PRECLINICAL & COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUGS **"SIGAMANI CHOORANAM"** (INTERNAL) AND **"ARKKASHEERATHY THYLAM"** (EXTERNAL) IN THE TREATMENT OF "**CAGANA VAATHAM" (CERVICAL SPONDYLOSIS)** WITH AND WITH OUT **VARMAM** THERAPY**"**

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "Preclinical and comparative clinical trial of Siddha drugs ***"Sigamani Chooranam"*** (Internal) and ***"Arkkasheerathy Thylam"*** (External) in the treatment of **"*Cagana Vaatham"* (Cervical Spondylosis)** with and without ***Varmam*** **therapy** is a bonafide and genuine research work carried out by me under the guidance of **Prof. Dr.N.J. Muthukumar, M.D(s)., Ph.D.** H.O.D. Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date: **Signature of the Candidate**

Place: Chennai-47 **Dr.L. Nilopher**

BONAFIED CERTIFICATE

Certified that I have gone through the dissertation submitted by **Dr.L. Nilopher (Reg.No:321613206)** a student of final year M.D(s), Branch-III, Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai-47, and the dissertation work has been carried out by the individual only. This dissertation does not represent or reproduce the dissertation submitted and approved earlier.

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INTRODUCTION

Siddha System of Medicine was introduced by Siddhars who practiced spiritual practise to attain salvation. Siddhars are persons who practiced Meditation, *Pranayamam* and other *Yogam* practices to reach a stage of insight which would provide them super natural power to cure the sufferings. They discovered many natural medicines which are widely used for treating many diseases.

Siddha System of Medicine is a special significant and scientific system being in practice. Since time immemorial it is one of the ancient system of medicine contemporaneous with Grecian, Egyptian, Mesopotamian, Chinese medicines. It is a unique system which dealt among the tamil people of south India rendering service to humanity for more than five thousand years in combating diseases and then maintaining Physical, Mental, Social and Spiritual Health.

Siddha System of Medicines includes 32 types of internal medicines and 32 types of external medicines. Siddhars have contributed tremendous work on raw materials from herbal, herbo - Mineral, Metal and Animal origin and formulated by many medicines. The medicines like ***Chooranam, Legiyum, Manapagu, Parpam, Chendurum, Chunnam, Kattu, Kalangu, Etc..,,*** where prepared by the following special techniques like Calcination, Sublimation, Dissolution, Fusion, Distillation, Separation, Conjunction & Combination, Coagulation, Fermentation, Exaltation, Fixation, Purification, Incineration Of Metals, Liquefaction, Extraction Etc., These medicines where used to treat chronic diseases especially in cases where in the prognosis is grave.

Varmam is the special branch of Siddha System of Medicine still in practice in Southern parts of Tamil Nadu especially in Kanya Kumari and in Southern parts of Kerala. Though it gained popularity as a martial art in the past two decades, its immense medical benefits for many ailments are still ignored. The basic principles of *Varmam* science explain the fundamentals of Siddha system of medicine. This treatment methodology is employed in the clinical practice, especially for musculo - skeletal disorders, neuro-musculature disorder and neurological disorders.

Siddhar *Yugi munivar* has classified *vali* disease into 80 types in the text *Yugi vaithya chindamani 800, Cagana vaatham* is one among them. The symptoms are pain around the neck, giddiness, pain in the upper limbs burning sensation of the eyes and

pain all over the body like a sting of a scorpion. This condition may be correlated with cervical spondylosis in modern science.

Cervical spondylosis is a disease which causes pain, swelling, restriction of movements in the cervical region and produces lot of troubles in day to day activities of an individual. Nowadays Neck pain has become a matter of major concern which is mainly due to life style modifications. Most of the people are following sedentary way of life and occupational issues such as laboratory investigator, IT sector. So the chances of developing Cervical Spondylosis is also highly increased.

Degenerative changes in the body which used to happen only after the 5^{th} decades of life Nowadays degenerative changes started in the 3^{rd} decades itself. Many youngsters are affected by cervical spondylosis due to degenerative changes of the spine.50% of people over the age of 50 and 75% of those over the age of 65 have typical radiographic changes of cervical spondylosis 40% of people have some restriction of neck movements and 60% have neurological abnormality.

The hectic schedule followed by the people has reduced the time which was utilized for doing yoga, physical exercises, relaxation etc..

So, the need of the hour is to search an effective drug and therapy to treat cervical spondylosis with less or no adverse effects. Hence an attempt had been made to validate the drugs and therapy for the management of cagana vaatham. Therefore, I have chosen this polyherbal formulation ***'SIGAMANI CHOORANAM'*** from the classical literature ***Kannusamy parambarai vaithyam*** for internal administration and external medicine '***ARKKASHEERATHY THYLAM'*** from ***Siddha vaithya thirattu.*** Most of the ingredients of the trail drug have anti-inflammatory and analgesic activity. Moreover most of the ingredients possess *veppaveerium* (Hot potency) and *kaippusuvai* (Pungent taste) which will balance and rectify the deranged *Pitha Vathadhosham*.

AIM AND OBJECTIVES

AIM:

Preclinical and Comparative clinical trial of Siddha drugs ***"SIGAMANI CHOORANAM"*** *(*Internal) and ***"ARKKASHEERATHY THYLAM"*** *(*External) in the treatment of ***CAGANA VAATHAM*** (Cervical Spondylosis) with and without "***VARMAM***" therapy.

OBJECTIVE:

a). PRIMARY OBJECTIVE:

To evaluate the safety and therapeutic efficacy of ***"SIGAMANI CHOORANAM"*** (Internal) and ***"ARKKASHEERATHY THYLAM"*** **(**External) in ***"CAGANA VAATHAM"*** (Cervical Spondylosis) through clinical study along with and without *Varmam.*

b). SECONDARY OBJECTIVE:

1). To evaluate the Safety of the trail drug.

2). To study the Siddha parameters before and after treatment of the trail drug.

3). To evaluate biochemical analysis of the trial drug.

SIDDHA ASPECTS

CAGANA VAATHAM:

Cagana vaatham is one among the 80 types of Vaatha diseases. It is a condition involving pain around the neck, giddiness, pain in the limbs, burning sensation of the eyes, pain all over the body like a sting of a scorpion.

"தானென்ற கசப்போடு துவர்ப்புறைப்பு
சாதகமாய் மிஞ்சுகிலும் சமைத்த வண்ணம்
ஆனென்ற வாறினது பொசித்தலாலும்
ஆகாயத்தேறலது குடித்தாலும்
பானென்ற பகலுறக்க மிரா விழிப்பு
பட்டினியே மிகவுறுதல் பாரமெய்தல்
தேனென்ற மொழியார் மேற்சிந்தையாதல்
சீக்கிரமாய் வாதமிது செனிக்குந்தானே"

"பகரவே வாதமது கோபித்தப்போ
பண்பாக பெண்போக மதுதான்
நகரவே வெகுதூரவழி நடக்கில்
நளிரான காற்றுமே பனி மேற்ப்பட்டால்
மிகரவே காய்கள் கனி கிழங்கு தன்னை
மிக வருந்தி மீறியே தயிர்தான் கொண்டால்
முகரமே முதுகெலும்பை முறுக்கி நொந்து
முழங்காலும் கணைக்கலும் கடுப்புஉண்டாமே"

AETIOLOGY:

- ✓ Excessive consumption of bitter, astringent and pungent food items
- ✓ Consumption of food cooked on the previous day
- ✓ Drinking polluted water
- ✓ Changing sleep pattern

- ✓ Excessive starvation
- ✓ Lifting heavy weight
- ✓ Excessive lust
- ✓ Sexual indulgence
- ✓ Walking long distance
- ✓ Living in cold environment
- ✓ Excessive consumption of Tubers, Fruits, Curd, Etc

CLINICAL FEATURE OF CAGANA VAATHAM:

The signs and symptoms of *Cagana vaatham* are described in *Yugi Vaidhya Chinthamani* and *Pararasasekaram* as:

"கேளுமே கழுத்தின்கீ ழரைக்கு மேலுங்
கெடியான கரமிரண்டு மிகவே நொந்து
வாளுமே சரிரமெலாங் கனத்திருக்கும்
வாலிபர்க்கு மனங்கண்ணு மயக்கமாகும்
ஏளுமே யிரண்டுகண்ணு மெரிச்சலுண்டா
மேற்றமாய் சலந்தானு மிறுகிக் காணுந்
தேளுமே கொட்டினது போற்க் கடுக்கும்
சகனவா தத்தினிட தீர்க்கந்தானே"

- யூகி வைத்திய சிந்தாமணி

- Pain in the neck
- Radiating pain in the shoulders and upper limbs
- Heaviness of the body
- Mental depression
- Giddiness
- Burning sensation of the eyes
- Constipation
- Pain felt like sting of a scorpion
- Numbness and tingling sensation of the upper limbs.

VAATHAM

Vaatham represents Vaayu, Dryness, Pain, Sensitiveness and Lightness. "***Vaatham = Vali + Aagayam***".

LOCATION: As per *Yugi muni,* "Vaatham" lives in,

1. Abaanan
2. Edakalai
3. Kamakodi
4. Undhiyin Keezh moolam
5. Iduppu
6. Elumbu
7. Thasai
8. Narambu
9. Thol
10. Malam

FUNCTIONS OF VATHAM:

1. Body ache
2. Bony Prickling pain
3. Tearing pain
4. Nerve weakness
5. Mental distress
6. Joint pain
7. Dislocation of joints
8. Weakness of organs
9. Paralysis of limbs
10. Polydypsia
11. Severe pain in calf and thigh muscles
12. Anuria and constipation
13. Unable to do flexion and extension of the limbs
14. All tastes felt as astringent.

NATURAL PROPERTIES OF VATHAM:

1. To create spirit
2. Expiration and Inspiration

3. To tone up the activities of the Mind, Speech & Body.
4. Regulation of the "Fourteen Physiologically Reflexes" (Vegam)
5. Functioning of the ''Seven Udal Kattukal" uniformly
6. Protection and strengthening of the five sensory organs (lymphorigal).

TYPES OF VATHAM :

1.PRAANAN:

It maintains the action of the heart, the functioning of the mental faculties of perception and concentration it also cares for the arteries, veins and nerves. It regulates the respiration and digestion. It is otherwise called as "***Uyirkkal***".

2.ABAANAN:

It controls the excretion. It is focussed in the lower part of the gut and also occupies the sites in the bladder and genitalis. It has a tendancy to travel downwards. It Completely occupies the Genito urinary tract and regulates Defaecation, Micturition, Parturition and Ejaculation. Its is otherwise termed as *"**Kezhnokkumkaal**"*.

3.VIYAANAN:

It helps in the circulation of energy throughout the entire nervous system and the movements of various parts of the body. It also transports nutrients and blood throughout the body. It is also known as *"**Paravukaal**"*.

4.UDHAANAN:

It controls speech and breathing. It is also responsible for the physiological reflex actions like vomiting, hiccup, cough, etc.., It has the tendancy to travel upwards. It is otherwise named as *"**Melnokkukaal**"*.

5.SAMANANAN:

It corresponds to the solar plexus in the navel region and controls digestion. It selects the useful substances from the swallowed food and supplies them to the whole body. It balances the other *"Vayus*" and it is also called as *"**Nadukkal**"*.

6.NAAGAN:

It is responsible for the intelligence of an Individual, Blinking, Singing and Pilo Erection.

7.KOORMAN:

It is responsible for yawning, closing of mouth, blinking shedding of tears, vision and opening of the eyes.

8.KIRUGARAN:

It is responsible for salivation and nasal secretion. It helps in digestion and remembering things. It produces cough and sneeze.

9.DHEVATHATHAN:

It is responsible for laziness, latitude, arguing and also anger. It helps movements of the eyeball in various directions. It dwells in between the anus and the sex organ.

10.DHANAJEYAN:

It start from the nose and it causes the whole body to swell. It leaves from the body by blowing up the cranium only on the third day after death.

In *Cagana vaatham*, ***Viyanan, Samanan*** are afftected.

QUALITIES OF VAATHAM:

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

OPPOSITE QUALITIES OF VAATHAM:

1. Mirudhu	-	Softness
2. Pasumai	-	Unctuous
3. Baluvu	-	Heaviness
4. Akkini	-	Hot
5. Isthiram	-	Stableness
6. Katti	-	Solidity

INCREASED FEATURES OF VAATHAM:

1. Reduced immunity
2. Giddiness
3. Insomnia
4. Laziness
5. Body weakness and dark complexion
6. Desire to eat hot foods
7. Shivering
8. Abdominal distension
9. Constipation

DECREASED FEATURES OF VAATHAM:

1. Generalized body pain
2. Hoarseness of voice
3. Loss of memory
4. Semi consciousness
5. Difficulty in performing work

PITHAM:

Pitham is located in the Urinary bladder, Heart, Head, Umbilicus, Pinkalai, Abdomen, Stomach, Sweat, Blood, Eye and Skin. It is classified into five types as,

Anala pitham	-	It digests all the food substance
Ranjaga pitham	-	It gives colour to the blood
Saadhaga pitham	-	It is used to accomplish a work properly
Alosaga pitham	-	It gives vision to the eye
Piraasaga pitham	-	It gives colour to the skin

1). Involvement of *Saadhaga Pitham* produces the features like mental depression and difficulty in performing regular duties because of the pain in the neck and upper limbs.

2). ***Saadhaga pitham*** is affected in *Cagana vaatham*.

KABAM:

Kabam is located in Semen, Fat, Bone Marrow, Nose, Chest, Nerves, Bones, Brain, Large Intestine, Stomach, Pancreas. It is divided into five types they are,

1. Avalambagam	-	It controls all other four types of kabam
2. Kiledhagam	-	It moistens the food
3. Podhagam	-	It helps to feel the taste
4. Tharpagam	-	It gives cooling effect to the eyes
5. Sandhigam	-	It gives lubrication to the joints

Tharpagam and **s*andhigam*** are affected in *Cagana vaatham.*

UDAL THATHUKKAL:

1.Saaram	-	It strengthens the body and mind
2.Senneer	-	It gives power, knowledge and boldness to a person
3.Oon	-	It is responsible for the movement of the body
4.Kozhupu	-	Lubricates the joints and facilitates their function
5.Enbu	-	Protects all the internal organs and gives structure to the body.
6.Moolai	-	It is present in bones and strengthens them
7.Sukkilam (or) suronitham	-	Useful in reproduction

Panchaboothangal forming the basic constituents of Seven *Udal thathukkal* (*Saaram, Senneer, Oon, Kozhuppu, Enbu, Moolai and Sukkilam*) also get deranged.

Commonly affected *Udal thathukkal* in *Cagana vaatham* are ***Saaram, Oon*** *and* ***Enbu.***

KANMENDHIRIYAM:

1.Kai	-	Work done by hands
2.Kaal	-	For walking
3.Vaai	-	For speaking
4.Eruvai	-	For defecation
5.Karuvai	-	For reproduction

Commonly affected *Kanmenthiriyum in Cagana vaatham* (organs of actions) are ***Kai.***

GNAANENDHIRIYAM :

1.Mei	-	Feels all types of sensation
2.Vaai	-	For taste
3.Kan	-	For vision
4.Mooku	-	For smell
5.Sevi	-	For hearing

Commonly affected *Gnanenthiriyams in cagana vaatham* are ***Mei, Kan*****.**

DIAGNOSIS:

ENVAGAI THERVU

"நாடி ஸ்பரிசம் நா நிறம் மொழி விழி
மலம் மூத்திரம் இவை மருத்துவராயுதம்"
"மெய்க்குறி நிறத்தொனி விழிநாவிருமலம் கைக்குறி"

- *Naadi*
- *Sparism*
- *Naa*
- *Niram*

- *Mozhi*
- *Vizhi*
- *Malam*
- *Moothiram*

1.NAADI

Naadi means a vital force it is divided into three humours *Vaatham, Pitham, Kabam*. It can be assessed in 10 sites.The commonest site is radial artery.

- ✓ In *Cagana vaatham*,Naadi felt are ***Vathapitham and Pithavatham***.

2.SPARISAM:

By sparisam the temperature of the Body, Smoothness Or Roughness, Dryness, Hardness, Patches, Abnormal Growth, Sweating, Tenderness and Nourishment can be felt.

- ✓ In *Cagana vaatham*, general body temp-slight warmth **(*Mitha vaeppam*)** and Tenderness present in neck and upper extremities.

3.NAA:

Colour, coating, dryness, movement, deviation, sensory, changes, ulcer, conditions of Tooth and gums are noted

- ✓ In *Cagana vaatham*, the Tongue may be coated.

4.NIRAM:

Colour of the skin,mucous membranes,hair and nail are examined.

- ✓ In *Cagana vaatham* there is no change in *Niram.*

5.MOZHI:

Disturbance in Speech, Hoarseness of voice are assessed.

- ✓ In *Cagana vaatham*, No change or Disturbance of voice were found.

6.VIZHI:

Testing for acuity of vision, colour, redness, pallor, whiteness, burning sensation, Excessive lacrimation.

- ✓ In *Cagana vaatham*, burning sensation of the eyes is present.

7. MALAM:

The excretory products of the body are called as *malam*. The feaces should be semi-solid without hardness and looseness.

Nature, quantity, colour odour, froth, presence of blood and mucous are noted.

- ✓ In *Cagana vaatham*, Constipation is present in some of the patients.

8.MOOTHIRAM

The urine is examined by two methods

- *Neerkuri*
- *Neikuri*

NEERKURI:

Urine is collected after taking well balanced diet, which do not alter the three *thodams*. It should be examined within 3 ¾ *nazhigai* (90 minutes).

In *Neerkuri* the *Niram* (colour), *Manam, Nurai* (Froth), *Edai* (Specific Gravity), *Enjal* (Quantity) are noted. Apart from these the frequency of urination, presence of abnormal constituents such as sugar, proteins, etc., and sediments are also noted.

NEIKURI:

The collected urine is kept in a glass bowl and is placed under direct sunlight. A drop of gingelly oil is dripped on the surface and nature of *neikuri* is noted. If the drop of oil lengthens like a snake it indicates *vatham*, if it appears like a ring it indicates *pitham*, if it appears like a pearl it indicates *kabam*.

When the drop of oil shows two shapes enclosed within one another it indicates *thontha neer.*

NOI KANIPPU VIVADHAM:

Other type of *vatha* diseases which shows similar symptoms of *Cagana vaatham* are mentioned. They are

- ✓ *Karnaavarthan nookkadu*
- ✓ *Kumbavatham*
- ✓ *Kazhuthu vaaham (kooni kirigavatham)*

- ✓ *Pani kambavatham*
- ✓ *Sirakamba vatham*

1. Karnaavartham nookkadu:

"வர்த்தமாய் மார்போடு பிடரி காது
வலித்துமே வாப்புகொண் டடித்தாற்
குற்றமாய் காதிரண்டுங் குடைச்சலாகுங்
கோணியே கபத்துங் காதுங் கனக்கும்
அற்றமா யுச்சியிலும் நெற்றி தன்னில்
அடிக்கடிக்கு நோயாகியசதி யாகும்
பற்றமாய்ப் பசியின்றி உறக்க மின்றேல்
பாரகர்னா வர்த்தமென்றே பகர லாம''.

-(யூகி முனி வாத நோய்கள் & கன்னியாகுமரி மாவட்ட வாதநோய் தொகுதி)

- Heaviness of neck
- Referred pain to the ear and nape of the neck
- Headache

2.Kumba Vaatham:

"நவிலவே தோள்மீது கரகத்தின் மீதும்
நலிந்து மெத்த வாகியே நசவுண்டாகும்
கவிலவே கன்னமொடு நயனந் தானும்
கழுத்துமே விறுவிறுப்பு மெரிவுங் காணும்
துவிலவே துடிப்பாகுஞ் சிரசு தன்னிற்
சுழற்சியே நாபிக்கிழ் வலியு முண்டாம்
அவிலவே யடிநாக்கி லழன்று காணும்
அலருமே வரு கும்பவாதந் தானே''.

– (சித்த மருத்துவம் பொது)

- Burning sensation in shoulder and upper limbs
- Burning sensation in the cheek and the eyes
- Twitching over the scalp
- Spasmodic pain in the lower abdomen
- Glossitis

3. Kazhuththu Vaatham (Kooni Kiraga Vaatham):

"கழுத்தை திருப்பாதே பிடித்து
கதிரிட்டு உளைந்தாற் போலே காணும்
செழித்தே நரம்பு தடித்து நிற்கும்
சீராக அசைக்க வொட்டாது
கழுத்தே பிடித்து இராப்பகலும்
இடரே செய்யும் கழுத்து வாதம்
வழுத்தும் குணங்கள் தரணி தன்னில்
வசையாய் அறிவீர் பண்டிதரே".

- (வாதநோய் மருத்துவம்)

- Stiffness and restriction of movements of the neck
- Burning pain in neck
- Thickening of nerves in neck
- Symptoms continuing day and night

4). Paanikamba vatham:

"மார்க்கமாய் வாய்வுமாய் மெய்நி றைந்து
வயிறுதனிற் பசியிலா தூணு மற்ற
நார்க்கமாய் ஞாலத்து நடக்கை யற்று
நடுக்கமாங் கையிரண்டுந் திமிரு முண்டாம்
ஊர்க்கமா யுறக்கமில்லா துணர்ச்சி யற்று
உதறியெ சரீரமெங்கு முலர்ந்து காணும்
பார்க்கமாய் வாய்விட்டு அலத்த லாகும்
பாணிக்கம்ப வாதத்தின் பாங்கு தானே".

- (சித்தமருத்துவம் பொது)

- Anorexia
- Tingling sensation of upper limbs
- Tremor of upper limbs
- Sleeplessness
- Dryness all over the body

5). Sirakamba vatham:

"தம்பமாய் உதிரகண்ட நரம்பிற் புக்கித்
தலையோடு சாரீமெலாந் தாக்கிப் புக்கும்
கம்பமாய் காதிரண்டு மிகவுங் கேளா
கையோடுன் காலிரண்டும் வசக்கே டாகும்
நிம்பமாய் நினைவுதான் கலங்கிக் காணும்
நெடுமூச்சுங் கொட்டாவி நித்திரை யாகும்
சிம்பமாய் தலைநடுங்கிக் கனப்பு முண்டாஞ்
சிரக்கம்ப வாதமென்றே செப்ப லாமே.

