதுவரை நோயாளிகளிடம் எந்த வித பக்க விளைவுகளை ஏற்படுத்தவில்லை. மேலும் உணவு முறையில் **உங்களுக்கு கூறப்பட்டுள்ளமுறைகளை** பத்திய **முறைகளை** காக்குமாறு அறிவுறுத்த படுகிறது.

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

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Reporting Form for Suspected Adverse Reactions to Siddha Drugs

Please note: i. All consumers / patients and reporters information will remain confidential.

ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code: State:

Name	Father name	Patient / Record No.
Ethnicity	Occupation	
Address Village / Town Post / Via District / State		Date of Birth / Age: Sex: Male / Female Weight : Degam:

2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation		Season:
Description of reaction		Geographical area:

3. List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:

Medicine	Daily dose	Route of administration & Vehicle – Adjuvant	Date		Diagnosis for which medicine taken
			Starting	Stopped	
Siddha					
Any other system of medicines					

4. Brief details of the Siddha Medicine which seems to be toxic :

Details	Drug – 1	Drug – 2	Drug – 3
a) Name of the medicine			
b) Manufacturing unit and batch No. and date			
c) Expiry date			
d) Purchased and obtained from			
e) Composition of the formulation / Part of the drug used			

b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

5. Treatment provided for adverse reaction:

6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)

<table>
<tr><td>Recovered:</td><td>Not recovered:</td><td>Unknown:</td><td>Fatal:</td><td>If Fatal

Date of death:</td></tr>
<tr><td colspan="2" rowspan="2">Severe: Yes / No.</td><td colspan="3">Reaction abated after drug stopped or dose reduced:</td></tr>
<tr><td colspan="3">Reaction reappeared after re introduction:</td></tr>
</table>

Was the patient admitted to hospital? If yes, give name and address of hospital	

7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:

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

Hepatic Renal Cardiac Diabetes Malnutrition

Any Others

9. H/O previous allergies / Drug reactions:

10. Other illness (please describe):

11. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)
Name:
Address:
Telephone / E – mail if any :

Signature of the reporter: **Date:**

Please send the completed form to:

Name & address of the RRC-ASU / PPC-ASU

The Director

National Institute of Siddha,

(Pharmacovigilance Regional Centre For Siddha Medicine),

Tambaram Sanatorium, Chennai-600 047.

☏ (O) 044-22381314 Fax : 044 – 22381314

Website : www.nischennai.org

Email: nischennaisiddha@yahoo.co.in

* ** * * * *

This filled-in ADR report may be sent within one month of observation /occurrence of ADR

Who Can Report?

⇒ Any Health care professionals like Siddha Doctors / Nurses / Siddha Pharmacists / Patients etc.

What to Report?

⇒ All reactions, Drug interactions,

Confidentiality

⇒ The patient's identity will be held in strict confidence and protected to the fullest extent

Date :

Station :

Signature of the Investigator:

Signature of the Lecturer: Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

Pre Clinical and Clinical Evaluation of KARAPPAN NEI (Internal and External medicine) Siddha drug for BALA KARAPPAN (Eczema) in children.

FORM IX – DIET FORM

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. Reliablity:

தவிர்க்க வேண்டிய உணவுகள்

கத்திரிக்காய், கருவாடு, சோளம், கம்பு, தினை, வரகு, சாமை, காரரிசி, லவாழைக்காய், பாகற்காய், கெளிற்று மீன், கிழங்கு ஆகிய கரப்பான் பண்டங்களை தவிர்க்கவும்.

புண்களை கழுவ சிகைக்காய் தூள் பயன்படுத்தக்கூடாது.

கொசுக்கடி இல்லாமல் பார்த்துக்கொள்ள வேண்டும்.

நகங்களை வளர விடாமலும், சுத்தமாகவும் வைத்துக கொள்ளவும்.

தோலை உறுத்தும் ஆடைகளை அணிவதை தவிர்க்கவும்.

மலக்கட்டு இல்லாமல் பார்த்துக் கொள்ள வேண்டும்.

குளிப்பதற்கு சோப்பு உபயோகிப்பதை தவிர்க்கவும்.

நலங்குமாவு பயன்படுத்தவும்.

சேர்க்க வேண்டிய உணவுகள் :

காய்கறிகள், கீரைகள், பாலும் பால் பொருட்களும் ஆகிய சத்துள்ள பொருட்கள்.

தண்ணீர் அதிக அளவு குடிக்கவும்.

நல்ல கற்றோட்டமுள்ள இடத்தில் வசிக்கவும்

சுத்தமான ஆடைகளை அணியவும்.

கைகளை சுத்தமாக வைத்துக் கொள்ளவும்.

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Karappan Nei"** (Internal & External) taken up for Post Graduation Dissertation studies by **Dr.M.Bakkiya devi** M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2017, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Andrographis paniculata (Burm.f.) Wall.ex Nees (Acanthaceae), Whole plant

Pterocarpus santalinus Linn. f. (Fabaceae), Heart wood powder

Terminalia chebula Retz. (Combretaceae), Fruit

Cyperus rotundus Linn. (Cyperaceae), Tuber

Piper longum Linn. (Piperaceae), Fruit

Cedrus deodara (Roxb.) Loud. (Pinaceae), Wood

Murraya koenigii Spreng. (Rutaceae), Leaf

Strychnos potatorum Linn. (Loganiaceae), Seed

Curcuma longa Linn. (Zingiberaceae), Finger rhizome

MEDICINAL BOTANY ★ CHENNAI 600 047 ★ National Institute of Siddha

Certificate No: NISMB3042017

Date: 10-07-17

Authorized Signatory

Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047, INDIA

CERTIFICATE

This is certify that the project title Preclinical and clinical study of Siddha drug "Karappan Nei" internal and external medicine in the treatment of "Balakarappan"(eczema)**Has been approved by the IAEC.** 20 -Rats (10 Male + 10 Female)

Approval No: NIS/IAEC-IV/03/05012017.

V. Banumathi

Prof. Dr.V.BANUMATHI
Chairman IAEC:

Prof. Dr. K.Nachimuthu
CPCSEA nominee: 7/11/17

Signature with date

Chairman/Member Secretary of IAEC:

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

Name of the Principle Investigator: Dr. N. BAKKIYA DEVI P.G. IInd YEAR

Name of the Institution: NATIONAL INSTITUTE OF SIDDHA

Name of the Department: KUZHUNDHAI MARUTHUVAM

TAMIL NADU VETERINARY AND ANIMAL SCIENCES UNIVERSITY

Laboratory Animal Medicine, Centre for Animal Health Studies, Chennai - 51

Laboratory Animals Request/ Reservation Form

Name of the Investigator : Dr. M. BAKKIYA DEVI
Designation : PG Scholar - IInd year
Department : Kuzhandhai maruthuvam,
Institution Name : National Institute of Siddha,
Postal Address : Tambaram Sanatorium, chennai - 47

Phone / Mobile : 9994627411
Email ID : bakkiyadevim@gmail.com
CPCSEA approval Number : 1248 | G10 | Re | s | 2009 | CPCSEA

S.No	Species	Strain	No of animals required		Date Required	IAEC protocol Number* (MANDATORY)	Whether copy of IAEC approval attached? (MANDATORY)
			Male	Female			
1.	Rat	wistar	10	10	30.5.17	NIS | IAEC - IV | 03 | 050 | 2017	Yes

(for price of animals, payment procedures, procedures for the receipt and transport of animal - please see http://www.tanuvas.tn.nic.in/lam.html)

Payment details:

DD No: _____ for rupees _____ drawn bank _____

(OR) Internet Banking (NEFT/ RTGS) transaction ID _____ transaction date _____

M. Bakkiya Devi
Signature of Project Investigator / Guide
Date: 20/5/17
Place: Tambaram Sanatorium Chennai - 47

20/05/17
Signature of HOD/ Institution with official seal
Date: 20/5/17
Place: Tambaram Sanatorium Chennai - 47

For Office Use Only

Form received on:
Breeding required:
Species: Male: Female:

Application No:
Animals Issued No:
Total:

Payment details:
Entered in P.No. _____ of stock register
Vehicle No:

Signature and Date

The Tamil Nadu Dr.M.G.R.Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.... BAKKIYA DEVI. M .....