- (சித்த மருத்துவம் பொது)

- Stiffness of neck
- Deafness
- Yawning
- Hypersomnia
- Tremor in the head and neck
- Difficulty in using lower and upper limbs

LINE OF TREATMENT:

In Siddha system the treatment is based upon the *Mukkutram* principle. Treatment is not only for perfect cure but also for the prevention of diseases and rejuvenation of Body Constituents.

1).Purgation

2).Internal Medicine

3).External Medicine

PURGATION :

Agasthiyar kuzhambu – 200 mgs given with ginger juice, in early morning with empty stomach (for the first day only).

INTERNAL MEDICINE:

Sigamani Chooranam – 1 gm bd, with water for 21 days.

EXTERNAL MEDICINE:

Arkkasheerathy Thylam (QS).

DIET TO BE AVOIDED:

Bottle gourd, Pumpkin, Cucumber, Snake gourd, Ridged gourd, Black gram, Indian butter Bean, Cow gram ,Horse gram, Mustard, Gingellyoil, Sour, Salt, Vatha diet, Potato, Plantain, Tobacco, Alcohol, Sexual intercourse.

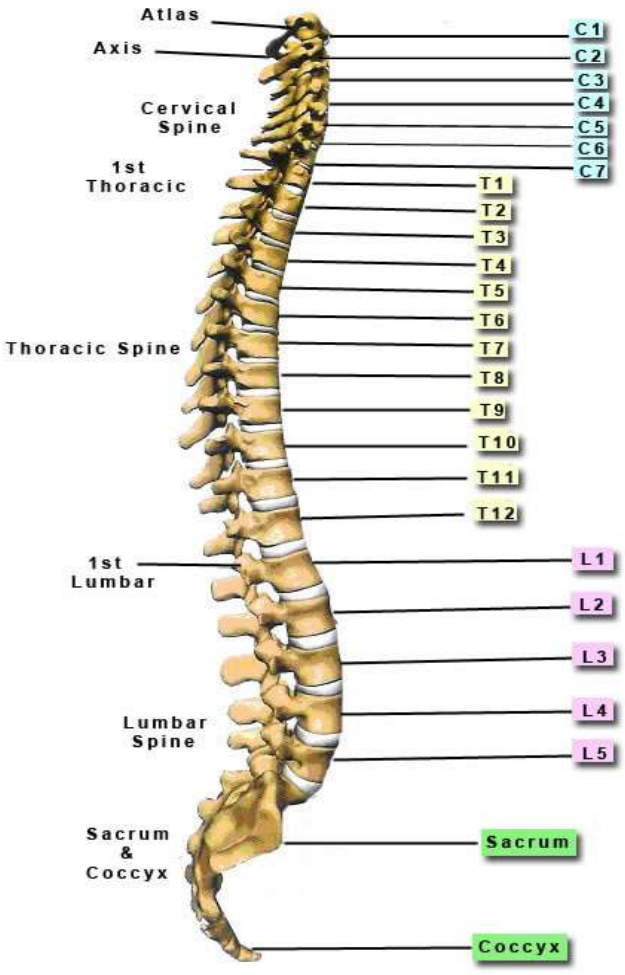
“கடுகு நற்றிலத் தெண்ணெய் கூழ்பாண்டங்கள் கடலை
வடுவதாகிய தெங்குமா வருக்கை நற்காயம்
மடிவிலாத வெள்ளுள்ளி கொள் புகையிலை மதுபெண்
இடறு பாகலோ டகத்தி நீக்கிடலிச்சா பத்தியம்”

- சித்த மருத்துவாங்க சுருக்கம்

MODERN ASPECT

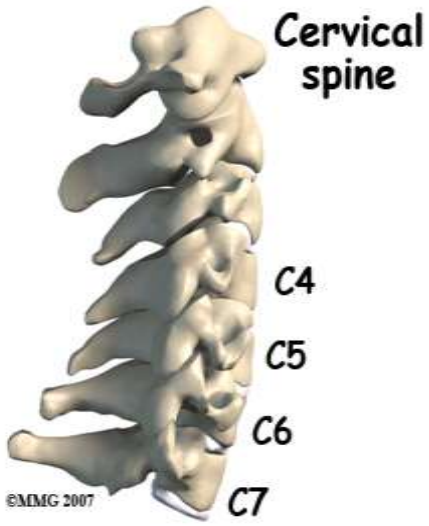
THE VERTEBRAE:

The Vertebrae can be divided into vertebral body and a dorsal vertebral arch.The Vertebral Arch has 2 Pedicles, 7 Process and 2 Laminae. Pedicles are thick bars projecting backward from the body. The Laminae are vertical plate like structures, fuses together to form spinous process. The Spinous process projects downwards and is the level for the muscles. The articular process are four in number,bearing the articular facets and articulate with the adjacent vertebrae. Transverse processes project laterally from the junction of pedicle and laminae. In thoracic region they articulate with ribs.



THE CERVICAL VERTEBRAE:

The Cervical segment of Vertebral column contains 7 Vertebrae. The 1st , 2nd and the 7th are Atypical vertebrae and the 3-6 are Typical. All the cervical vertebrae have a foramen in the transverse process known as Foramen transversarium.It is identical to the Cervical Vertebrae.



ATYPICAL VERTEBRAE:

THE ATLAS (FIRST CERVICAL VERTEBRAE):

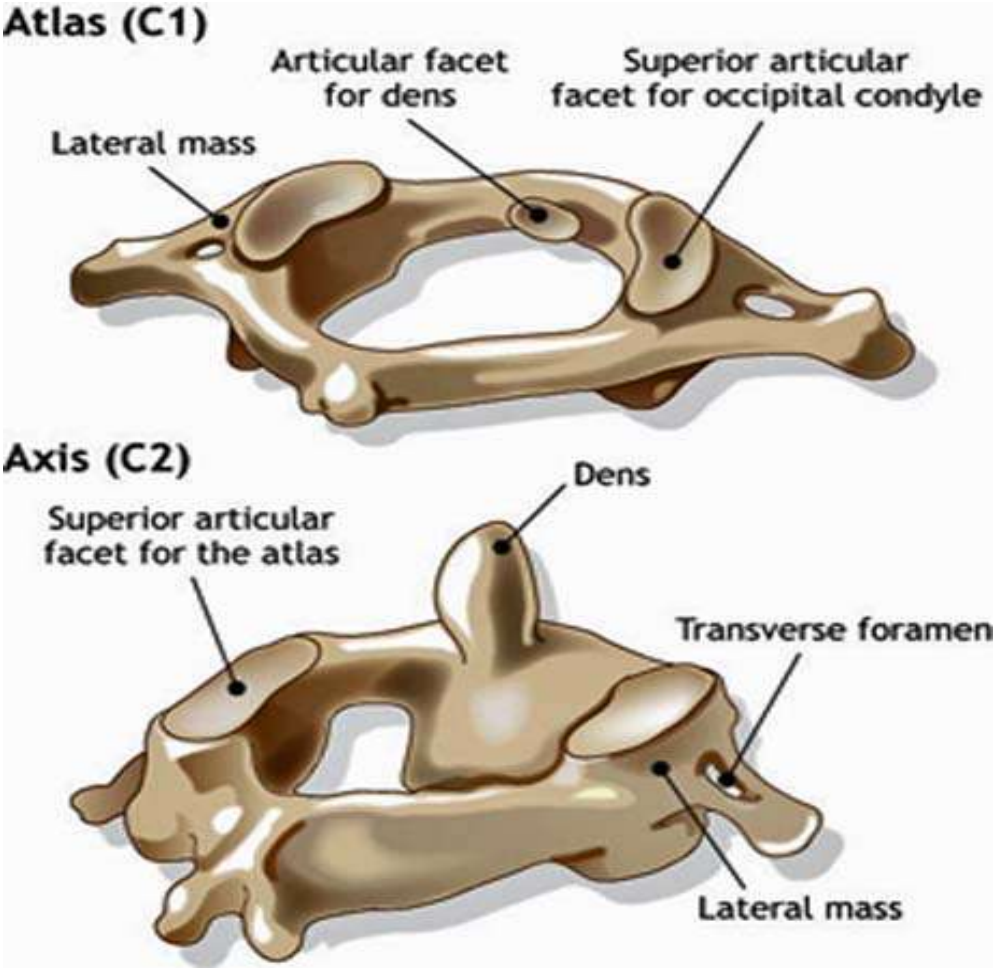
The atlas is ring shaped and has four parts. The anterior arch, the posterior arch and two lateral masses. It have five articular surfaces. It has no body and no spine. The atlas is the top most vertebra and along with the axis forms the joint connecting the skull and spine.

THE AXIS (SECOND CERVICAL VERTEBRAE):

The axis forms the pivot upon which the atlas rotates. The most distinctive characteristic of this bone is the strong odontoid process (dens) that rises perpendicularly from the upper surface of the body. The body is deeper in front than behind, and prolonged downward anteriorly so as to overlap the upper and front part of the third vertebrae.

THE SEVENTH CERVICAL VERTEBRAE:

It is also known as the vertebra prominens because of its long spinous process. The spine is thick, long and nearly horizontal. It is not bifid, but ends in a tubercle. The transverse processes are comparatively large in size. The anterior tubercle is absent. The transversarium is relatively small, sometimes double or may be entirely.



TYPICAL CERVICAL VERTEBRAE:

BODY

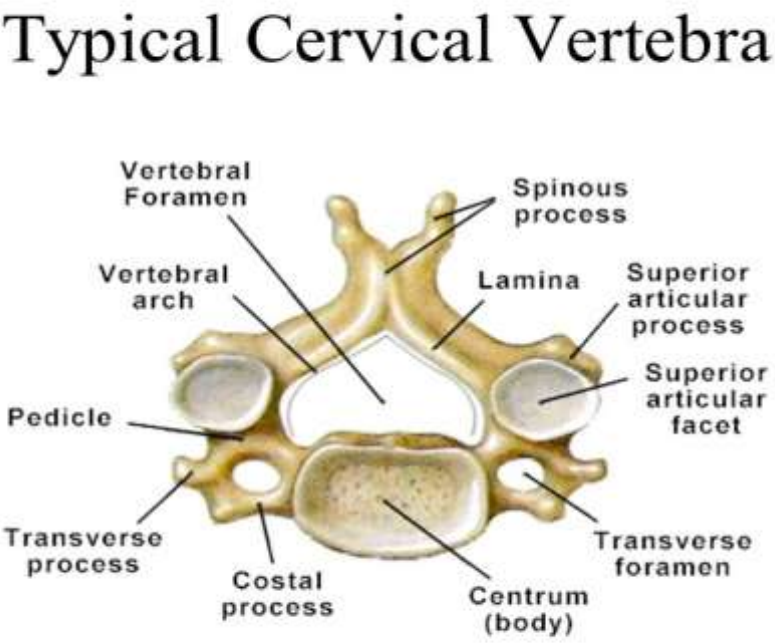
The bodies of these four vertebrae are small, and broader from side to side than from front to back. The bodies are separated from each other by intervertebral disc and are held together by anterior and posterior longitudinal ligaments. They have four surfaces, superior, inferior, anterior and posterior surfaces.

THE VERTEBRAL FORAMEN

It is larger than the body. It is triangular in shape because the pedicles are directed backwards and laterally.

PEDICLE

The pedicles are directed laterally and backward and are attached to the body midway between its upper and lower borders, so that the superior vertebral notch is as deep as the inferior, but it is at the same time narrower.



LAMINAE:

The laminae are relatively long and narrow, being thinner above than below.

ARTICULAR PROCESSES

The transverse processes are each pierced by the foramen transversarium which in the upper six vertebrae gives passage to the vertebral artery and vein, as well as a plexus of sympathetic nerves. Each process consists of an anterior and a posterior part. These two parts are joined outside the foramen by a bar of bone that exhibits a deep sulcus on its upper surface for the passage of the corresponding spinal nerve.

THE INTERVERTEBRAL DISC

The intervertebral disc is thicker in infants than in adults. At birth the discs occupy half the length of the cervical spine. In adults the length is one third of the cervical spine and after the age of 50 it is reduced further. The nucleus changes its shape to accommodate the changes due to motion. It bears loads during movements of the spine. The dense collagen fibres of the annulus are running vertically in the front and are strong. Posteriorly run horizontally and are prone to be fissured.

THE LIGAMENTS:

1.Capsular Ligament.

2.The Anterior Atlanto-Occipital Ligament

3.The Posterior Atlanto-Occipital Ligament

THE MUSCULATURE:

Several muscles support the vertebrae of the spine. The spinalis moves the spine and helps maintain correct posture.

Spinalis cervicis: This muscle begins in the middle region of the spine and travel up to the axis. It may begin at the lower cervical vertebrae or the upper thoracic vertebrae (the section of the spinal column just below the cervical spine) it helps extend the neck.

Spinalis dorsi: This muscle begins at the upper thoracic vertebrae and extends down to the lower back.

Spinalis capitis: This muscle begins at the upper and middle thoracic spine and lower cervical spine. It extends up to the occipital bone, near the base of the skull. This muscle is inseparably connected with another muscle in the neck, the semispinalis capitis.

BLOOD SUPPLY OF VERTEBRAL COLUMN:

The vertebrae and the longitudinal muscles attached to them are supplied by segmental arteries.The arteries give multiple small branches to the vertebral bodies.The extensor muscles of the neck are supplied by the occipital, the deep cervical and the transverse cervical arteries.

VENOUS DRAINAGE:

The Internal vertebral venous plexus lie within the vertebral canal,but outside the spinal dura.It receives tributaries from.

i)The vertebrae through the basilo vertebral veins.

ii)The meninges and the spinal cord.

The internal vertebral venous plexus is drained by the intervertebral veins,which pass out through the inter vertebral foramen.Here they are joined by the tributaries from the external vertebral and sacral veins.The internal venous plexus communicates with the occipital and basilar veins through the foramen magnum.

NERVE ROOT SUPPLY TO THE MUSCLES:

SPINAL ACCESSORY NERVE

Trapezius	C3C4

BRACHIAL PLEXUS

Rhomboidus	C4C5
Serratus anterior	C5C6C7
Clavicular	C5C6
Axillary nerve deltoid	C5C6

MUSCULO CUTANEOUS NERVE

Biceps	C5C6
Brachialis	C5C6

RADIAL NERVE

Triceps lateral head	C6C7C8
Medail head bracheoradialis	C5C6

MEDIAN NERVE

Pronator teres	C6C7
Flexor carpi radialis	C6C7
Flexor digitorum superficialis	C7C8T1

ANTERIOR INTEROSSEOUS NERVE

Flexor digitorum profundus	C7C8
Flexor pollicis longus	C7C8

ULNAR NERVE

Flexor carpi ulnaris	C7C8T1
Hypothenar muscle	C8T1
Abductor pollicis	C8T1

CERVICAL SPONDYLOSIS:

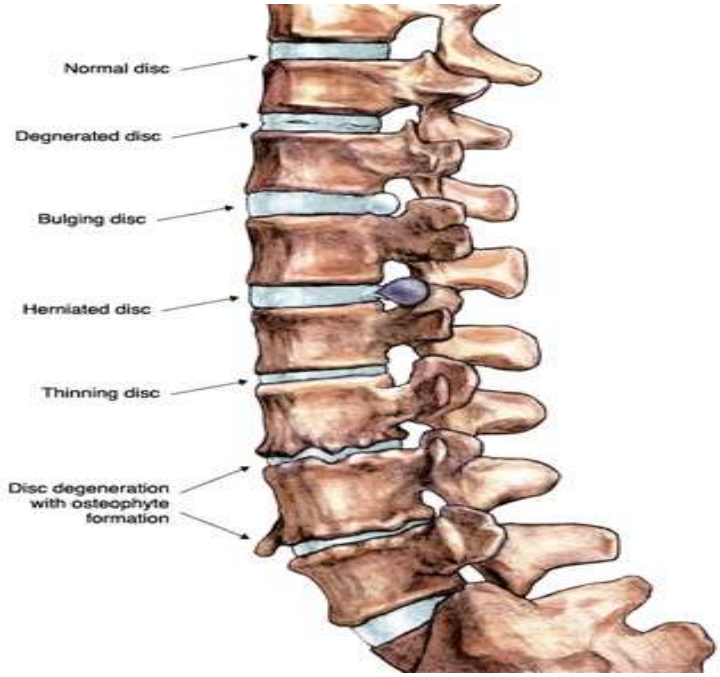
It is characterised by degeneration of the intervertebral disc and osteophyte formation. Such "wear and tear" is extremely common and radiological changes are frequently found in asymptomatic individuals over the age of 50. Spondylosis may be associated with neurological dysfunction. In order of frequency, the C5/C6, C6/C7 & C4/C5 vertebra levels affect C6,C7 & C5 roots, respectively.

EPIDEMIOLOGY:

SEX: The prevalence of cervical spondylosis is similar for both sexes, although the degree of severity is greater for males. Spondylotic changes in the cervical spine occur at solitary disc space levels in 15-40% of patients and at multiple levels in 60-85%. The discs between the third and seventh cervical vertebrae are most commonly affected.

AGE: It occurs as early as 25 years of age. As age increases so does the incidence rate. 60% of the population older than 45 years of age and 8% older than 65 years of age account for the case of cervical spondylosis reported. In males, the prevalence was 13% in

the third decade, increasing to nearly 100% by age 70 years. In females, the prevalence ranged from 5% in the fourth decade to 96% in women older than 70 years.



MECHANISM OF DEGENERATION:

1).Narrowing of the intervertebral disc space (due to nucleus pulposus herniation or annulus bulging)

2).Osteophytic spur formation (dorsal surface of vertebral bodies)

3).Partial subluxation of vertebrae

4).Hypertrophy of the dorsal spinal liganment and dorsolateral facet articulations.

5).Hypertrophied ligamentum flavum with fibrosis and calcification.

6).C5-C6 intervertebral disc has strong attachement to the vertebral column and thid predisposes to degenerative changes

The most common intervertebral joint to undergo degenerations is between C5-C6. It is due to maximal movements occuring at this cervical spine. However, C6-C7 and at times C4-C5 can also be involved.

AETIOLOGY:

1.DEGENERATIVE CHANGES:

Primary-Senility, Genetic factors, Metabolic factors and Manual labour. Secondary Osteoarthritis, Rheumatoid arthritis, Metastatic carcinoma or Lymphomas of the spine and TB spine.

2.OCCUPATIONAL CAUSES:

The physical discomfort, which arises through an occupation is occupational stress. The physical strain, intensity of work and duration of working hours all constitutes the occupational strain.

3.INJURY:

Automobile accidents"Whiplash" injury, Athletic injury. Sudden jerks on the arms during fall down previous injury with fracture or Disc prolapses.

4.HEREDITORY FACTOR:

Congenital narrowing of the cervical spinal canal(myelopathy is often seen when anal's sagital diameteris 12mm or less) Segmental defects-Hemi vertebra,Fused vertebra.

5.ACQUIRED NARROWING OF CERVICAL SPINAL CANAL DUE TO OSTEOPHYTES:

Ossified Posterior Longitudinal Ligament (OPLL) Facet joint hypertrophy (results formainal stenosis and compression of root of radicular artery). Hypertrophoid Ligamentum Flavum (Compress the cord during extension). Outgrowths of bone that sometimes occur with ageing. Intervertebral disc protrusions are commonest in the cervical region which is due to degeneration of the intervertebral disc and if it involves severe discs with osteoartheosis liable to interfere with blood supply of the cord and thus leads to further damage.

SYMPTOMS AND SIGNS:

RADICULOPATHY

- ✓ Neck pain (local or referred pain)
- ✓ Sensory loss and paraesthesia in the corresponding dermatomes (due to sensory nerve root involvement)
- ✓ Weakness and wasting of the muscles supplied (due to motor root involvement) and vertebral biceps reflex (C5 lession)
- ✓ The wasting of the small muscles of the hand is uncommon.

CLINICAL FEATURES OF CERVICAL SPONDYLOSIS:

- Neck pain
- Stiffness
- Weakness
- Pain referred to the interscapular area and upper limb.
- Numbness and parasthesia in the upper limb or side of the face.

EXAMINATION OF CERVICAL VERTEBRAE:

- ➢ Sprulings test
- ➢ Chin chest test
- ➢ Lateral roatation
- ➢ Lateral flexion

SPULINGS SIGN:

In cervical spondylosis, cervical extension results in narrowing of vertebral canal therby producing pain in neck.

SHOULDER ABDUCTION RELIEF SIGN:

Abbduction of shoulder relieves pain in cervical spondylosis.

MYELOPATHY:

The most common presentation of spondylitic myelopathy. It presents with insidious onset of spastic weakness of the legs, dragging of the toes and stiffness of the legs. An accompanying radiculopathy is reported in 40 to 80% of cases. The features of root involvements are asymmetric, asymptomatic or present with focal weakness or wasting or loss of a reflex.

The sensory signs (loss of VS PS, rombergism +) in myelopathy is due to posterior column involvement.

SYMPTOMS:

- ✓ Tingling, numbness, and/or weakness in the arms, hands, legs or feet" s
- ✓ Lack of coordination and difficulty walking
- ✓ Abnormal reflexes
- ✓ Muscle spasms
- ✓ Loss of control over bladder and bowel (incontinence)

PATHOLOGY:

- Narrowing of cervical vertbra with disc space reduction
- Friction between two vertebral bodies created by this narrowing, with an osteophyte (bony spur formation)
- Loss of normal concavity in the cervical region, i.e. loss of lordosis
- Symptoms of vascular insufficiency
- Numbness and tingling sensation in the hands or feet due to compression of the cervical nerve roots.

COMPLICATION:

1. Incontinence of urine and feaces
2. Loss of muscle function or permenanet disability

DIFFERENTIAL DIAGNOSIS:

- ❖ Compression of cord or root (TB or neurofibromas)
- ❖ Syringomyelia
- ❖ Multiple sclerosis
- ❖ Peripheral nerve lession (distal ulnar or median nerve)
- ❖ Motor neuron disease
- ❖ Spinal cord tumors

COMPLICATIONS:

- o Cord compression
- o Nerve root compression
- o VBI (vertebro bascillary insuficiency)

INVESTIGATIONS:

1). Plain X-ray of Neck

Antero posterior view

Lateral view

Oblique view

Features,

1). Loss of normal cervial lordosis

2). Spondylotic bars

3).Disc narrowing and subluxation

4). Reduction of sagital diameter is less than 11mm or 7mm (in neck extension)

2. Myelogram-May show compression of the spinal cord

3. C.T Scan (Computerised Tomography)

- Comprises degenerative changes
- May demonstrate posterior osteophytes and disc herniation

4.MRI-(Magnetic Resonance Imaging)

- Neural compression
- Intristic cord changes
- Disc generation

5 Examination of CSF

- Very high protein

6. EMG(electromyelogram):

It is used to check that your nerves are functioning normally when sending signals to muscles.