For participating as ~~Resource Person~~ / Delegate in the Twenty First Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 25th to 29th April 2016.

Dr.N.KABILAN, MD(S),
PROF & HEAD
DEPT.OF SIDDHA

Prof.**Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.S.GEETHALAKSHMI,** M.D., Ph.D.,
VICE CHANCELLOR

NATIONAL INSTITUTE OF SIDDHA

(An Autonomous body under Ministry of AYUSH, Govt. of India)
Tambaram Sanatorium, Chennai- 600 047

Workshop on

"BASIC RESEARCH TECHNIQUES AND PRACTICES INVOLVED IN LABORATORY ANIMAL CARE"

06 -10 February 2017

CERTIFICATE

This is to certify that Dr. M. Bakkiya Devi has participated as Delegate/~~Resource~~ Person in the workshop on "Basic Research Techniques and Practices involved in Laboratory Animal Care" held on 06-10 February, 2017 at National Institute of Siddha, Chennai-47, Tamilnadu.

Dr. V. Suba
Organizing Secretary

Dr. P. Muthusamy
Veterinary Consultant

Prof. Dr. V. Banumathi
Director / Chairperson

NATIONAL INSTITUTE OF SIDDHA- राष्ट्रीय सिद्ध संसथान
Ministry of AYUSH- आयुष मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियमचेन्नई -600 047
फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16 Dt: 14.10.2016

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr. M.Bakkiyadevi– I year, Dept.of Kuzhanthai Maruthuvam	
Protocol Title:- Preclinical and Clinical Evaluation of Karappan Nei (Internal and External Medicine) in the treatment of Balakarappan (Eczema) in Children.	
Documents filed	1) Protocol, 2) Data Collection forms
Clinical trial Protocol (others – Specify)	**Yes-(M.D-Dissertation)**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/2016/11-18/ 14.10.2016**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

(Dr.V.Subramanian)
Chairman

(Prof.Dr.V.Banumathi)
Member Secretary

NATIONAL INSTITUTE OF SIDDHA * CHENNAI 600 047

Noble research solutions
We Trust in Quality and Ethics

Noble Research Solutions

We Trust in Quality and ethics

E-mail : nobleresearchsolutions@gmail.com
info@nobleresearchsolutions.com
Contact : 9710437419, Admin : 044 - 42691289

Date: 10.04.2018

To,

Dr.M.Bakkiyadevi
National Institute of Siddha,
Tambaram Sanatorium, Chennai 600047, Tamil Nadu, India.

Project Id: **NRS/AS/0088/01/2018**

This is to certify that Dr.M.Bakkiyadevi from National Institute of Siddha, Tambaram Sanatorium, Chennai, has carried out the following activity at our facility for the trial drug *Karappan Nei (KN)*

S.No	Study Description	Annexure no
1.	Standardization and Physicochemical Evaluation of study drug *Karappan Nei (KN)*	I

Note:

- *Annexures was attached as a separate enclosure along with this report.*

NOBLE RESEARCH SOLUTIONS TAMIL NADU INDIA CHENNAI

For NOBLE RESEARCH SOLUTIONS

Clinical Trial Details (PDF Generation Date :- Tue, 03 Jul 2018 07:56:23 GMT)

CTRI Number	CTRI/2017/05/008722 [Registered on: 31/05/2017] - **Trial Registered Prospectively**
Last Modified On	29/05/2017
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Single Arm Trial
Public Title of Study	Pre clinical and Clinical evaluation of karappan nei (internal and external medicine) in the treatment of Eczema in children
Scientific Title of Study	Preclinical and Clinical evaluation of karappan nei (internal and external medicine) in the treatment of Bala karappan (Eczema) in children on open clinical study