7. Other tests:

- Nerve conduction studies.

VARMAM ASPECT

VARMAM:

Varmam is the subtle energy that functions inside the body. It is the manifestation of the five elements (*Iym Bootham*), vital airs (*Vayu-10*), *Naadis, Vaasi, Kundalini*. This is revealed in the following verse of *Vagada Nithanam* and *Varma sara nool* as,

காணுகின்ற கேசாதி பாதமெங்கும்
கதிந்தோடும் வாசிநிலை வர்மம்

உடலுயிர் நாடிதனில் ஊன்றிடும் வாசியதாம்
ஊனுடல் மருவியே ஊடாடும் நிலை வர்மம்

உயிருக்குள் உயிராய் எங்கும்
தானாக நின்ற தற்பரன்

பரமான அசைவதற்குள் ஊடாடி
மருவினதோர் வர்மம்

VARMAM POINTS:

The places where the *Varmam* energy resides and activates both body and life-energy are *Varmam* points. These points are located in the nerves, *naadi*, muscle and bones. They are the sites of bio-energy which aid physiological functions of the body.

It is also said that *Varmam* points are the places where the vital energy *Vaasi* strikes. The following lines express this as

வாசி தட்டும் தலமெல்லாம் வர்மதலம்
வாசி மறைக்க மயங்கிடும் காயம்

உடலுயிர் பரவுஞ் சக்தி
ஊர்ந்தேறு மிடங்கள் வர்மம்

செப்புறு தசைகளென்பு சிறுபெரு நரம்புசந்து
தப்புறு நாடியாலும் தங்குமிடம் வர்மமாகும்

CLASSIFICATION OF VARMAM:

There are two kinds of classification. One is based upon region wise distribution and the other is based upon *aadharams*. In both kinds, the total number of *Varmam* points is said to be 108 in number.

The number of *Varmam* points located in upper limb is 15, lower limb is 14, below the navel is 9, above the navel is 45 and above the neck is 25.

ஆச்சென்றால் காலில் மூவைந்தாச்சே அப்படிகையில் ஈரேழுமாச்சு
மெச்சென்று உந்திக்குக் கீழ்மேவிய ஒன்பதுவுமாச்சு
நேச்சொன்றால் உந்திக்கும் மேல் நேர் மூன்று ஆறேழாச்சு
மிச்சமென்றால் கண்டத்திற்கும் மேல் அய்யஞ்சு அதுவுபாரே

ஓமென்ற ஆதாரம் ஆறுக்குள்ளே
உண்டப்பா நூற்றி எட்டு வர்மந்தானே

TYPES OF VARMAM:

Varmam points are the places which activate, regulate, supplies energy and functions according to the body needs. The *Varmam* text *"Varma Vilvisai"* enumerates 8000 *Varmam* points and *Kumbamuni narambarai* describes 251 points. Most of the *Varmam* texts enlist 108 *Varmam* points of which 12 are *padu varmams* and 96 are thodu varmams. Other types of Varmam mentioned in the texts are *vatha varmam (64), pitha varmam(26), silaethuma varmam(6).*

ஆகுமே தொடுகருவி தொண்ணூற்றாறும்
தொகுப்பான தொடுவர்மம் ஆகும்பாரு
வேகமாய் படுவர்மம் பன்னிரண்டில்
வேந்தனே நின்றகருவி அறிய சொல்லு
ஏகமாய் பன்னிரண்டு கருவி எங்கே
என்னப்பா இல்லாவிட்டால் நூற்றெட்டேது
ஊகமாம் நூற்றெட்டு வர்மம் ஆனால்
உத்தமனே பன்னிரண்டும் அறிந்தோன் ஆசான்.

வர்மமென்ற வாத வற்மம் எட்டெட்டாகும்
வகையான பித்தவற்மம் இருபத்து ஆறாம்
தர்மமென்ற சிலேர்பன வர்மம் ஆறதாகும்
தயவான படுவர்மம் பன்னிரண்டாம்
கர்மமென்ற இவைகூட்டி தொகையைப் பாரு
கருவான தொகைசரியாய் நூற்றெட்டாச்சு
சர்மமென்ற இவைதானே சப்த தாது
சடமான தேகம் எழுவகையில் மூணுபங்கே

Padu varmams are the varmam points which are directly connected to brain energy and serve as major energy storage points. According to "*Pingala nigandu"*, the word *'padu'* means brain. *Thodu varmams* are the *varmam* points which are connected to *padu varmams.* The word *'thodu'* refers to touch. It means through the act of touch, one *varmam* point is connected to another *varmam* point. Such a way, eight *thodu varmams* are connected to one *padu varmam* i.e 8 x12 = 96 *Thodu varmam*. They serve as minor energy storage points.

அறிவான வாசிதட்டும் தலம் ஈராறில்
அறிந்து பார் படுவற்மத்தலம் இராறு
குறியான வாசிதட்டும் இடம் ஒன்றில்தான்
கூறுவேன் கருவிக் கெட்டு தொடுகாலம் தான்
பிரியாத தேகதேகி அறிந்து தத்துவ
கருவிகளை அறிந்தவன்தான் ஆசானாகும்

The total number of *Varmam* points which accounts to 108 comprises two terminologies *Varmam* and *Kaalam.* The word *Varmam* refers to static energy and the term *Kaalam* refers to kinetic energy.

மாளப்பா வர்மம் வேறு காலம் வேறாம்
நாளப்பா வர்ம மென்றால் வளமையுடன்
நிலை பெற்று எந்நாளும் இருப்பதாகும்

VARMAM APPLICATION:

When anyone of the basic functions of *Varmam* is affected it leads to disease. The treatment Protocol includes

1) Stimulation of *Varmam* points
2) External treatment like Oileation, *Ilaikizhi*, *Neikizhi*, etc.

தயவாக கையதனா லிதமுஞ் செய்தால்
வாற்முருகன் கிருபையினால் நன்மையாகும்

செய்பாகம் அறியவேணும் புனிதமுடன்
கைபாகம் தலங்கள் வேணும்
ஓமென்ற மாத்திரையின் விபரம் வேணும்
உத்தமனே பாதைகள் ஓர்மை வேணும்

நீங்கிடும்நீ படுவற்மம் பதினெட்டுக்கும்
நிலையான தொடுவற்மம் தொண்ணூற்றாருக்கும்
வாங்கிடுநீ தலங்களெல்லாம் அறிந்து கொண்டு
வகையறிந்து செய்தாலே நன்மையாகும்

அறிந்து செய் தேகமதும் வயசும் காலம்
அவரவர்க்கு இசைந்த வண்ணம் தடவல் மாத்திரை
தெரிந்து செய் இதம் பதமாய் நடத்தாவிட்டால்
தேசத்தில் நீயேதான் காலனென்பார்
பிரிந்து வரும் இனமறிந்து பேணிச் செய்யில்
பிரம்மனவன் வந்தாலும் பிசகாதப்பா
சரிந்து நின்று சர்குருவை மனதில் வைத்து
சண்முகனை தியானித்து சலியாமல் இளக்குவாரே

The stimulation of *Varmam* points is called as *'Kaibaham', 'seibhagam'*. This is executed in 12 different ways like *anukkal, asaithal, thattal, thadaval, yenthal, oondral, pidithal, nazhukkal, amarthal, pathukkal, karakkal, pinnal.*

பிடிக்க நழுக்கு கணக்கு பதுக்குத்
தாக்கு துன்பம் வந்து அணுகாமல்
பதிவு செய்யும் துறையைக் கேளு
இடக்கை கொடியில் வைத்து
தப்பாமல் வலக்கையால் பஞ்சதட்டு
தட்டையிலே மயக்கம் போடும்

Each *Varmam* can be applied in 12 different ways in four different amount of pressure (*Mathirai*) i.e. *Mathirai Kanakku – Pathi Kanakku.* These parameters refer to amount of pressure applied during *Varmam* treatment. The depth of touch is *Mathirai Kanakku* and the Pressure of touch is *Pathi Kanakku*. Thus a *Varmam* point can be activated in 48 ways. A sound knowledge of application of *Varmam* points in this context can be best gained in Gurukula Training,

செய்வதற்கு குணடங்களுடன் குறிப்பறிந்து
குருவருளால் குருதொட்டுக் காட்டிச் செய்தால்
நய்வதென்று நோயதுவும் நழுகிப் போகும்

A deep knowledge about Medical Varmalogy is needed to exhibit the Siddha pathology. It is further needed to execute *Thadaval Murai* (Massage). Because each and every stroke advocated is based upon *thuvathasa naadi, thasa vaayu, vaasi, ethirkalam, marukalam, adangal, adukkugal, sarappai, amirtha nilaigal, kona nilaigal.* Treatment should be started considering the *Naadi, Ethir Kaalam, Maru Kalam.*

ஆகுமே அடங்கல் பலவாறான மார்க்கம்
இயம்புகிறேன் புவியோர்கள் அறியத் தானே
ஆகுமென்ற நரம்பது தான் பின்னிவரும்
நலமான தானமதே அடங்கலாகும்

Adangals are the places of enormous energy storage. They are used for emergency treatment to revive a person from unconsciousness. When *adangals* are ineffective, *thiravukols* are advocated. *Varmam* texts describe in detail about 110 adangals and 13 thiravukols.

LOCATIONS OF VARMAM POINTS:

Varmam Points in the body can be determined by

- Anatomical location
- Proportional Measurement
- Graphical measuring method
- Locating by reference to adjacent *Varmam* points
- Location by Classification
- Finger breadth Measurement Method
- Thread - Measurement Method

VARMAM STIMULATION FOR CAGANA VAATHAM:

The following *Varmam points* will be given thrice in a week for *cagana vaatham*

1).Sara Mudichu Varmam:

முடிச்சியப்பா கழுத்தடியில் புசம் நேராக
முன்னொளியாம் சரமுடிச்சி ஒன்று

“இருப்பென்னும் கழுத்தினோடு தோள்
புஜம் சேரும்ஸ்தானம்
விருப்பென்னும் தண்டெலும்பில்
வலுக்கட்டும் நிலையம் இங்காகும்
உறுப்பெறும் தலைகழுத்து வலுகட்டும்
தன்மைஇங்கேயாம்”

It is located at the back in the cervical prominence, at the C7- T1 junction.

2).Kakkattai Kaalam.

“வழுவிலா தோளில் இரண்டங்குலம் மகுவு
வன்மையுள்ள காக்கட்டைக் காலம்”

“பாரடா தோளில் இருவிரல்தான் நீங்கி
பரவு காக்கட்டை காலமாகும்”

“சுழியாடி வர்மத்தின் பக்கமாக
சுட்டமிறை நடுவு காக்கட்டைக்காலம்”

“வாறான தோள் ரெண்டங் குலமே நீக்கி
மருவுகின்ற தலமதிலே காக்கட்டைக் காலம்”

It is located in the supraclavicular fossa.

‘பாரிதுவே காக்கட்டைக் காலமதாய்ப் புஜப்பொய்கையில்
புஜகழுத்தின் வில்லாகவும் விசையாகவும் சார்ந்திருப்பதுவே”

“ஆகுமிந்த யுடலின்கீழ் முண்டத்திற்கு பலமதாய்
வாகுபெரும் மேலுறுப்பிற்கும் இவ்விதமாக நாளமதுயிருப்பதாய்வீர்
அசைத்தலுடன் திருப்புதல்தான் வேகமாய் தலைமைதரும்
நாளத்தின் வலுவாய்கட்டு இவ்விடத்தில் யிருப்பதுணர் வன்மையாமே”

The above verse from *varma sootcham* explains the physiological functions of *kakkatai kalam*. It reveals that *kakattai kalam* supplies energy and acts as an anchorage to the whole body below the neck and it helps in the movement of neck.

“காக்கட்டை காலத்தின் செய்கை கேளு
மின்னியே யிருபக்க கலைகள் தன்னை
வெட்டியே யிருவிரலால் பிடித்து தூக்கே
உன்னியே நாடியின் யிருபக்கம் சுற்றி
நெட்டியே அசைத்துவிடு நிமிசத்தில்தான்”

“விரலூன்றி வைத்துக் கொண்டு
தலையை யிருபக்க அசைக்க சொல்லு
சுத்தினதான் தலைமேல்கீழ் அசைக்க சொல்லு
அண்ணாரும் போலப்ப சுழியில் ஊன்றே”

The above lines from *varma kaandam* describe the technique of stimulation of *kakkatai kalam.*

“வன்னமாம் தலை தின்னமாய் பெந்தமுற்ற
சக்திநாளம் நிலையாகி யிருப்பதந்த தலபிதமாமே
ஆகுமிந்த கைதளர்ந்து தரிப்பு மீறும்
உயர்த்தி தாழ்த்தி வைத்துக்கொள்ள வொண்ணதாகும்’

Varma sootcham reveals the clinical symptoms of any energy loss to this *varmam* leads to weakness of the upperlimbs, radiculopathy with numbness and movement restriction.

3).chavvu Varmam:

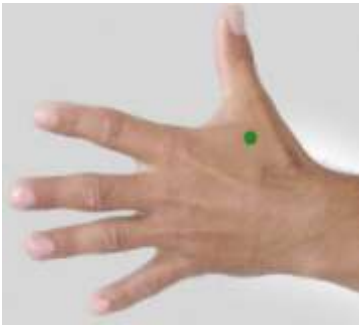
புயந்தனிலே அசைவு வர்மம் புகலலாமே”
“மாற்றிய தோர் அசைவு வர்மம் குணமே தெனி”

“ஏகுமே புசத்தடியில் அசைவு வர்மம்”
வேணவே கைக்குழி மடக்கில் தானே
விதமான அசைவு வர்மம் எனவும் சொல்வார்
புஜத்தோடு கமுக்கூடு சேர்கின்ற உறைவானயிடத்தில் நின்று
கைஎன்பின் அகம்பற்றி மேல்நோக்கி பிரிவுநாளம்
நாளத்தின் இடையில் வர்மம் கூறுகிறேன்
கை அசைவிற்கு உற்றதொரு நரம்பிங்கே”

“புஜத் தொடைய விசையும் வில்லும்
கழுத்து சுழியாடி சங்குதிரியைப் பற்றும்
வலப்பமான விசையிங்கே கடந்துசெல்லும்
புஜகுண்டின் வலுவிற்காம் வில்லுமிங்கே”

It is located medially in the upper arm down the meeting place of the shoulder and the axilla. The *narambu* traversing this region helps in the movement of the hand and *vil visai* travels through this point strengthens the shoulders.

4).Kavuli Kaalam:



“தானிதே கையிடைலில் கவளி தன்னில்
மானிதே பெருவிரலின் இடுக்கிலப்பா
மகத்தான இடுக்கு வர்மமிதற்கு பேரு”

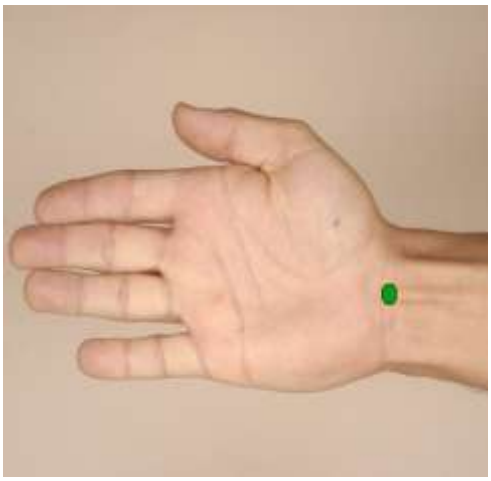
“கற்ப மென்ன கையிடையில் கவளிக் காலம்
இப்படியே பெருவிரலிடையில் இருக்கு வர்மம்”

“பேர் பெரிய பெருவிரலுக்கிடையில்
கையில் பெரிதான கவுளி”

“சார்ந்திட்ட தலமிங்கே பின்தலை சுழியாடி
கூர்ந்திட்ட நரம்புநாளம் கடந்துசெல்லும் தலமிது
புஜகுண்டிற்கு பெலத்தைக் கொடுக்கும்”

It is located in the first web space between the thumb and index finger. It surpasses the blood vessels supplying posterior part of the head and *suzhiyadi* and it gives strength to the shoulder joint.

5).Manibantha Varmam’



“இனகயதாம் மணிக்கெட்டாகும் இடத்திலே
மணிபொந்தம் பார்

“தானென்ற மணியது ரெண்டிறைக்கு மேலே
தரணிதனில் பந்த மென்ற காலமப்பா
பிரியாக மணிக்கட்டில் மணி பந்த வர்மம்

It is located in the middle of the wrist joint

“முழமுங்கையை பிடித்துக்கொண்டு
பிடிப்படி மணிக்கட்டில்தான் உடன்விடும்”

The above lines reveal the application method of *manibantha varmam.*

MATERIALS AND METHODS

STUDY TYPE	**:**	An open clinical trial.
STUDY PLACE:	**:**	Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47.
STUDY PERIOD	**:**	12 months
SAMPLE SIZE		40 patients (20 patients with Trial Medicine 20 patients Trial Medicine with Varmam)

TRIAL DRUGS:

INTERNAL MEDICINE:

Drug	**:**	*SIGAMANI CHOORANAM*
Reference book	**:**	*Kannusamy parambarai vaidhyam*
Page No	**:**	118
Dosage	**:**	1gm (*Thirikadi alavu*) bds/after food
Adjuvant	**:**	water
Duration	**:**	20 days
Edition	**:**	fifth print-2006
Author	**:**	*C.Kannusamy pillai*
Publication	**:**	*B.Rathna nayakkar & sons*

PREPARATION OF TRIAL DRUGS:

Ingredients:

Arugam ver (*Cyonodon dactylon)* ***Veppam pattai*** *(Azaridacta indica,A.juss)* ***Narsangan ver pattai*** *(Azima tetracantha,lam)*	Each 4 palam(140gms)

Chukku *(Zingiber officinale,Roscoe)*

Omam *(Carum copticum,linn)*

Narseeragam *(Cuminum cyminum,linn)*

Thippili *(Piper longum,linn)*

Milagu *(Piper nigrum,linn)*

Poolangkizhangu *(Curcuma zeodora,Roscoe)*

Arathai *(Alpinia galanga,linn)*

Vaalmilagu *(Piper cubeba,linn)*

Vaivilangam *(Embelia ribes,Burm.f)*

Parangisakkai *(Smilax china,linn)*

Kurosaaniomam *(Hyoscyamus niger,linn)*

Kadukurogini *(Veratri virdi Rhizome)*

} each ½ palam (17.5gms)

Akkarakaram *(Anacyclus pyrethrum,linn)*

Siruthekku *(Cleodendrum serratum)*

Kirambu *(Syzygiyum aromaticum,linn)*

Jaathikaai *(Myristica fraganans)*

Elam *(Eletteria cardomum,linn)*

Karunjeeragam *(Nigella sativa,linn)*

Lavangapattai *(Cinnamomum verum)*

Jaathipathiri *(Myristica fragnans,houtt)*

} each ½ kazhanju (2.56gms)

Koshtam *(Costus specious)*

PURIFICATION OF RAW DRUGS:

***1). Arugamver*:**

Dried under sunlight.

2). Veppampatta*i:*

Gently scraped the outer layer of the bark.

3). Narsanganverpattai:

Gently scrapped the outer layer of the drug dried under sunlight.

4). Chukku:

Fried in lime stone water and peeled the outer portion.

5). Omam:

The drug soaked in lime stone water and then dried.

6). Narseeragam:

Removed the dust particles and dried under sunlight.

7). Thippili:

The drug Soaked in lemon juice and dried.

8). Milagu:

The drug soaked in butter milk and fried.

9). Poolankizhangu:

Washed with pure water and then peeled out the outer layer.

10). Arathai:

Scrapped the outer layer and then dried under sunlight.

11). Vaalmilagu:

Gently removed the knob of vaalmilagu and dried under direct sunlight.

12). Vaaivilangam:

Removed the dust and dried under sunlight.

13). Parangisakkai:

Powdered and purified with milk by steaming method.

14). Kurosaani omam:

Removed the dust particles.

15). Kadugurogini:

Soaked in neem leaf juice or nochi leaf juice for 3 hours and then dried under sunlight.

16). Akkarakaaram:

Scraped out the outer layer.

17). Sirutheku:

Removed the dust and dried under sunlight.

18). Kiraambu:

Removed the dust and dried under sunlight.

19). Jaadhikkai:

Removed the dust and dried under sunlight.

20).Elam:

Removed the dust and dried under sunlight.

21).Karunseeragam:

Drug soaked in lime water and dried.

22).Elavangapattai:

Removed the dust and dried under sunlight.

23).Jaadhipathiri:

Removed the dust and dried under sunlight.

24).Koshtam:

Removed the dust and dried under sunlight.

(REF: Sarakku Suthimurai)

METHOD OF PREPARATION:

1). The drugs which is mentioned above ingredient no.1 is made into small pieces and allowed to boil in the drug milk mixture under low flame without evaporating the whole milk then dried in sunlight and powdered it finely.

2). Rest of the drugs should be roasted and powdered along with above powdered drug and filtered through a dry clean cloth (Vasthirakayam).

3). Finally finishing the whole procedure to adding equal quantity of sugar (Naattu Sarkarai) to the drug.

DRUG STORAGE:

The trial drug *Sigamani Chooranam* is stored in clean dry air tight container and it is dispensed to the patients in packets.

EXTERNAL MEDICINE:

Drug	**:**	**"***ARKKASHEERATHY THYLAM"*
Dosage	**:**	Q.S(for external application)
Reference	**:**	*Siddha vaithiya thirattu*
Page no	**:**	261
Edition	**:**	2009
Author	**:**	*Dr.Ka.Na.Kuppusamy muthaliyar, Dr.Ka.Su.Utthamarayan*
Publication	**:**	Kannan press private limited.

B. EXTERNAL MEDICINE:

Ingredients:

Erukkampaal *(*milk of *Calotropis gigantea)*	Each 5 palam (875gms)
Erukkanilaisaaru *(*juice of leaves *Calotropis gigantea)*	
Sathurakallipaal *(*milk of *Euphorbia antiqurom)*	
Sathurakallisaaru *(*juice of *Euphorbia antiqurom)*	
Pirandairasam *(*juice of *Cissus quadrangularis)*	
Parpadaga kudineer *(*decotion of *Indoneesiella echioides)*	
Merugankizhangu saaru *(*juice of *Dioscorea esculenta)*	
Nallennai *(*oil of *Sesamum indicum)*	10 palam (350gms)
Saerangkottai *(Semicarous anacardium)*	5 palam (875gms)
Naervaalam *(Croton tiglium)*	1/2 palam (17.5 gms)

PURIFICATION OF DRUG:

1). Saerangakottai:

Removed the knob of serangkottai and boiled in cowdung water (Saanappal).

(Ref: Gunapadam mooligai vaguppu)

2). Naervaalam:

Boiled the drug in cowdung water and then soaked in lemon juice after that removed the inner portion and then fried with ghee. (Ref: Marunthu Sei iyalum kalaiyum)

METHOD OF PREPARATION:

Mix all the ingredients together and boiled it in low flame and allowed it to attain favorable consistency (Manal Patham).

DRUG STORAGE:

The trial drug "***Arkkasheerathy thylam"*** is stored in clean dry bottles and distributed in dry plastic container.

VARMAM POINTS:

1). Mudichu
2). Kakkattai
3). Chavvu
4). Kavuli
5). Manibandham

SUBJECT SELECTION:

Patients reporting with symptoms of inclusion criteria will be subjected to screening test and documented using screening proforma.

INCLUSION CRITERIA:

- Age: 20 - 60Yrs
- Sex: Both male and female, transgender.
- Pain present in the cervical region radiating to the back of the head, top of the shoulders, shoulder blades, upper arms and hands.

- Numbness and paraesthesia.
- Difficulty in flexion and extension of neck.
- Degenerative changes of cervical vertebra.
- Patients willing to undergo radiological investigation and Laboratory investigations.
- Patients willing to sign the informed consent.

EXCLUSION CRITERIA:

- Spondylolisthesis
- Rheumatoid arthritis
- Cervical injury
- Tuberculous arthritis
- Cervical myelopathy
- Cervical rib
- Torticollis (wry neck)
- Pyogenic bone infection
- Vertebral fracture
- Tumour in vertebral body
- Osteochondritis
- Ankylosing spondylitis
- Sexually transmitted disease.

WITHDRAWAL CRITERIA:

- ✓ Intolerance to the drug and development of adverse reactions during trial.
- ✓ Poor patient compliance and defaulters.
- ✓ Patient turning unwilling to continue in the course of clinical trial.
- ✓ Occurrence of any serious illness

TESTS AND ASSESSMENTS:

A. Clinical assessment
B. Laboratory investigations
C. Radiological investigations
D. Siddha system assessment

A. CLINICAL ASSESSMENT:

- Tenderness
- Pain in nape of neck
- Numbness
- Difficulty in flexion and extension
- Difficulty in lateral rotation
- Neck Stiffness
- Radiating pain.

B. LABORATORY INVESTIGATION:

Blood :

- Hb
- Total WBC Count
- DC-
    1. Polymorphs
    2. Lymphocytes
    3. Eosinophil
    4. Monocytes
    5. Basophils
- Total RBC count
- ESR
    ½ Hr:
    1 Hr:
- Blood sugar
    Fasting :
    Post prandial :

Urine:

- Albumin
- Sugar
    Fasting :
    Post prandial :
- Deposit

Renal function tests:

- Urea
- Creatinine

Liver function tests:

- Serum total bilirubin
- Direct bilirubin
- Indirect bilirubin
- Serum Alkaline phosphatases
- SGOT
- SGPT

Lipid profile:

- Total cholesterol
- TGL
- LDL
- VLDL
- HDL

SPECIFIC INVESTIGATIONS:

- CRP
- ASO TITRE
- RA FACTOR

C.SIDDHA PARAMETERS:

Envagai thervugal:

- Naadi
- Sparisam
- Naa
- Niram
- Mozhi
- Vizhi
- Malam

- Moothiram
    A. NeerkKuri
    B. Neikkuri

C. RADIOLOGICAL INVESTIGATION

X-ray for cervical region

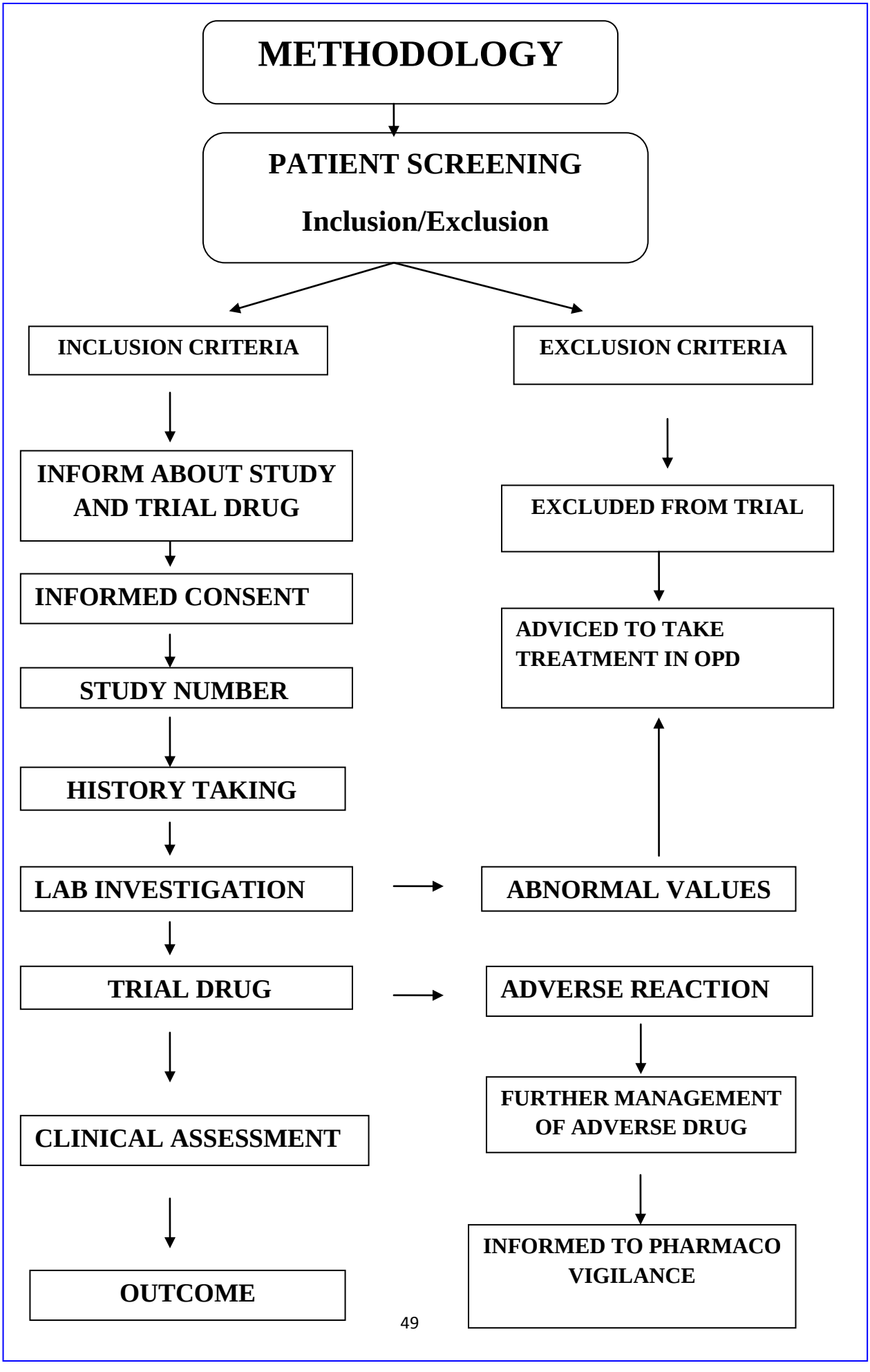
AP & Lateral view

DATA COLLECTION FORMS:

Required information will be collected from each patient by using the following forms:

FORMS:

Form I	Screening and selection Proforma
Form II	History taking & Clinical assessment Proforma
Form III	Laboratory investigation Proforma
Form IV	Drug compliance form
Form V	Patient information sheet
Form VI	Consent form
Form VII	Withdrawal form
Form VIII	Dietary Advice form


METHODOLOGY
PATIENT SCREENING
Inclusion/Exclusion
INCLUSION CRITERIA
EXCLUSION CRITERIA
INFORM ABOUT STUDY AND TRIAL DRUG
EXCLUDED FROM TRIAL
INFORMED CONSENT
ADVICED TO TAKE TREATMENT IN OPD
STUDY NUMBER
HISTORY TAKING
LAB INVESTIGATION
ABNORMAL VALUES
TRIAL DRUG
ADVERSE REACTION
FURTHER MANAGEMENT OF ADVERSE DRUG
CLINICAL ASSESSMENT
INFORMED TO PHARMACO VIGILANCE
OUTCOME

STUDY ENROLLMENT:

Patients reporting at the OPD with clinical features of pain in nape of the neck radiating to upper limbs, stiffness are chosen for enrollment based on the inclusion criteria.

The patients who are enrolled had been informed (Form V) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and then informed consent would be obtained in writing from them in the consent form (Form VI).

Complete clinical history, complaints, duration, examination findings and laboratory investigations - would be recorded in the prescribed Proforma. Screening Form-I would be filled up: Form –II and Form –III would be used for recording the patients history, clinical examination of symptoms, signs and laboratory investigation.

If there is any abnormal laboratory reports obtained then the patient excluded from that study. Patients would be advised to take the trail drug and to follow the appropriate dietary advice (Form VIII).

CONDUCT OF THE STUDY:

On the first day of the treatment Purgation had been given with ***Agasthiyar kuzhambu - 200 mg*** early morning with Ginger juice for balancing the vitiated humous. The next day onwards the trial drugs ***Sigamani Chooranam*** (internal) ***Arkkasheerathy Thylam*** (external) would be given for 45 days. 20 patients would be given varmam treatment along with trial medicine and remaining 20 would be given trial medicine only. If there is a need of IP the patient would be admitted for clinical assessment.

For out-patients, the trial drugs had been given in the Out-patient Department of Sirappu Maruthuvam of National Institute of Siddha. The out-patients would be asked to have a regular follow-up in the OP Department once in 7 days. (Form IV) In each and every visit, the clinical assessment had been recorded in the prescribed proforma. The laboratory investigations would be done before and after treatment and recorded in the prescribed format. At the end of the trial the patients are advised to have follow-up for 2 months Defaulters would not be allowed to continue and had been withdrawn (Form VII) from the study.

DATA ANALYSIS:

After enrolling the patient for the study, a separate file for each patient will be opened and all forms will be kept in the file. Study No. and Patient No. will be written on the top of file for easy identification. Whenever the patient visits OPD during the study period, the respective patient's file will be taken and necessary entries 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. All forms will be further scrutinized in presence of Investigators by Sr. Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased report.

PHARMACO VIGILANCE:

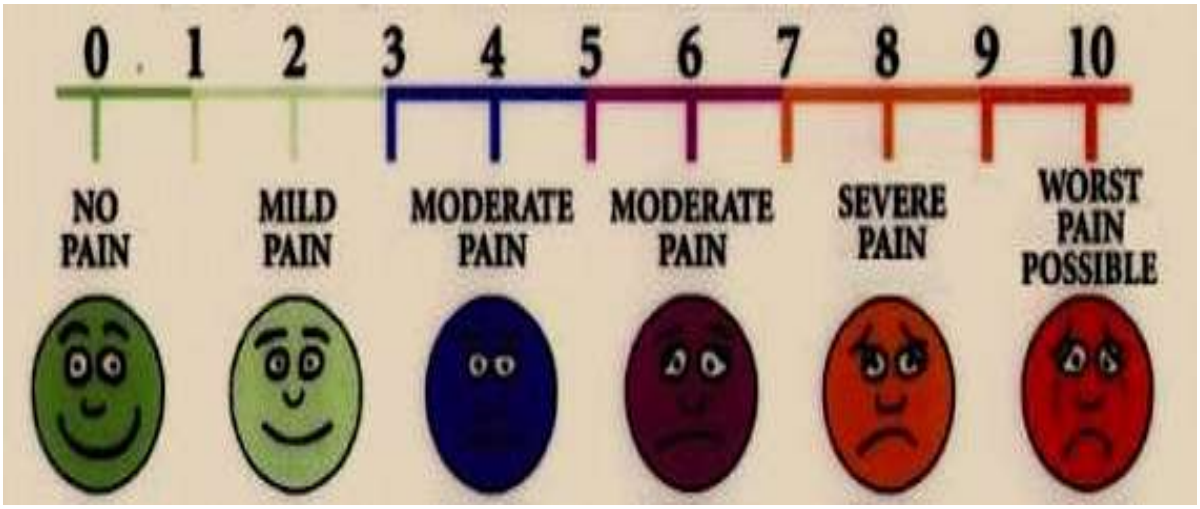
ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT

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 informed to the Pharmaco-vigilance (FormVII) committee of NIS.

OUTCOME:

The outcome will be assessed by using Universal Pain assessment scale (before and after treatment).

UNIVERSAL PAIN ASSESMENT SCALE:



Grade 0	**:**	**No Pain**	**0 - Good improvement**
Grade 1-3	**:**	**Mild pain**	**1-3 - Moderate improvement**
Grade 4-6	**:**	**Moderate pain**	**4-6 - Mild improvement**
Grade 7-10	**:**	**Severe pain**	**7-10 - No improvement**

ETHICAL ISSUES:

1. To prevent any infection, while collecting blood sample from the patient, only disposable syringes, disposable gloves, with proper sterilization of laboratory equipment will be used.

2. No other external or internal medicines will be used, other than the trial drug for ***CAGANA VAATHAM***. There will be no infringement on the rights of the patient.

3. The data collected from the patient will be kept confidential.

4. After getting the consent of the patient only (through consent form in their own vernacular language) they will be enrolled in the study.

5. Treatment would be provided free of cost.

6. In any adverse reaction observed during the trial the patients will be withdrawn and given alternative treatment at National Institute of Siddha for further management.

PROPERTIES OF TRAIL DRUG

அறுகன் வேர்

Tamil name	:	அறுகு
Botanical name	:	*Cyonodon dactylon*
Family	:	Poaceae
Parts used	:	Herbs & Root Stalks
சுவை	:	இனிப்பு
தன்மை	:	தட்பம்
பிரிவு	:	இனிப்பு
Chemical constituents	:	Ergonorine, Ergine
Therapeutics actions	:	Astringent, Emolient, Styptic, Diuretic

பொது குணம்:

"அறுகம்புல் வாதபித்த ஐயமோ டீளை
சிறுக அறுக்குமின்னுஞ் செப்ப அறிவுதரும்
கண்ணோ யொடுதலைநோய் கண்புகையி ரத்தபித்தம்
உண்ணோ யொழிக்கு முரை".

வேம்பு

Tamil name	:	வேம்பு
Botanical name	:	*Azaridacta indica*
Family	:	Meliaceae
Parts used	:	Whole tree
சுவை	:	கைப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கைப்பு
Chemical constituents	:	Azadiractin, Nimbin, Tannin, Margositostrol, Margosine, Nimbinin, Nimbidin.
Therapeutics actions	:	Antihelmenthic, Stimulant.

பொது குணம்:

"கிருமிகுட்டம் மாந்தங் கெடுவிடைஞ்சு ரகங்ள்
பொருமியம சூரிகையின் புண்கள் ஒருமிக்க
நிம்பத் திலையிடுக்க நீடுலகில் நீங்காமல்
கம்பத் திலையிருக்கக் காண்".

சங்கன்

Tamil name	:	சங்கம் செடி
Botanical name	:	*Azima tetracantha*
Family	:	Salvadoraceae
Parts used	:	Root, Bark, Leaves, Milk
சுவை	:	கைப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Azcarpine, Azimine, Carpaine.
Therapeutics actions	:	Antipyretic, Diuretic, Stimulant, Astringent, Tonic, Expectorant.

பொது குணம்:

"வீக்கம் கரப்பான் விதாகம் கிரந்திகுன்மம்
ஊக்கமிகு சூலைவாய் வோடுபித்தம் தாக்குவிடம்
வீறுமோ கண்துலங்கும் வீசுபசி ரத்தமுண்டாம்
கூறுசங்கம் வேரிலை கட்கு".

சுக்கு

Tamil name	:	சுக்கு
Botanical name	:	*Zingiber officinale*
Family	:	Zingiberaceae
Parts used	:	Scraped and dried rhizomes

சுவை	:	கார்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Phellandrene, Gingerol, Gingerin
Therapeutics actions	:	Sialogogue, Stomachic, Carminative, Stimulant, Rubefacient

பொது குணம்:

"சூலைமைந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை
மூலம் இரைப்பிருமல் மூக்குநீர் வாலகப
தோடமதி சாரைந் தொடர்வாத குன்மநீர்த்
தோடம்ஆ மம்போக்குஞ் சுக்கு".

ஓமம்

Tamil name	:	ஓமம்
Botanical name	:	*Carum copticum*
Family	:	Umbelliferae (Apiaceae)
Parts used	:	Seeds
சுவை	:	கார்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Tymol, Aromatic Oil
Therapeutics actions	:	Stomachiac, Antispasmodiac,Carminative, Antiseptic, Stimulant, Tonic, Sialogogue.

பொது குணம்:

"சீதசுரங் காசங் செரியாமந் தம்பொருமல்
பேதியிரைச் சல்கடுப்பு பேராமம் ஓதிருமல்
பல்லோடுபல் மூலம் பகமிவைநோ யெந்செயுமோ
சொல்லோடுபோம் ஓமமெனச் சொல்".

சீரகம்

Tamil name	:	சீரகம்
Botanical name	:	*Cuminum cyminum*
Family	:	Umbelliferae (Apiaceae)
Parts used	:	Seeds and essential oil
சுவை	:	கார்ப்பு, இனிப்பு
தன்மை	:	தட்பம்
பிரிவு	:	இனிப்பு
Chemical constituents	:	Thymene, Cuminol, Cymene
Therapeutics actions	:	Carminative, Stimulant, Stomachiac, Astringent

பொது குணம்:

"பித்தமெனும் மந்திரியைப் பின்னப் படுதியவன்
சத்துருவை யுந்துறந்து சாதித்து மத்தனனும்
ராசனெயு மீவென்று நண்பைப் பலப்படுத்தி
போசனகு டாரிசெயும் போர்".

திப்பிலி

Tamil name	:	திப்பிலி
Botanical name	:	*Piper longum*
Family	:	Piperaceae
Parts used	:	Dried unriped fruits
சுவை	:	இனிப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	இனிப்பு
Chemical constituents	:	Piperine, Aromatic Oil
Therapeutics actions	:	Stimulant, Alterative, Diuretic, Carminative, Aphrodisiac.

பொது குணம்:

"ஆசனநோய் தொண்டைநோய் ஆவரண பித்தமுதல்
நாசிவிழி காதிவைநோய் நாட்புழுநோய் வீசுடுவி
யங்காலைஞ்ச னஞ்சிதையும் அம்பாய் அழிவின்றும்
பொங்காலாஞ்ச நைங்கையர்கோட்போல்".

மிளகு

Tamil name	:	மிளகு
Botanical name	:	*Piper nigrum*
Family	:	Piperaceae
Parts used	:	Dried unriped fruits
சுவை	:	கைப்பு, கார்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Chavicine, Piperine, Piperidine, Piperetine, Aromatic Oil
Therapeutics actions	:	Acrid, Carminative, Antiperiodic, Rubefacient, Stimulant, Resolvent.

பொது குணம்:

"அளவையுறாக்காரம் அடைந்திருக்கும் வாத
விளைவையெல் லாமறுக்கும் மெய்யே மிளகின்காய்
கண்டவர்க்கும் இன்பமாம் காரிகையே சீழ்முலங்
கொண்டவர்க்கு நன்மருந்தாங் கூறு".

பூலாங் கிழங்கு

Tamil name	:	பூலாங் கிழங்கு
Botanical name	:	*Curcuma zedoaria*
Family	:	Zingiberaceae
Parts used	:	Tubers and leaves

சுவை	:	கைப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Curcumin, Arabins, Albuminoids
Therapeutics actions	:	Stimulent, Carminative, Expectorant, Diuretic, Alterative, Aromatic

அரத்தை

Tamil name	:	அரத்தை
Botanical name	:	*Alpinia galanga*
Family	:	Zingiberaceae
Parts used	:	Root
சுவை	:	கார்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Galangal, Galangin, Aromatic Oil
Therapeutics actions	:	Expectorent, Febrifuge, Stomachiac.

பொது குணம்:

"தொண்டையிற்கட் டுங்கபத்தைத் தூரத் துரத்திவிடும்
பண்டைச்சீ தத்தைப் பறக்கடிக்கும் கெண்டைவிழி
மின்னே கரப்பனைவே றாக்கும் பசிகொடுக்கும்
சொன்னோம் அரத்தைச் சுகம்".

வால்மிளகு

Tamil name	:	வால்மிளகு
Botanical name	:	*Piper cubeba*
Family	:	Piperaceae
Parts used	:	Unripe fruit
சுவை	:	கார்ப்பு

தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Aromatic Oil, Olioresin, Cubebin, Arabic Acid.
Therapeutics actions	:	Stimulant, Carminative, Diuretic, Expectorant.

பொது குணம்:

"வாதபித்த ஐயம் வயிற்று வலிதாகைஞ்
சீதம் பலநோய் சிதையுங்காண் போத
அதீத பனமாம் அணங்கரசே நாளுந்
துதிவால் மிளகருந்தச் சொல்".

வாய்விளங்கம்

Tamil name	:	வாய்விளங்கம்
Botanical name	:	*Embelia ribes*
Family	:	Myrsinaceae
Parts used	:	Root bark
சுவை	:	கைப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Aromatic Oil, Fatty Oil, Embelic Acid, Tannin, Christembine.
Therapeutics actions	:	Antihelmenthic, Carminative, Stomachic, Stimulant.