Secondary IDs if Any

Secondary ID	Identifier
Nil	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Bakkiyadevi M
Designation	PG Scholar
Affiliation	Ayothidoss pandithar hospital
Address	Department of Kuzhandhai Maruthuvam, National institute of Siddha, Tambaram sanatorium, Chennai 47 Department of Kuzhandhai Maruthuvam, National institute of Siddha, Tambaram sanatorium, Chennai 47 Kancheepuram TAMIL NADU 600047 India
Phone	9994627411
Fax	
Email	bakkiyadevim@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr K Suresh
Designation	Lecturer
Affiliation	Ayothidoss pandithar hospital
Address	Department of Kuzhandhai Maruthuvam, National institute of Siddha, Tambaram sanatorium, Chennai 47 Department of Kuzhandhai Maruthuvam, National institute of Siddha, Tambaram sanatorium, Chennai 47 Kancheepuram TAMIL NADU 600047 India
Phone	9962571137
Fax	
Email	drsureshherbal@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr K Suresh
Designation	Lecturer
Affiliation	National institute of siddha
Address	Department of Kuzhandhai Maruthuvam, National institute of Siddha, Tambaram sanatorium, Chennai 47 Department of Kuzhandhai Maruthuvam, National institute of Siddha, Tambaram sanatorium,

	Chennai 47 TAMIL NADU 600047 India
Phone	9962571137
Fax	
Email	drsureshherbal@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Ayothidoss pandithar hospital National institute of siddha,Tambaram sanatorium, Chennai-47.

Primary Sponsor

Primary Sponsor Details	
Name	Ayothidoss pandithar hospital
Address	National Institute of siddha,Tambaram sanatorium, Cheenai-47
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
Nil	Nil

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Bakkiyadevi M	Ayothidoss pandithar hospital	OPD NO 9, Department of Kuzhanthai maruthuvam, National Institute of Siddha, Tambaram Sanatorium Kancheepuram TAMIL NADU	9994627411 bakkiyadevim@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional ethics committee	Approved	14/10/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Bala karappan

Intervention / Comparator Agent

Type	Name	Details
Comparator Agent	Nil	Nil
Intervention	Karappan nei(internal)	5-10 ml twice a day with honey for a period of 48 days

Inclusion Criteria

Inclusion Criteria	
Age From	6.00 Year(s)
Age To	12.00 Year(s)
Gender	Both
Details	1. Children with symptoms of pain in lower extremities, Itching, Papules, Vesicles, Pustules, Ulcer, Oozing, Hyper pigmentation, Sleep disturbances 2.Patients willing to Blood investigation when required 3. Patient willing to be admitted in the hospital or willing to attend OPD once in 7 days for 48 days.

Exclusion Criteria

Exclusion Criteria

Details	1.Scabies 2. Photo dermatitis 3. Jaundice 4. patients with any other serious illness

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Case Record Numbers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
It is mainly assessed by reduction of Clinical symptoms by using SCORAD scale	48 datys

Secondary Outcome

Outcome	Timepoints
It is mainly assessed by therapeutic efficacy of the trial drugs	48 days

Target Sample Size	**Total Sample Size=**30 **Sample Size from India=**30
Phase of Trial	Phase 3
Date of First Enrollment (India)	01/08/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	None yet
Brief Summary	It is the single non-randomized,open label trial to determine the efficacy of Karppan nei (internal and external medicine) prepared from herbal constitutents in the patients with Balakarappan (Eczema). In this trial 30 patients will be recruited and the trial drug will be administered 5-10 ml Twice a day with honey for a period of 48 days. During the trial period if any AE/SAE/SUSAR will be noticed and refered to pharmacovigilance department in NIS and further management will also be given in NIS OPD/IPD. The entire trial will be monitored by the research monitoring committee of NIS. During this trial all the safety efficacy parameters will be recorded in the CRF. After completion of the trial all the study related data will be analysed statistically. The outcome of this trial will be published in India Journal of Medical research.