பொது குணம்:

"பாண்டுகுட்டம் குன்மம் பருந்தூல நோய்வாதந்
தீண்டு திரிவிடைஞ் சிரந்துண்டாம் பூண்டமடி
நோய்விளங்கக் காட்டாத நுண்கிருமி யாசனப்புன்
வாய்விளங்கங்காட்டாவிருமார்".

பறங்கிப்பட்டை

Tamil name	:	பறங்கிப்பட்டை
Botanical name	:	*Smilax china*
Family	:	Liciaceae
Parts used	:	Tuber
சுவை	:	இனிப்பு
தன்மை	:	தட்பம்
பிரிவு	:	இனிப்பு
Chemical constituents	:	Starch, Glucoside, Saponoin Phytosterol
Therapeutics actions	:	Alterative, Anti Syphilitic, Aphrodisiac, Depurative.

பொது குணம்:

"தாகம் பலவாதந் தாதுநட்டம் புண்பிளவை
மேகங் கடிகிரந்தி வீழ்மூலந் தேகமுடன்
குட்டை பகந்தமேற் கொள்வமனம் போம்பறங்கிப்
பட்டையினை யுச்சரித்திப் பார்".

குரோசாணி ஓமம்

Tamil name	:	குரோசாணி ஓமம்
Botanical name	:	*Hyoscyamus niger*
Family	:	Solanaceae
Parts used	:	seeds
சுவை	:	கார்ப்பு, சிறுகைப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Hyoscyamine, Scopolamine, Atropine, Hyoscypikrin, Fatty Oil.
Therapeutics actions	:	Hypnotic, Sedative, Anodyne

பொது குணம்:

"வெகுமூத் திரம்வாதம் வீரியநட் டம்புண்
உகுபேதி யுட்கடுப்பி னோடே மிகுகரப்பான்
தீராக் கபமிவைபோம் செய்யகு ரோசானியன்றால்
வாரா மயக்கமுறு மால்".

கடுகு ரோகிணி

Tamil name	:	கடுகு ரோகிணி
Botanical name	:	*Picrorrhiza kurroa*
Family	:	Scrophulariaceae
Parts used	:	Dried rhizomes
சுவை	:	கைப்பு, கார்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Picrorhizin, Kutkin, Kutkisterol
Therapeutics actions	:	Antiperiodic, Cathartic, Stomachiac

பொது குணம்:

"மாந்தஞ் சுரமையம் வாயுகரப் பானாமைஞ்
சேர்ந்தமலக் கட்டு திரிதோடம் போந்தபொட்டுப்
புண்வயிறு நோயிவைபோம் பொற்கொடியெ பேதியுண்டாம்
திண்கடுகு ரோகணிக்குத் தேர்".

அக்கரகாரம்

Tamil name	:	அக்கரகாரம்
Botanical name	:	*Anacyclus pyrethrum*
Family	:	Asteraceae
Parts used	:	Root
சுவை	:	கார்ப்பு
தன்மை	:	வெப்பம்

பிரிவு	:	கார்ப்பு
Chemical constituents	:	Pellitorin, Pyrethrin, Aromatic Oil
Therapeutics actions	:	Stimulant, Sialogogue

பொது குணம்:

"அக்கரகாரம் அதன்பேர் உரைத்தக்கால்
உக்கிரக்கால் அத்தோடம் ஓடுங்காண் முக்கியமாய்க்
கொண்டால் சலம்ஊறும் கொம்பனையெ தாகசுரம்
கண்டால் பயந்தோடுங் காண்".

சாதிக்காய்

Tamil name	:	சாதிக்காய்
Botanical name	:	*Myristica officinalis*
Family	:	Myristicaceae
Parts used	:	Dried seed
சுவை	:	துவர்ப்பு, கார்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Volatile Oil, Fixed Oil, Fat, Starch, Mucilage
Therapeutics actions	:	Hypnotic, Sedative, Anodyne.

பொது குணம்:

"தாது நட்டம் பேதி சருவாசி யஞ்சிர நோய்
ஓதுசுவா சங்காசம் உட்கிரணி வேதோ
டிலக்காய் வரும்பிணிபோம் ஏற்றமயல் பித்தங்
குலக்கா யருவந்துவர்க்குக் கூறு".

கருஞ்சீரகம்

Tamil name	:	கருஞ்சீரகம்
Botanical name	:	*Nigella sativa*
Family	:	Ranunculaceae
Parts used	:	Seeds and dried fruit
சுவை	:	கைப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Fatty Oil, Aromatic Oil, Melanthin, Metarbin
Therapeutics actions	:	Carminative, Diuretic, Emmenagogue, Galactogogue, Anthelmintic, Staomachic.

பொது குணம்:

"கருஞ்சீ ரகத்தான் கரப்பனொடு புண்ணும்
வருஞ்சிராய்ப் பீநசமுமாற்றும் அருந்தினால்
காய்ச்சல் தலைவலியுங் கண்வலியும் போமுலகில்
வாய்ச்ச மருந்தெனவே வை".

இலவங்கப்பட்டை

Tamil name	:	இலவங்கப்பட்டை
Botanical name	:	*Cinnamomum zeylanicum*
Family	:	Lauraceae
Parts used	:	Dried inner bark of the shoots from truncated stalks and essential oil
சுவை	:	கார்ப்பு, இனிப்பு
தன்மை	:	தட்பம்
பிரிவு	:	இனிப்பு
Chemical constituents	:	Aromatic Oil, Cinnamic Acid, Tannin.
Therapeutics actions	:	Stimulant, Carminative, Aphrodisiac, Antiseptic, Local Anaesthetic.

பொது குணம்:

"தாது நட்டம் பேதி சருவவிஷம் ஆகியநோய்
பூதகிர கஞ்சிலந்திப் பூச்சிவடஞ் சாதிவிடம்
ஆட்டுமிரைப் போடிருமல் ஆகியநோய்க் கூட்டமற
ஓட்டுமில வங்கத் துரி".

சாதிபத்திரி

Tamil name	:	சாதிபத்திரி
Botanical name	:	*Myrstica officinalis*
Family	:	Myristicaceae
Parts used	:	Nutmegs
சுவை	:	கார்ப்பு, துவர்ப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Volatile Oil, Fined Oil, Fat, Starch, Mucilage
Therapeutics actions	:	Aphrodisiac

பொது குணம்:

"சாதிதரும் பத்திரிக்குத் தாபச் சுரந்தணியும்
ஓதுகின்ற பித்தம் உயருங்காண் தாதுவிர்த்தி
யுண்டாங் கிரகணியோ டோதக் கழிச்சலறும்
பண்டாங் குறையே பகர்".

கோஷ்டம்

Tamil name	:	கோஷ்டம்
Botanical name	:	*Costus speciosus*
Family	:	Zingiberaceae
Parts used	:	Rhizomes
சுவை	:	கைப்பு
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு

Chemical constituents	:	Rhizomes contains 2to 4% diosgenin, corticosteroids, sex hormones, mucilage and starch.
Therapeutics actions	:	Stomiachic, Expectorant, Stimulant, Diaphoretic.

பொது குணம்:

"நாட்டிலுறு வெட்டை நடுக்கம் எனுநோய்கள்
கோட்டமெனச் சொன்னால் குலையுங்காண் கூட்டிற்
சுரதோடந் தொண்டைநோய் தோலாத பித்தம்
பரதேசம் போமே பறந்து".

சிறுதேக்கு

Tamil name	:	சிறுதேக்கு
Botanical name	:	*Clerodendron serratum*
Family	:	Verbenaceae
Parts used	:	Leaves, Root
சுவை	:	கைப்பு,
தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Clerodin
Therapeutics actions	:	Stimulant, Sedative, Expectorant

கிராம்பு

Tamil name	:	கிராம்பு
Botanical name	:	*Eugenia caryophyllata*
Family	:	Myttaceae
Parts used	:	Fruit,dried flower,buds and oil
சுவை	:	கைப்பு

தன்மை	:	வெப்பம்
பிரிவு	:	கார்ப்பு
Chemical constituents	:	Eugenol, Caryophyllene, Eugenin
Therapeutics actions	:	Antispasmodiac, Carminative, Stomachic

<u>பொது குணம்:</u>

"பித்த மயக்கம் பேதியோடு வாந்தியும்போம்
சுத்தவிரத் தக்கடுப்புந் தோண்றுமோ மெத்த
இலவங்கங் கொண்டவருக் கேற் சுகமாகும்
மலமைங்கே கட்டுமென வாழ்த்து".

INGREDIENTS OF SIGAMANI CHOORANAM (INTERRNAL) AND ARKKASHERATHY THYLAM (EXTERNAL)

Arugam ver (*Cyonodon dactylon)*

Veppam pattai *(Azaridacta indica)*

Narsangan ver pattai

(Azima tetracantha)

Chukku

(Zingiber officinale)

Omam *(Carum copticum)*

Narseeragam *(Cuminumcyminum)*

Thippili *(Piper longum)*

Milagu*(Pipenigrum)*

Poolangkizhangu *(Curcuma zeodora)*

Arathai *(Alpinia galanga)*

Vaalmilagu *(Piper cubeba)*

Vaivilangam *(Embelia ribes)*

Parangisakkai *(Smilax china)*

Kurosaaniomam*(Hyoscyamus niger)*

Kadukurogini *(Veratri virdi)*

Akkarakaram*(Anacyclus pyrethrum)*

Siruthekku *(Cleodendrum serratum)*

Kirambu *(Syzygiyum aromaticum)*

Jaathikaai *(Myristica fraganans)*

Elam *(Eletteria cardomum*

Karunjeeragam *(Nigella sativa)*

Lavangapattai *(Cinnamomum verum)*

Jaathipathiri *(Myristica fragnans)*

Koshtam *(Costus specious)*

Erukku (*Calotropis gigantea)*

Sathurakalli *(Euphorbia antiqurom)*

Pirandai (*Cissus quadrangularis)*

Parpadagam(*Indoneesiella echioides)*

Merugankizhangu

(Dioscorea esculenta)

Nallennai *(Sesamum indicum)*

Saerangkottai

(Semicarous anacardium)

Naervaalam *(Croton tiglium)*

TRAIL DRUG

SIGAAMANI CHOORANAM

(INTERNAL)

ARKKASHEERATHY THYLAM

(EXTERNAL)

TOXICITY STUDIES OF SIGAMANI CHOORANAM:

The following in vivo toxicity studies were carried out on SIGAMANI CHOORANAM (SMC) by using Organization for Economic Co-operation and Development (OECD) guidelines.

REPEATED DOSE 28 DAYS ORAL TOXICITY STUDY (OECD guidelines -407):

The toxicity study was carried out at National Institute of Siddha, Chennai -47. The study was done after getting permission from the Institutional Ethical Committee. (IAEC Approved No: NIS / IAEC-VI / 24042018 / 10.

DESCRIBTION OF METHOD:

SELECTION OF ANIMALS:

Animals were selected as per guidelines. The Wistar Albino Rats of weighting 150-200 mg were obtained from authorized animal breeders of the animal laboratory in TANUVAS, Madhavaram, Chennai and stocked in the animal house at National Institute of Siddha, Chennai -47. Healthy adult animals of Wistar Albino Rats, both sex used in Repeated Dose-28 days oral toxicity study. The female animals used in nulliparous and non-pregnant.

HOUSING AND FEEDING CONDITION :

- The temperature in the experimental animal room- 22° C (±3°C)
- Humidity :60 ±10%
- Lightening: Artificial, the sequence being 12 hours light,12 hours dark.
- The animals were housed in Polypropylene cage provided with bedding of husk.
- The animals had free access to RO water.
- For feeding, standard pellet diet.

PREPARATION OF ANIMALS:

The animals were randomly selected to permit individual identification by cage number and individual marking on the fur of each animals 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 animals care were followed.

TEST SUBSTANCES:

" SIGAMANI CHOORANAM (SMC)"

ROUTE OF ADMINISTRATION:

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

Species and strain	:	Wistar Albino Rats
Sex	:	Male and Female
Age/Weight	:	8-12 weeks,150-200 gm
Test guidelines	:	OECD guidelines -407
Groups /Treatment	:	Grouped by randomization
Study duration	:	28 days
Number of animals	:	3 Female+ Male / Group
		40 animals
Control group	:	Vehicle (Water)
Route of administration	:	Oral

REPEATED 28 DAYS ORAL TOXICITY STUDY:

EXPERIMENTAL ANIMALS:

GROUPING OF ANIMALS:

Repeated dose 28 days oral toxicity study was carried out at different dose levels. The animals in both sexes were divided into four groups (Group I, II, III & IV). Each group consist of 10 animals (5 males and 5 females).

Group I served as a control group and other three groups (I, II & III) were treated as test group.

The doses (low, mid and high) were fixed from the result of Acute toxicity study

TABLE 1: GROUPING OF ANIMALS IN 28 DAYS ORAL TOXICITY STUDY:

GROUPS	NO. OFRATS
Group I: Control - Vehicle (***Water***)	10(5M+ 5F)
Group II: Test drug (SMC) - Low dose 450 mg/kg b. wt.	10(5M + 5F)
Group III: Test drug (SMC) - Mid dose 900 mg/kg b. wt.	10(5M + 5F)
Group IV: Test drug (SMC) - High dose 1800 mg/kg b. wt.	10(5M + 5F)

Total 40 (20 Female + 20 Male)

ADMINISTRATION OF DOSE:

The animals were dosed with drug daily for a period of 28 days. The test drug administrated by oral gavage and this was done in a single dose to the animals, once in daily for 28 days.

OBSERVATION:

Animals were noted twice daily for morbidity and mortality during the experimental period.

Body weight changes:

During the study period, body weight of all animals, food and water consumption per day were calculated weekly once.

Blood collection and laboratory investigations:

At the end of 28 days, blood samples were collected just prior to euthanasia in all overnight (12 hours) fasted rats from abdominal aorta using Sodium heparin containing vacutainer (200 IU/ml) for blood chemistry and Potassium EDTA containing vacutainer (1.5 mg/ml) for Hematology sample. Blood sample were processed by the following investigation.

- Complete blood count
- Renal function test
- Liver function test
- Lipid profile

NECROPSY:

At the end of the 28 day, after blood collection, the animals were sacrificed by excessive anaesthesia. Animals were subjected to gross necropsy. Gross necropsy includes examination of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Organs like brain, eye, thymus, lungs, heart, spleen, liver, kidneys, adrenals, testes, uterus were collected from all animals and preserved in 10% buffered neutral formation.

HISTOPATHOLOGY:

Control and highest dose groups animals will be initially subjected to histopathological investigation. If any abnormality found in the highest dose group then the low and mid dose group will also be examined. Various organs (brain, heart, lungs, liver, kidney, spleen, stomach, bone) will be collected from all the animals and preserved in 10% buffered neutral formalin, sliced, 5 or 6μm sections and will be stained with Haematoxylin and Eosin. Examined for histopathological changes.

STASTICAL ANALYSIS:

Finding such as clinical sign of intoxication, body weight changes, food consumption, Hematology and biochemical parameters were subjected to one-way ANOVA followed by Dunnet ‘t’ test using computer software programed graph Pad Instat-3.

28 DAYS REPEATED ORAL TOXICITY STUDY:

FOOD (G/DAY) INTAKE OF ALBINO RATS EXPOSED TO SIGAMANI CHOORANAM (SMC):

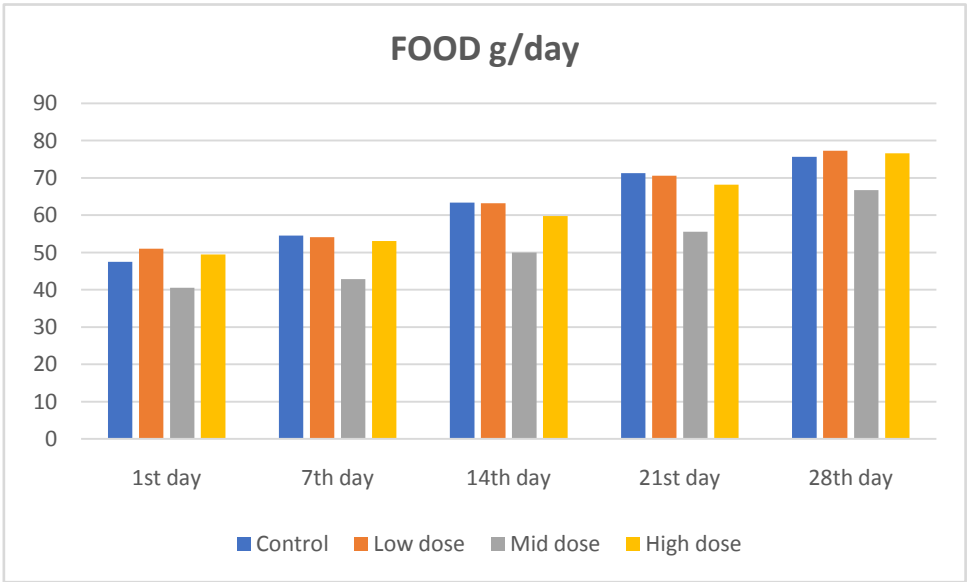
Food consumption of the animal's significant difference in Food intake the test group animals were observed when compared with control group during the study period but they are within physiological limit.

TABLE 2: Food (g/day) intake of albino rats exposed to SMC:

Dose (mg/kg/ day)	1st day	7th day	14th day	21st day	28th day
Control	47.5 ± 3.53	54.5 ±5.80	63.42 ±6.5	71.3 ±3.5	75.7 ±3.76
Low dose	51 ±1.41	54.1 ±2.36	63.21 ±2.39	70.6 ±2.30	77.25 ±2.1
Mid dose	40.5 ±0.70	42.83 ±1.52	50 ±1.94	55.6 ±3.08	66.7 ±5.55
High dose	49.5 ±13.4	53.1 ±9.52	59.8 ±9.8	68.16 ±9.62	76.6 ±8.27

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.0

Fig :1



WATER (ml/day) INTAKE OF WISTAR ALBINO RATS EXPOSED TO SIGAMANI CHOORANAM (SMC):

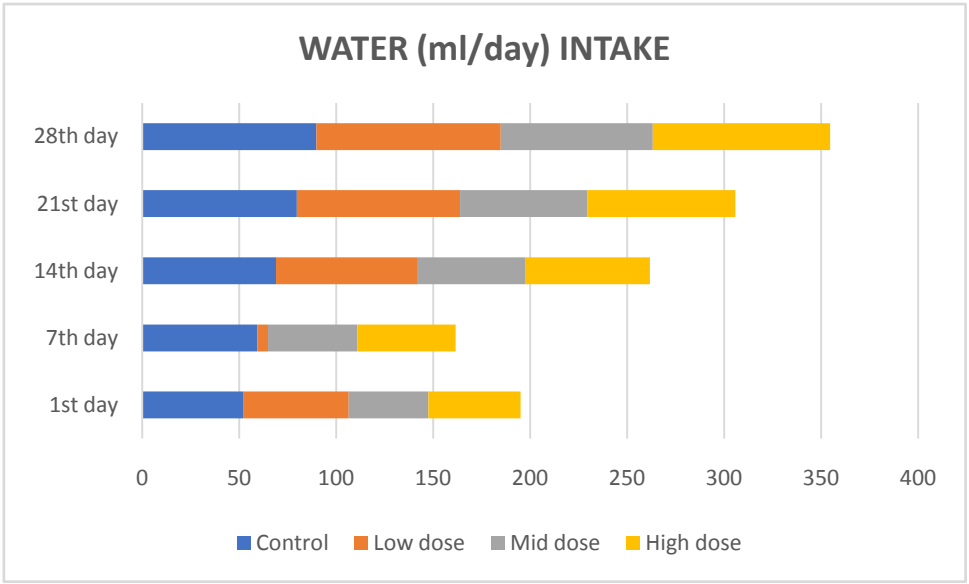
Water consumption the difference in Water intake of control and test group of animals observed during the study period. (Table 8), There was significant difference occurs in the group low and mid at 28 days compared with control group.

Table 3: Water (ml/day) intake of albino rats exposed to SMC

Dose (mg/kg/day)	1st day	7th day	14th day	21st day	28th day
Control	52 ±7.07	59.42 ±5.9	68.9 ±8.66	79.71 ±6.87	89.7 ±6.42
Low dose	54.5 ±6.36	5.5 ±5.90	73.14 ±7.9*	84.14 ±9.06**	95.14 ±10
Mid dose	41 ±1.41	46 ±3.32	55.4 ±2.97**	65.71 ±2.81**	78.35 ±4.49
High dose	47.5 ±3.53	50.64 ±5.1	64.2 ±4.49**	76.2 ±5.70	91.4 ±5.40

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.01.

Fig :2



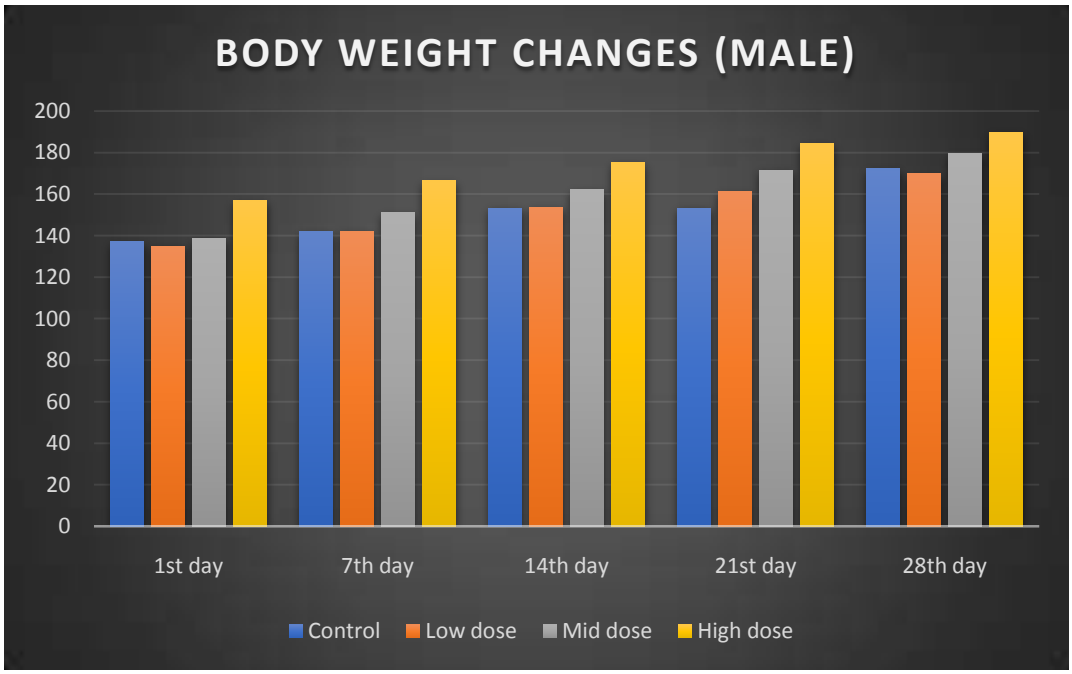
BODY WEIGHT (g) CHANGES OF ALBINO RATS (MALE) EXPOSED TO SMC:

Table : 4

Dose (mg/kg/day)	1st day	7th day	14th day	21st day	28th day
Control	137 ± 7.48	142 ±7.47	153.2 ±7.19	153.2 ± 6.47	172.2 ±9.79
Low dose	135 ±7.75	141.8 ± 9.57	153.6 ± 8.66	161.2 ±8.1**	169.8 ±11.2
Mid dose	138.6 ± 5.2	151 ± 6.89**	162 ±8.78**	171.4 ±9.43**	179.4 ±9.97*
High dose	157 ±6.78**	166.4 ±7.68**	175 ±7.89 **	184.2 ±7.27**	189.6 ±6.08**

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.01.

Fig :3



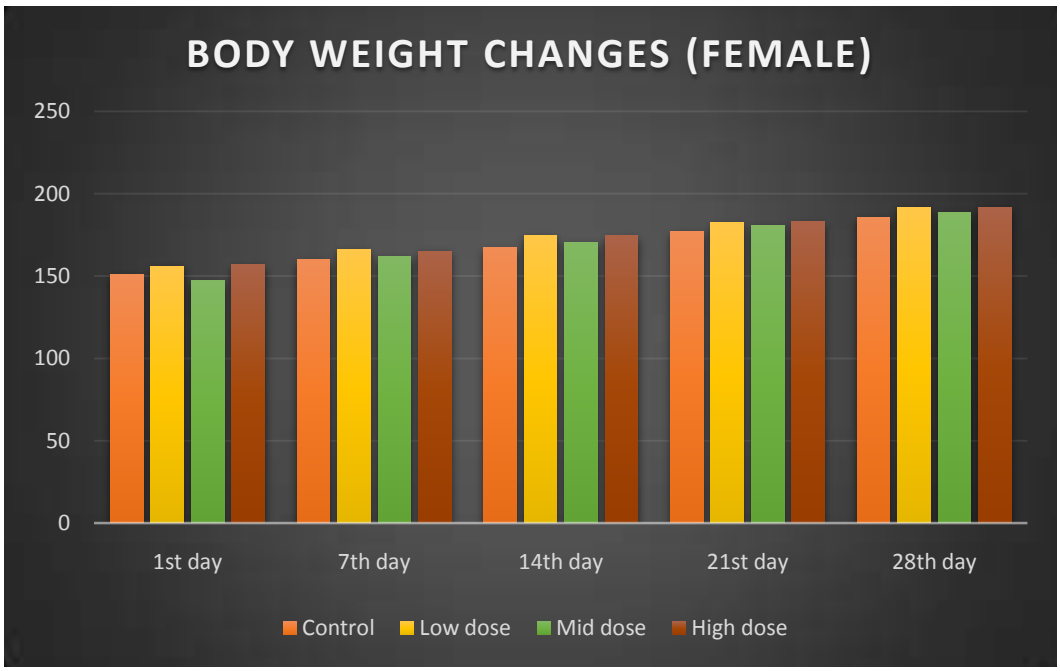
BODY WEIGHT (g) CHANGES OF ALBINO RATS (FEMALE) EXPOSED TO SIGAMANI CHOORANAM (SMC):

Table:5

Dose (mg/kg/day)	1st day	7th day	14th day	21st day	28th day
Control	151 ±6.63	159.8 ±4.62	167.2 ±3.72	177 ±5.62	185.6 ±7.55
Low dose	156 ±13.5	166 ±14.31	174.8 ±13.8*	182.4 ±14.0	191.8 ±12.2
Mid dose	147 ±7.48	161.6 ±5.4	170.2 ±5.91	180.4 ±4.49	188.8 ±3.81
High dose	157 ±6.78	165 ±8.41	174.4 ±7.44*	183 ±8.36	191.8 ±7.33

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.01.

Fig :4



EFFECT OF SIGAMANI CHOORANAM (SMC) ON HEMATOLOGICAL PARAMETERS

The results of hematological investigations conducted at the end of the study, the group revealed slightly significant changes in levels of hematological parameters, when compared with control group and post retrieval group. The Hematological parameters are normal, when compared with control group.

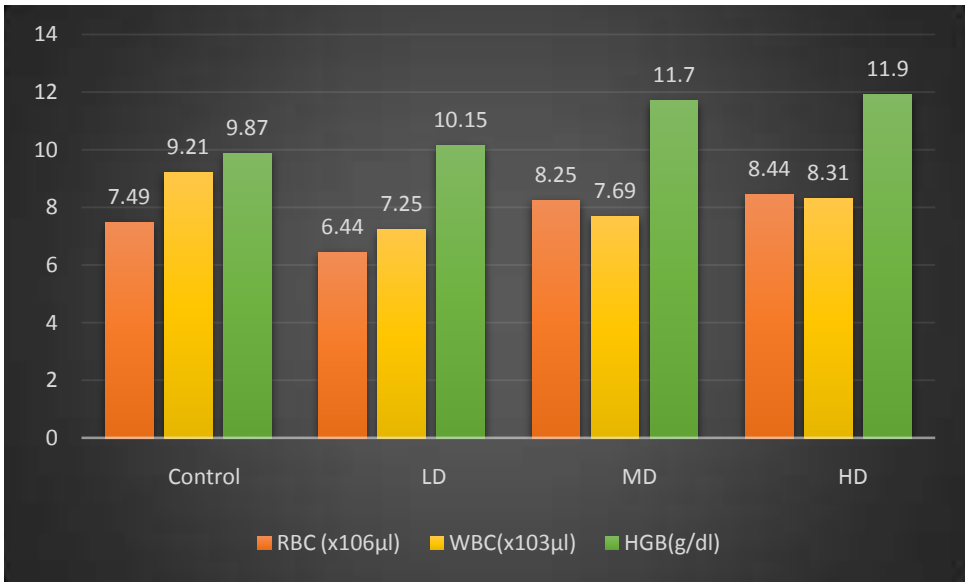
Table: 6

Parameter	Control	LD	MD	HD
RBC ($x10^6$µl)	7.49 ± 0.164	7.44 ± 1.056	8.25 ± 0.2201	8.44 ± 1.401
WBC($x10^3$µl)	9.21 ± 1.450	7.25 ± 2.433	7.69 ± 1.600	8.31 ± 0.891*
Platelets ($x10^3$µl)	619 ± 4.23	558.6 ± 90.16	650 .1 ± 33.93	580.9± 110.7
HGB(g/dl)	9.87 ± 0.45	10.15 ± 0.639	11.7 ± 0.388**	11.9 ± 0.611*
Neutrophil (**(**10^3mm^3)	4.33 ± 1.334	2.69 ± 1.002**	1.73 ± 0.3860**	2.48± 0.7130**
Lymphocyte (%)	86.98 ± 4.04	80.58 ± 10.89	77.17 ± 4.608*	64.82± 12.03**
Monocyte (%)	1.79 ± 0.633	2.81 ± 1.564	2.93 ± 1.223	2.18 ± 1.027
Eosinophil (%)	1.79 ± 0.694	1.71 ± 0.662	1.32 ± 0.364	1.48 ± 0.666
Basophil (%)	1.02 ± 0.4142	0.7 ± 0.483	0.85 ± 0.424	0.81 ± 0.671
MCH (pg)	19.6 ± 2.881	17.89 ± 1.670	20.45 ± 2.747	18.28 ± 4.22
MCV (fl)	63.89 ± 2.337	65.5 ± 2.646	57.2 ± 1.917**	63.58 ± 5.621

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.01.

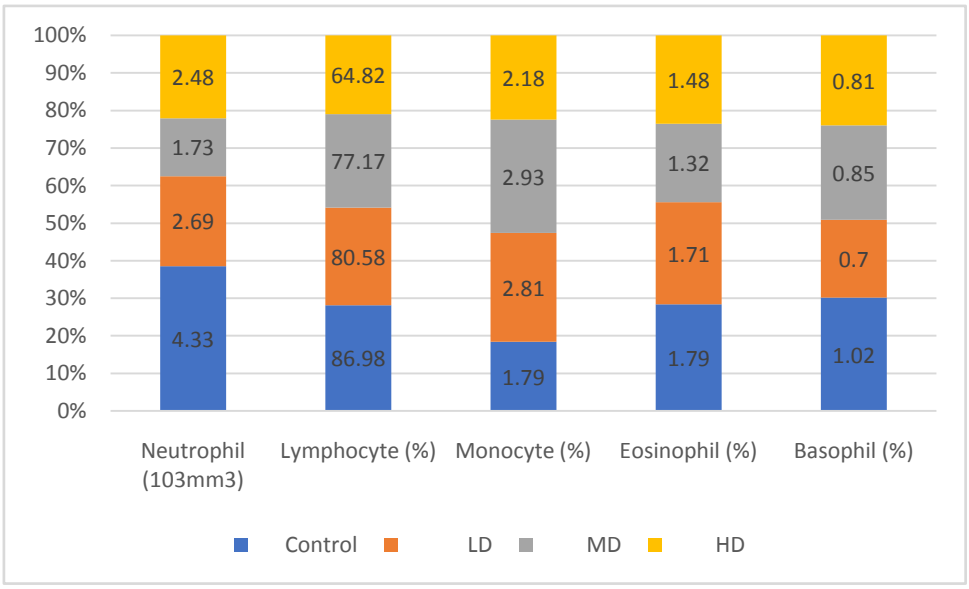
EFFECT OF SIGAMANI CHOORANAM (SMC) ON RBC, WBC & HGB

Fig : 5



EFFECT OF SIGAMANI CHOORANAM (SMC) ON NEUTROPHIL, LYMPHOCYTE, MONOCYTE, EOSINOPHIL AND BASOPHIL

Fig :6



EFFECT OF SIGAMANI CHOORANAM (SMC) ON BIOCHEMICAL PARAMETERS

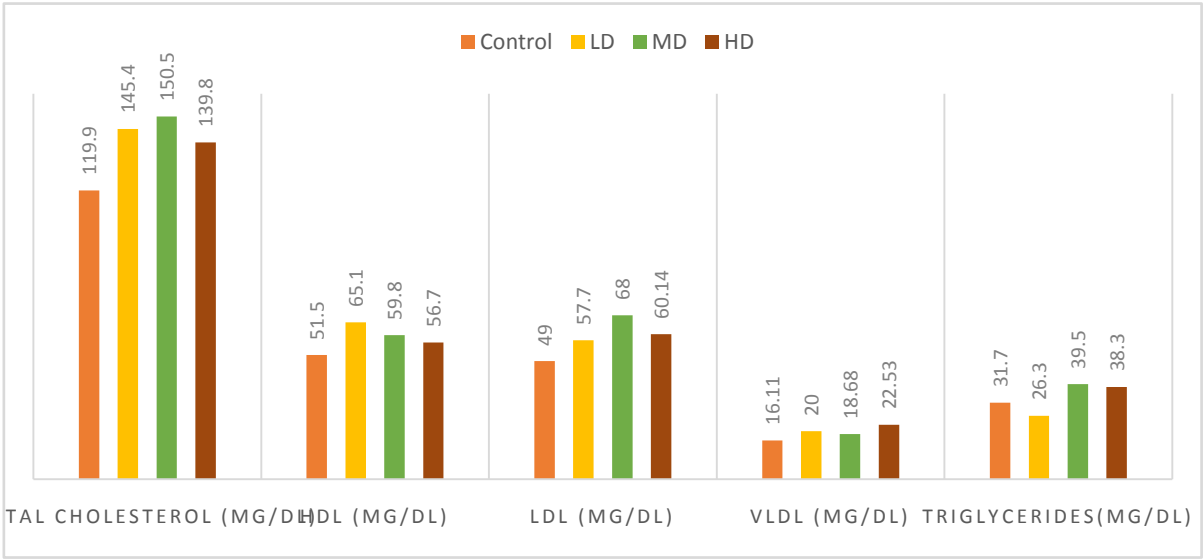
Biochemical investigations were conducted at the end of the study and the results were recorded. In test groups there was significant changes present in biochemical parameters, when compared with the control group. At the values were normal biological limits.

Table: 7

Dose (mg/kg)	Control	LD	MD	HD
Total cholesterol (mg/dl)	119.9 ± 4.66	145.4± 18.759**	150.5 ± 7.305**	139.8 ± 5.15**
HDL (mg/dl)	51.5 ± 2.061	65.1± 15.772**	59.8 ± 5.959*	56.7 ± 2.830
LDL (mg/dl)	49 ± 4	57.7 ± 9.043	68 ± 15.28**	60.14 ± 3.20*
VLDL (mg/dl)	16.11 ± 0.767	20 ± 5.468	18.68 ± 7.085	22.53 ± 4.467*
Triglycerides(mg/dl)	31.7 ± 3.316	26.3 ± 10.85	39.5 ± 3.628	38.3 ± 8.056*

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.01.

Fig : 7



EFFECT OF SIGAMANI CHOORANAM (SMC) ON RENAL PARAMETERS

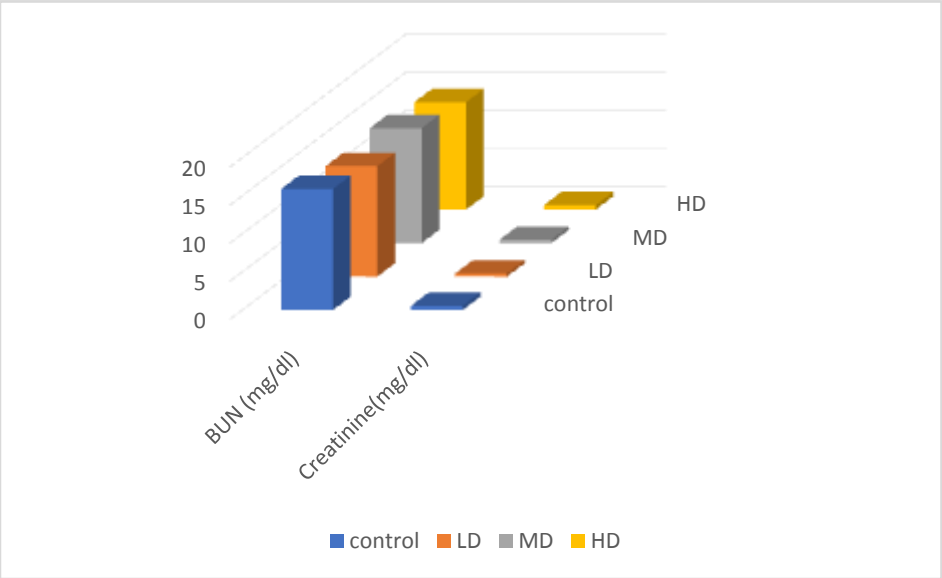
The results of the renal functions test conducted at the end of study, test groups revealed significant changes in levels of renal parameters, when compared with control group, and post retrieval group Renal function parameters towards normal, when compared with control group.

Table:8

DOSE (mg/kg)	control	LD	MD	HD
BUN (mg/dl)	15.9 ± 1.577	14.5 ± 1.354	15.1 ± 3.381	14.1 ± 1.449
Creatinine(mg/dl)	0.54 ± 0.23	0.4 ± 0.249	0.43 ± 0.240	0.59 ± 0.196

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.01.

Fig : 8



EFFECT OF SIGAMANI CHOORANAM (SMC) ON LIVER PARAMETER

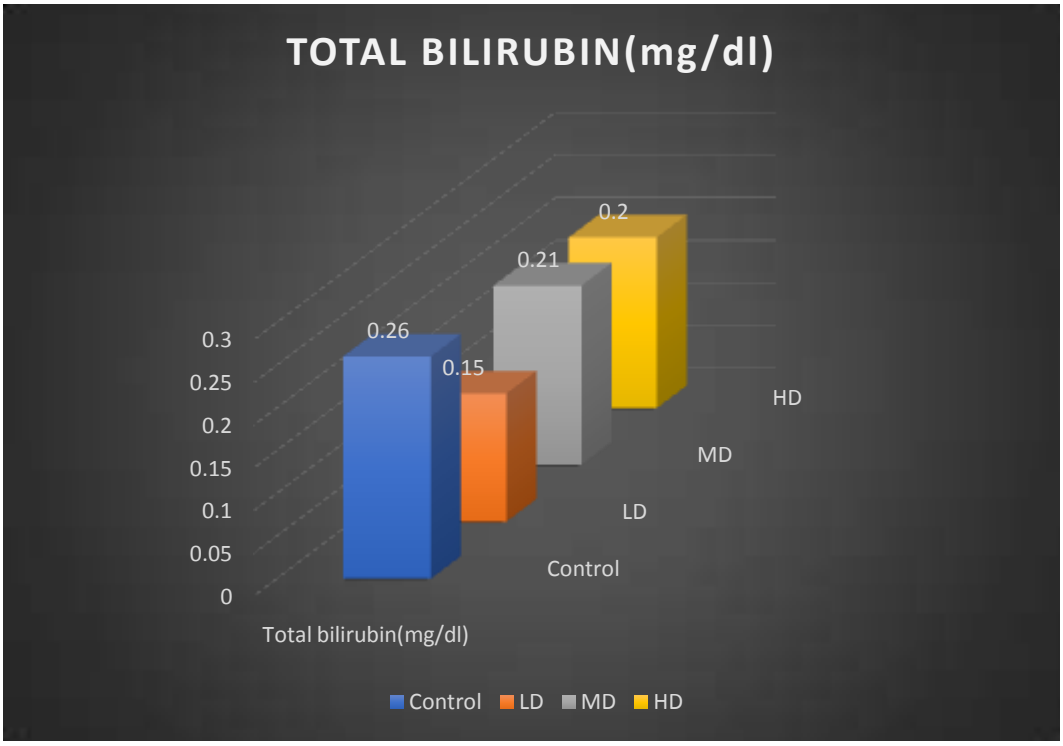
The results of the liver function test conducted at the end of the study, test groups revealed significant changes in levels of liver parameters, when compared with control group, and post retrieval group Liver function parameters towards normal, when compared with control group.

Table: 9

Dose (mg/kg)	Control	LD	MD	HD
Total bilirubin(mg/dl)	0.26 ± 0.066	0.15 ± 0.052	0.21 ± 0.099	0.2 ± 0.105*
SGOT(U/L)	84.9 ± 3.207	71.7 ± 8.92	98.7 ± 29.859	81.5 ± 3.922
SGPT(U/L)	18.9 ± 1.445	31.6 ± 13.09	37.5 ± 6.132**	28.9 ± 6.190**

Values were expressed as mean± S.D. for N=10 rats in each group one-way ANOVA followed by Dunnett's test. Significant indicates that *P<0.05,**P<0.01.

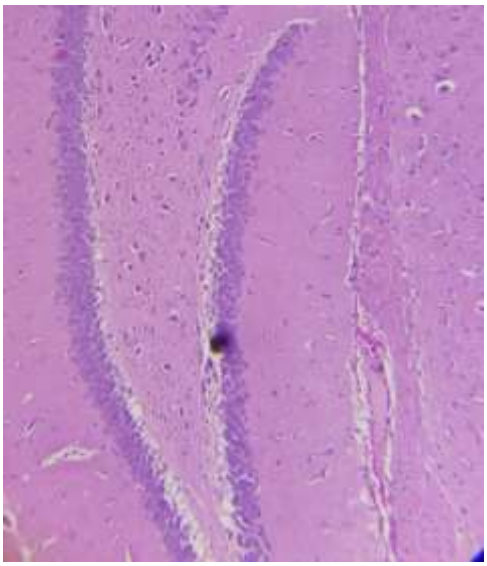
Fig : 9



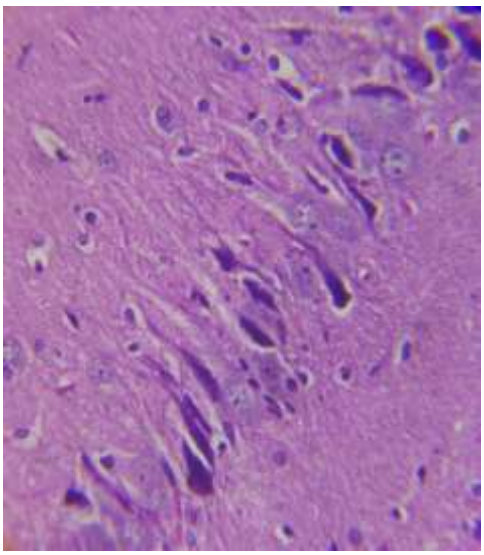
Sample Id: CFH

Histopathology of Brain

Low Power Magnification 10X

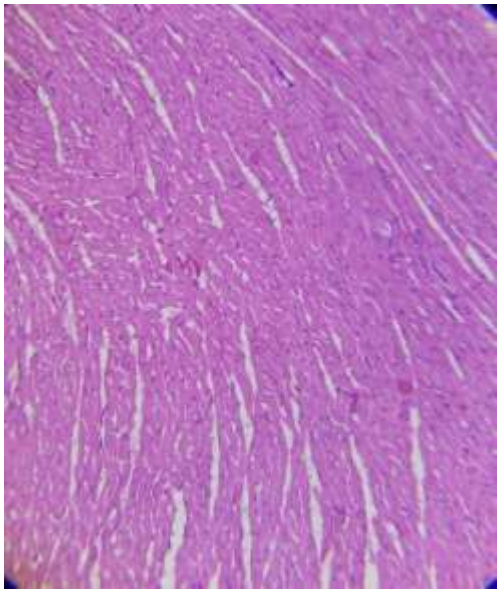


High Power Magnification 40X



Histopathology of Heart

Low Power Magnification 10X



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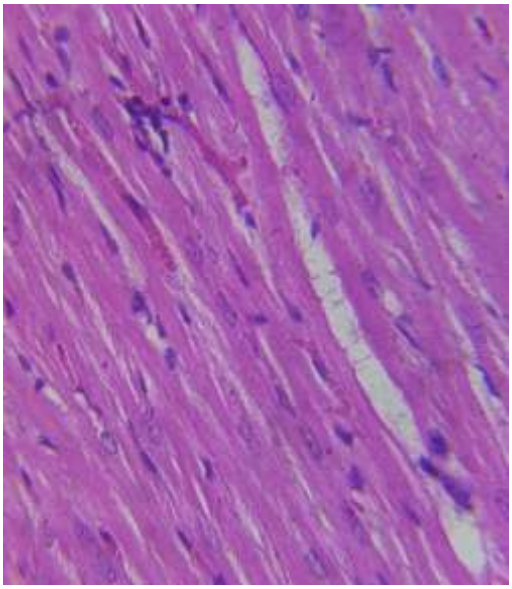
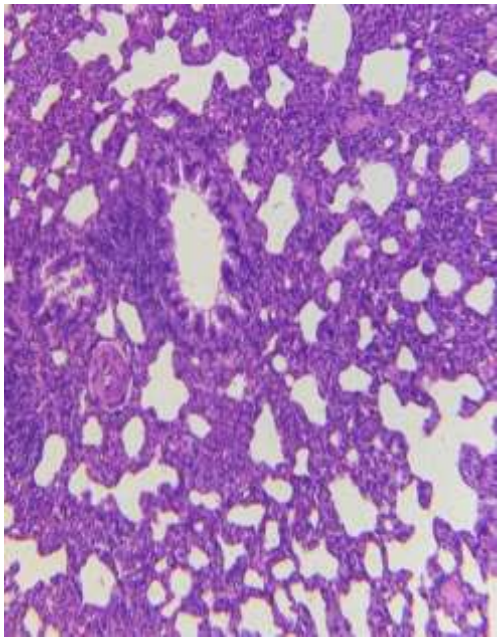


Histopathology of Lung

Low Power Magnification 10X



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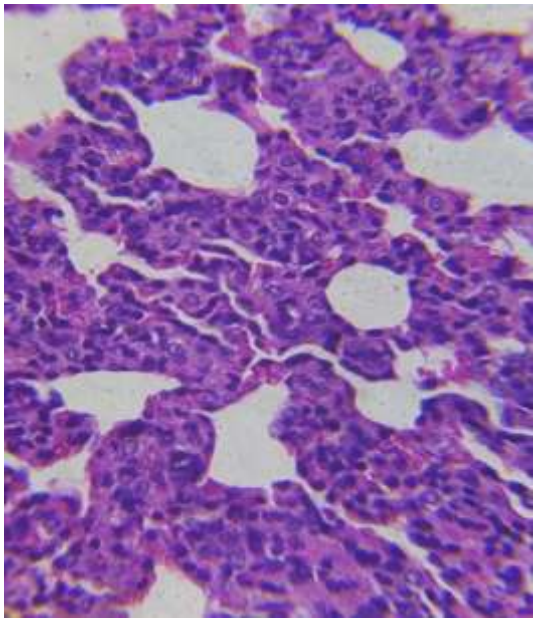
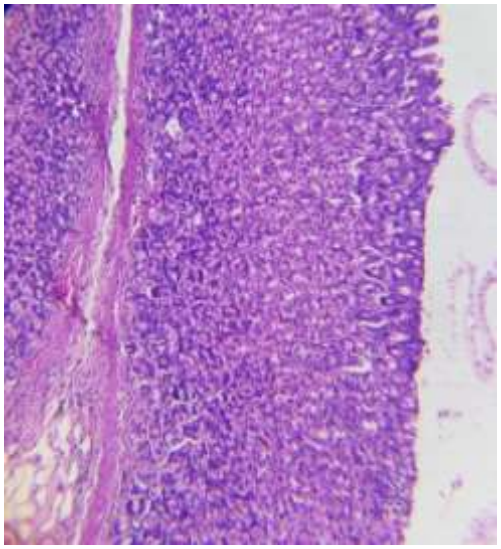


Histopathology of Stomach

Low Power Magnification 10X



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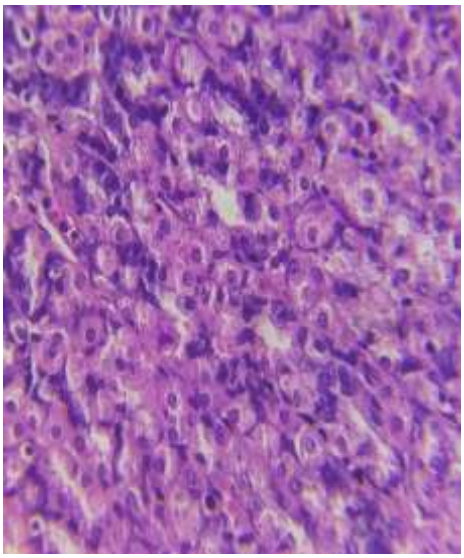
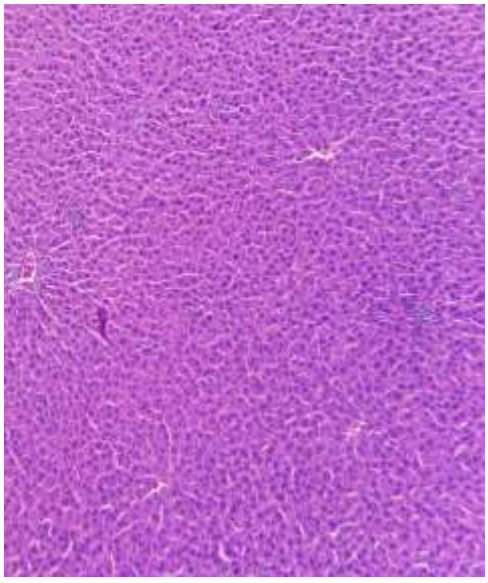


Histopathology of Liver

Low Power Magnification 10X



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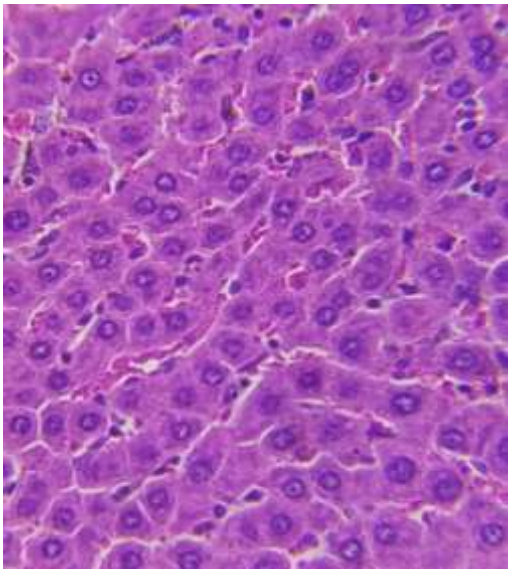
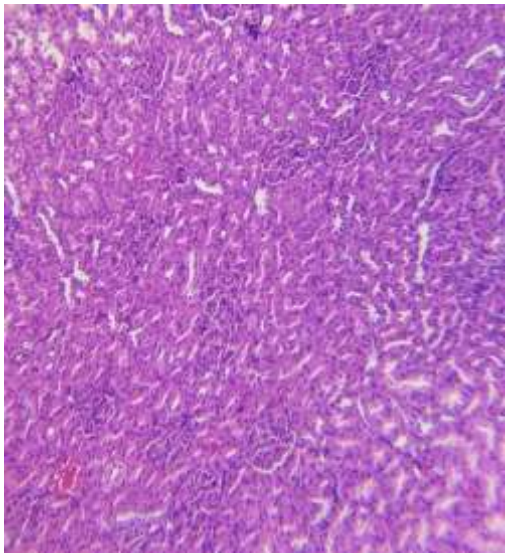


Histopathology of Kidney

Low Power Magnification 10X



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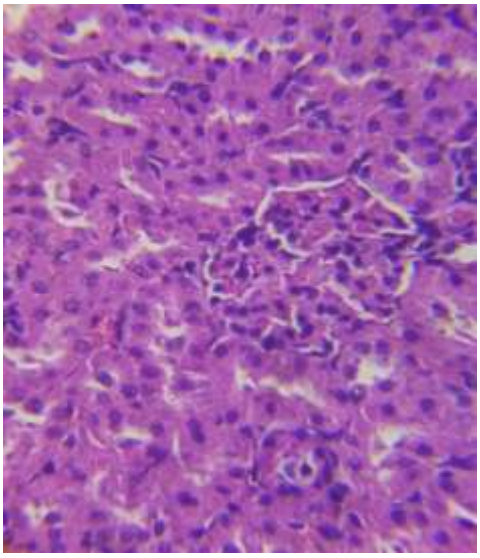
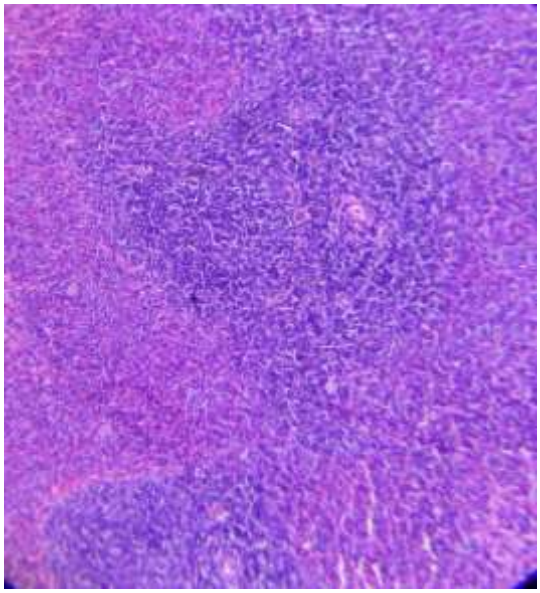


Histopathology of Spleen

Low Power Magnification 10X



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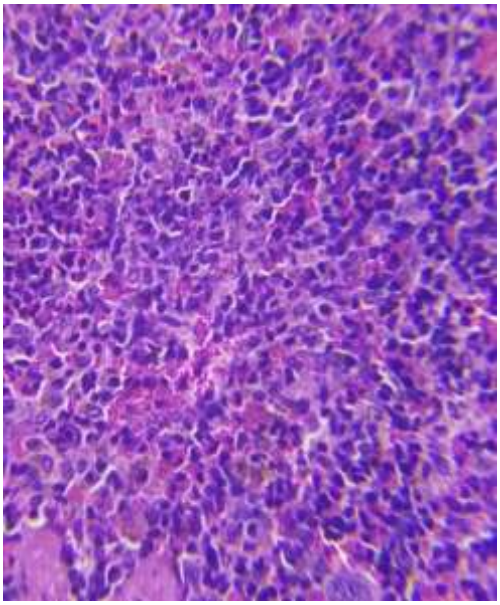
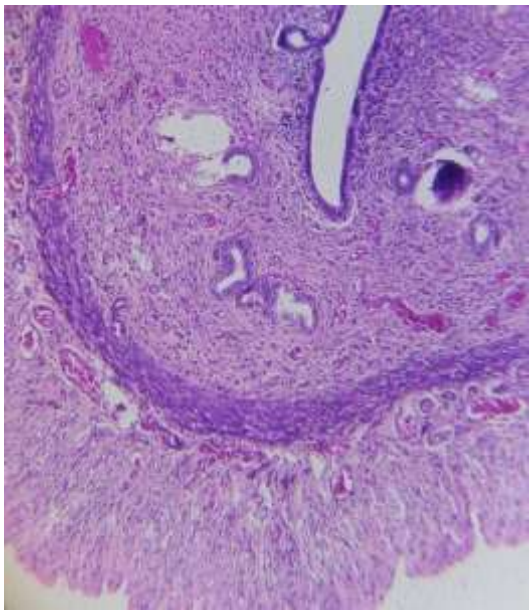


Histopathology of Uterus

Low Power Magnification 10X



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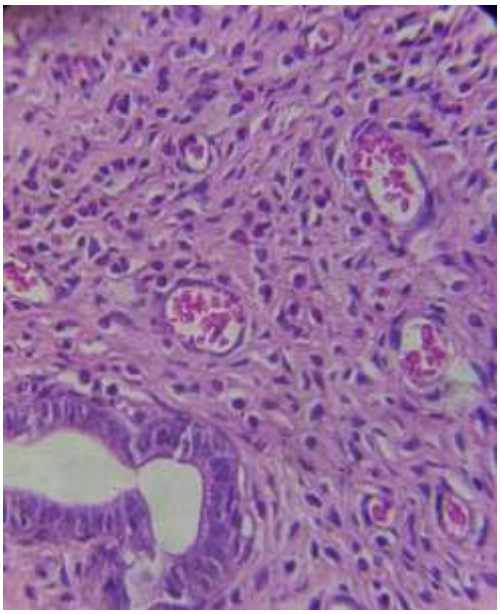
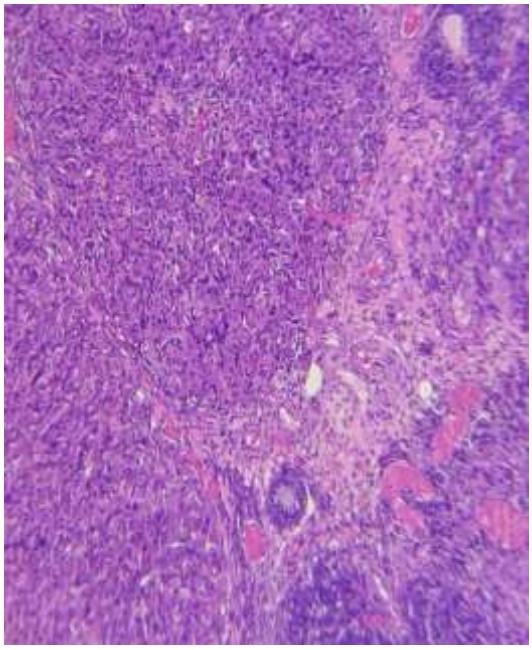


Histopathology of Ovary

Low Power Magnification 10X



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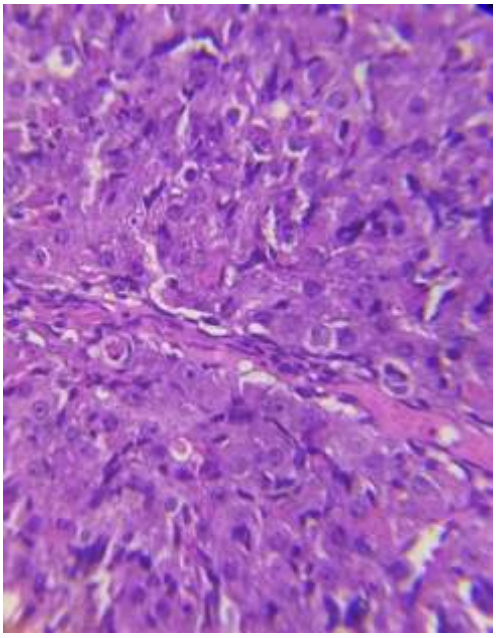


Pathology Report

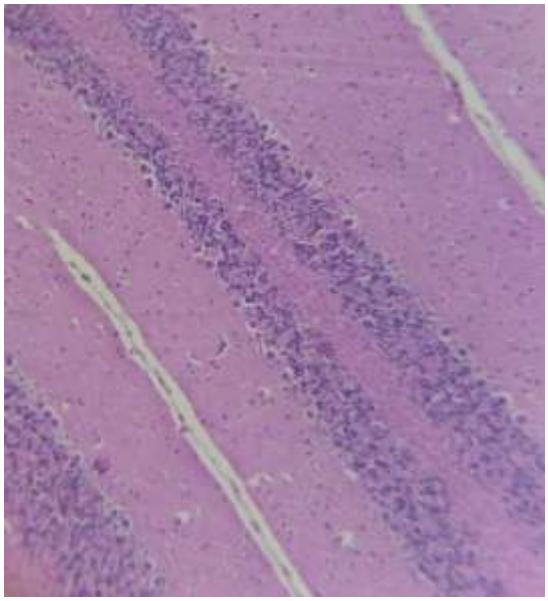
Sample Id: CFH

Brain	The CA zones of brain are filles with densely packed Pyramidal cells
Heart	Showing the normal histological structure of myocardium
Lung	Pulmonary alveoli and blood lumen appears normal
Stomach	Gastric epithelium and mucosa appears normal
Liver	Hepatic cords appears normal with radiating morphology
Kidney	Showing normal, intact renal tubules as well as renal glomeruli
Spleen	Central arterioles radiating around the red pulp were observed
Uterus	Endometrial gland, epithelium and blood vessels appears normal
Ovary	Follicular cells, cytoplasm and nucleus appears normal

Sample Id: CMH

Histopathology of Brain

Low Power Magnification 10X



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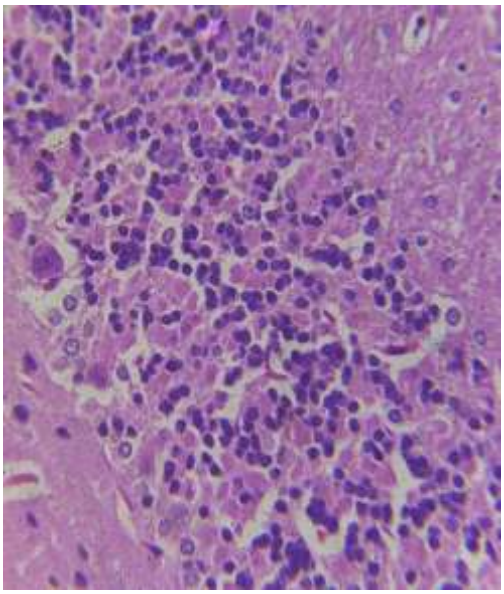
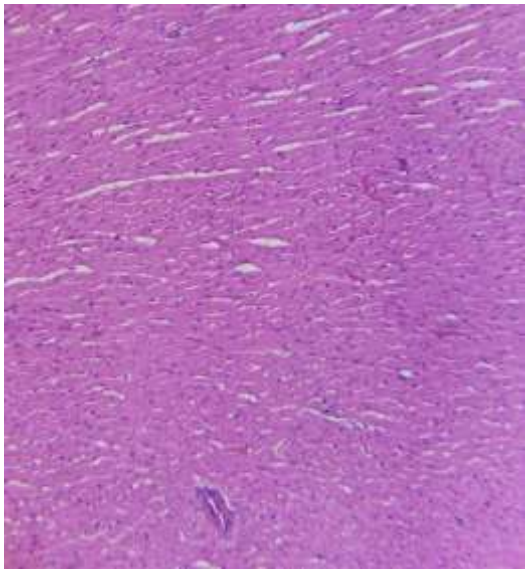


Histopathology of Heart

Low Power Magnification 10X



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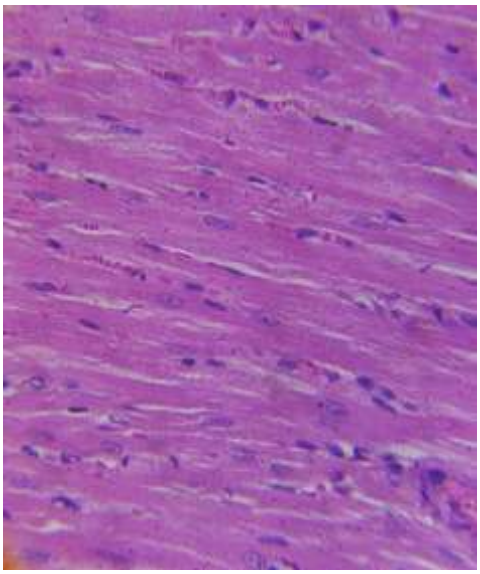
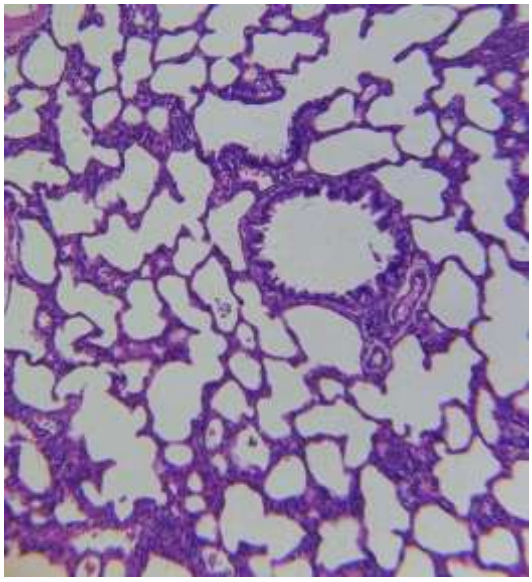


Histopathology of Lung

Low Power Magnification 10X



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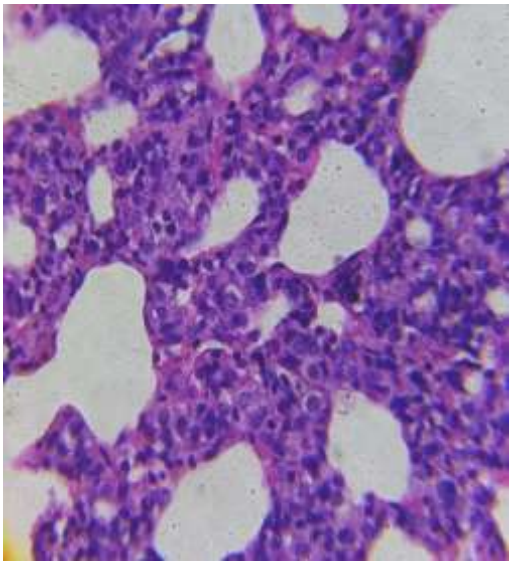
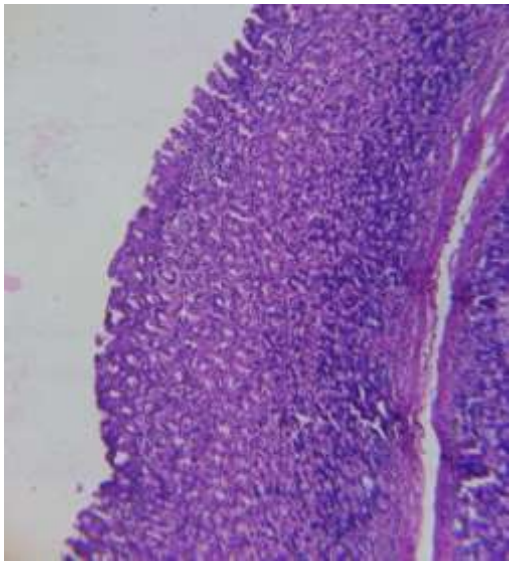


Histopathology of Stomach

Low Power Magnification 10X



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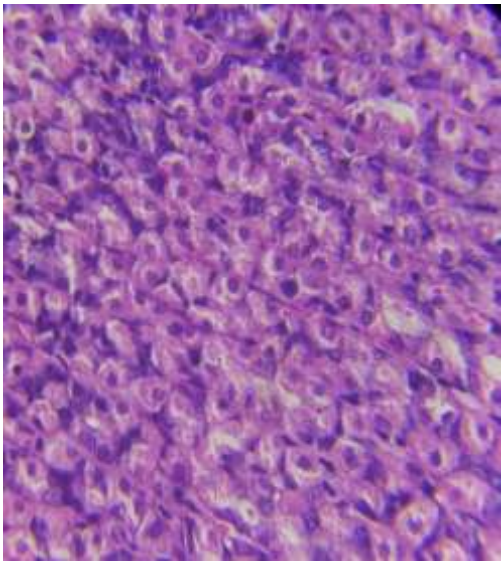
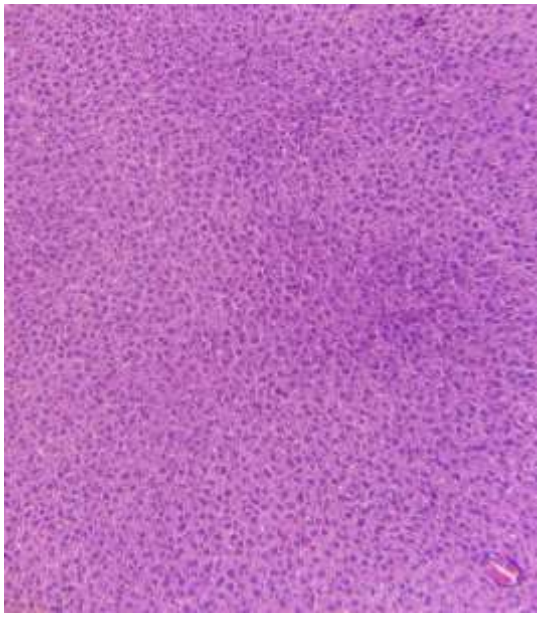


Histopathology of Liver

Low Power Magnification 10X



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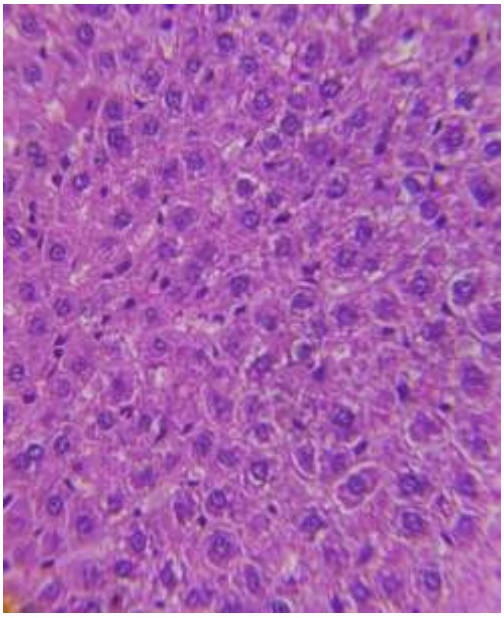
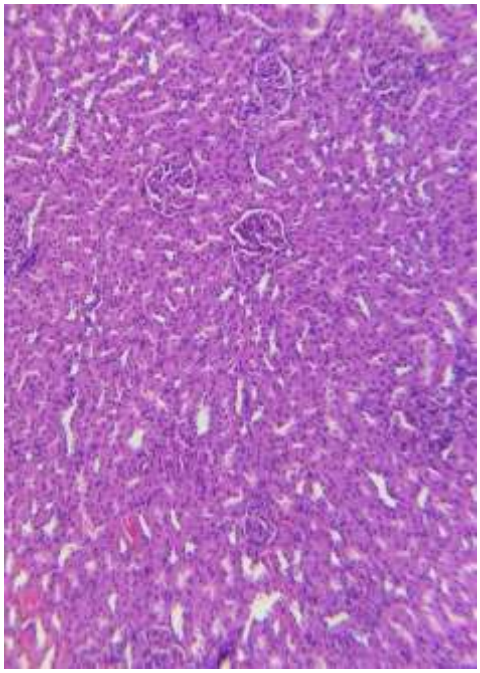


Histopathology of Kidney

Low Power Magnification 10X



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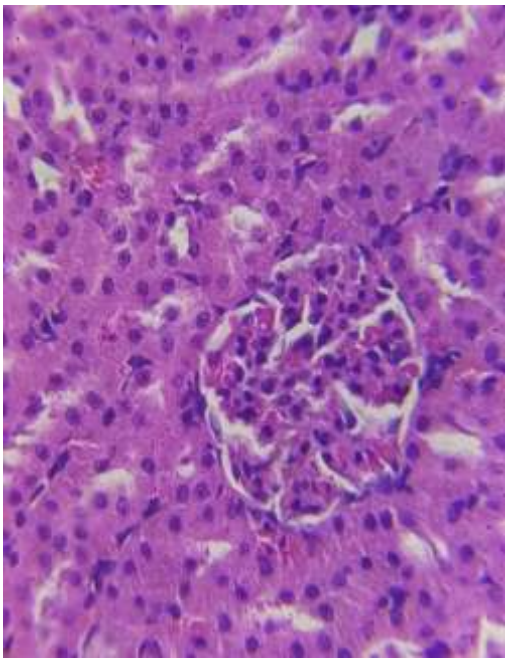
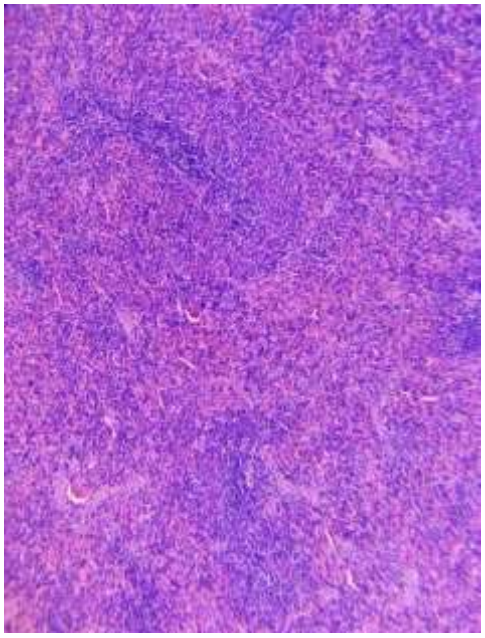


Histopathology of Spleen

Low Power Magnification 10X



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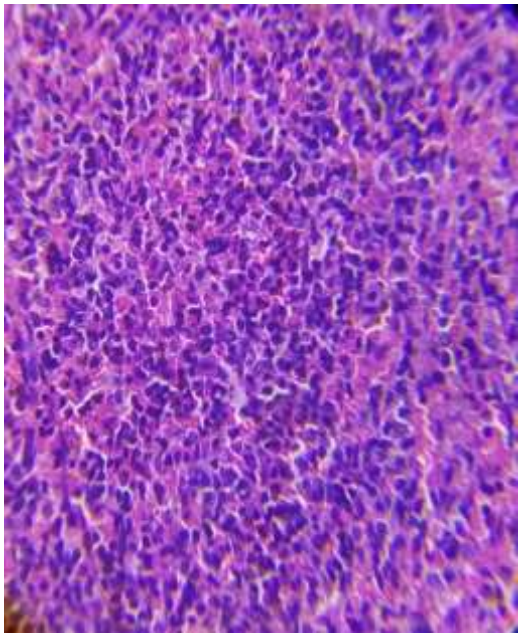
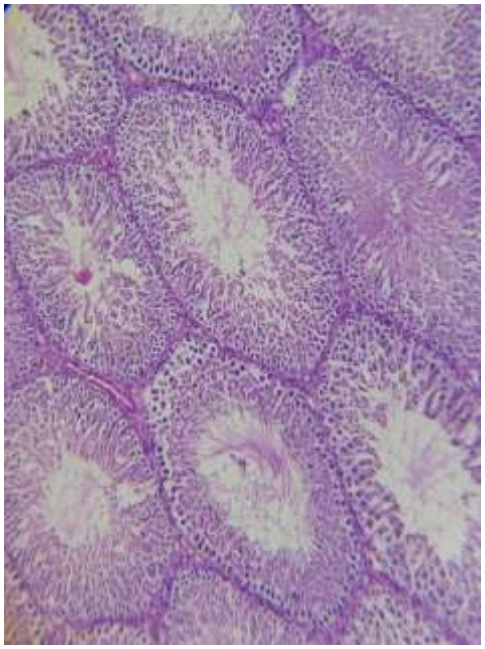
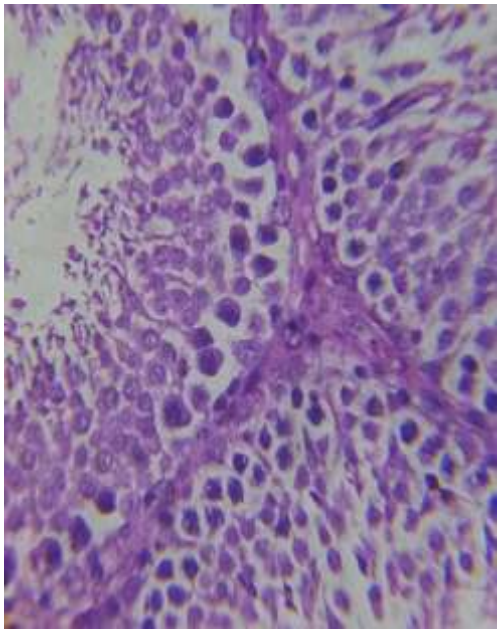


Histopathology of Testes

Low Power Magnification 10X



High Power Magnification 40X



Pathology Report

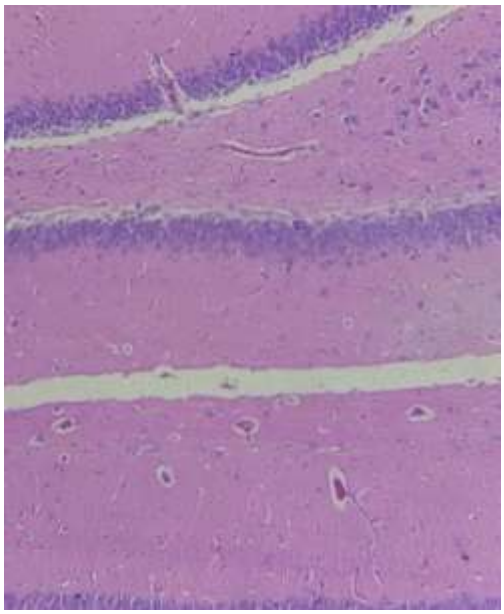
Sample Id : CMH

Brain	Showed normal architecture in both cortex and medulla where three layers of cerebellar cortex
Heart	Normal histology of myocardial tissue with prominent inter fiber distance
Lung	Bronchial opening appears regular with no signs of infiltration
Stomach	Mucosal wall appears normal with regular arrangement of connective tissue
Liver	Normal hepatocytes with no signs of necrosis
Kidney	Appearance of proximal and distal convolutes tubules was normal with no evidence of atrophy
Spleen	Regular appearance of red pulp is composed of a three dimensional meshwork of splenic cords and venous sinuses were observed
Testes	Histocytology of testicular tissue shows well differentiated germ cells with respect of spermatogonia includes spermatid and sperm were observed

Sample ID: SMC- HM

Histopathology of Brain

Low Power Magnification 10X



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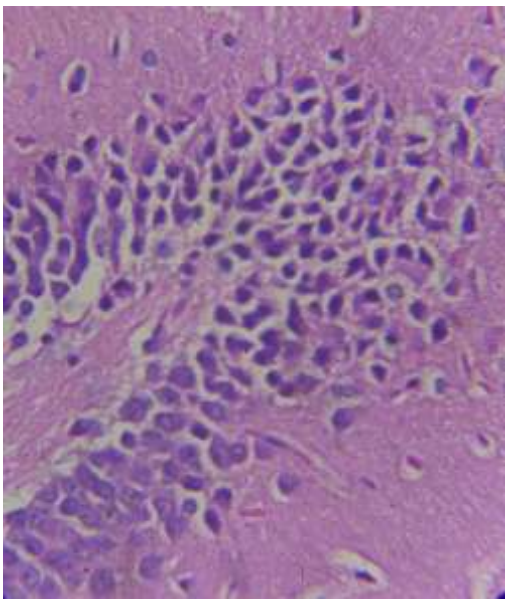
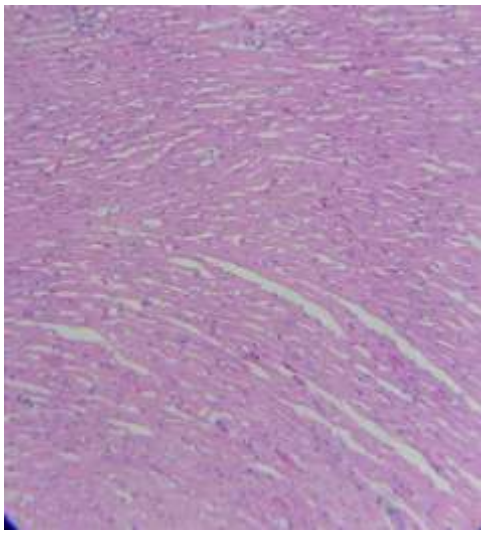
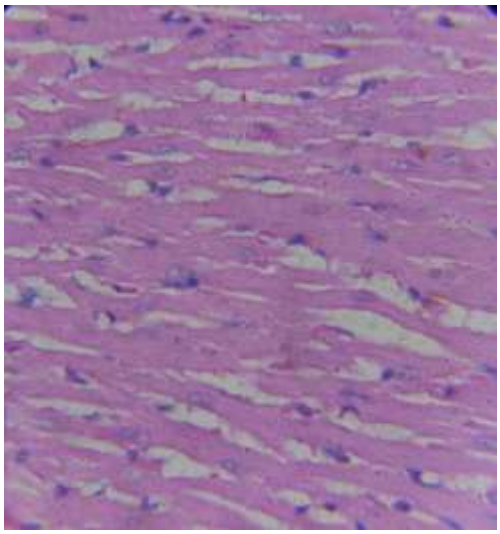


Histopathology of Heart

Low Power Magnification 10X

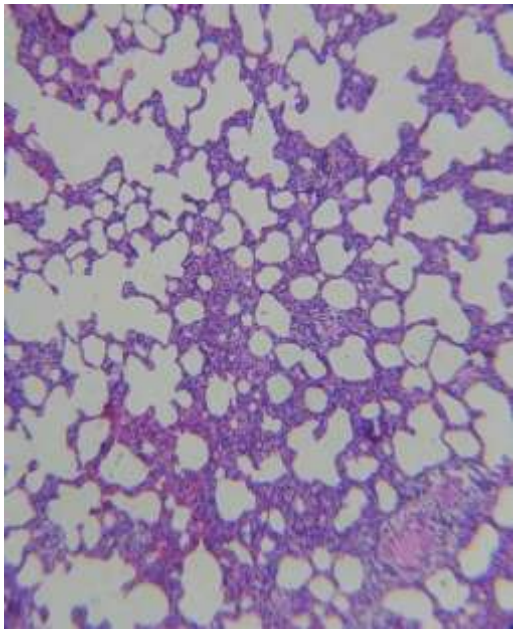


High Power Magnification 40X

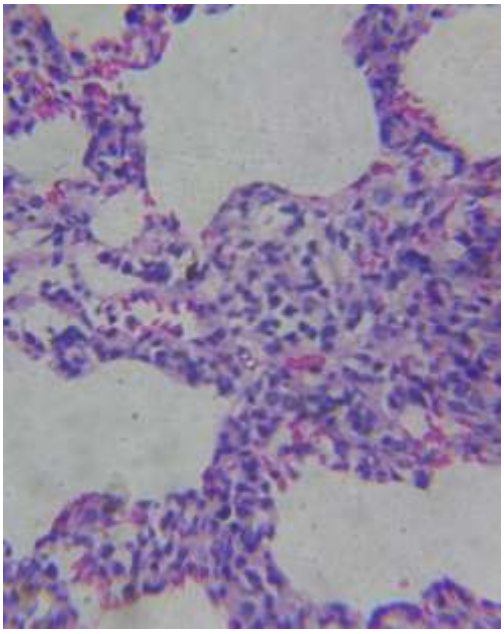


Histopathology of Lung

Low Power Magnification 10X

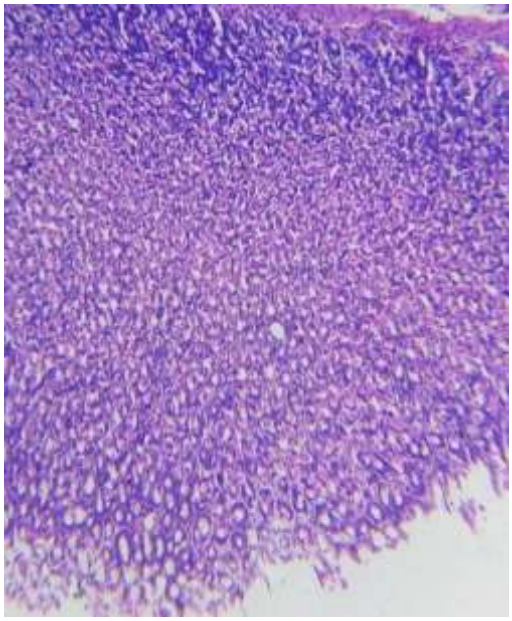


High Power Magnification 40X

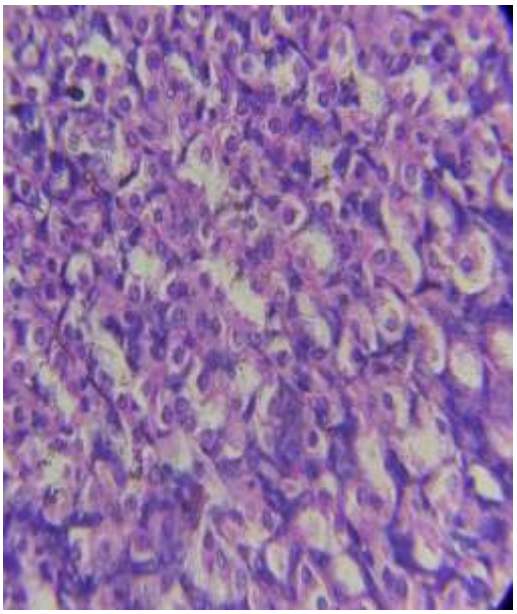


Histopathology of Stomach

Low Power Magnification 10X

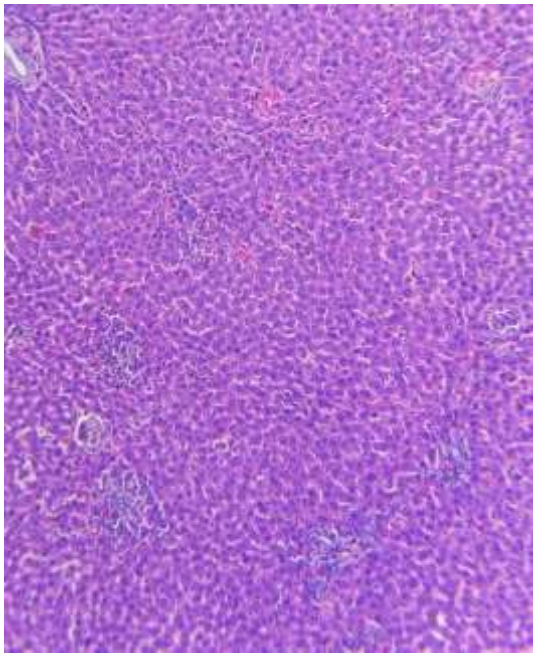


High Power Magnification 40X

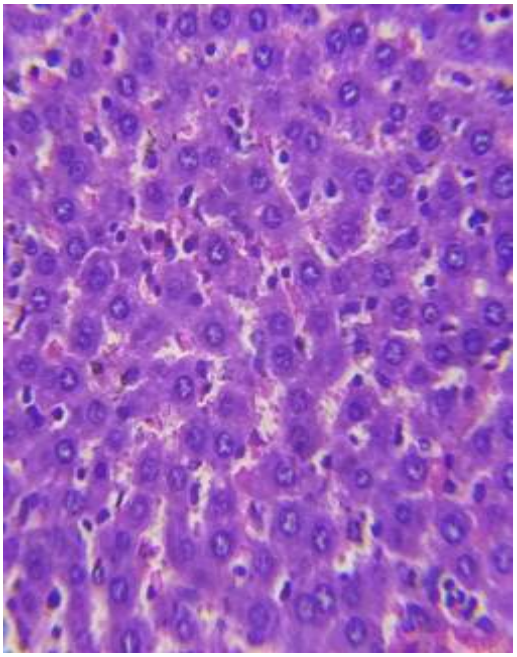


Histopathology of Liver

Low Power Magnification 10X

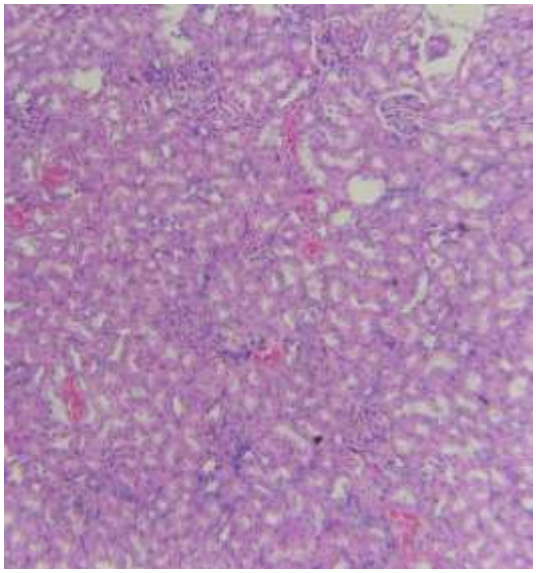


High Power Magnification 40X

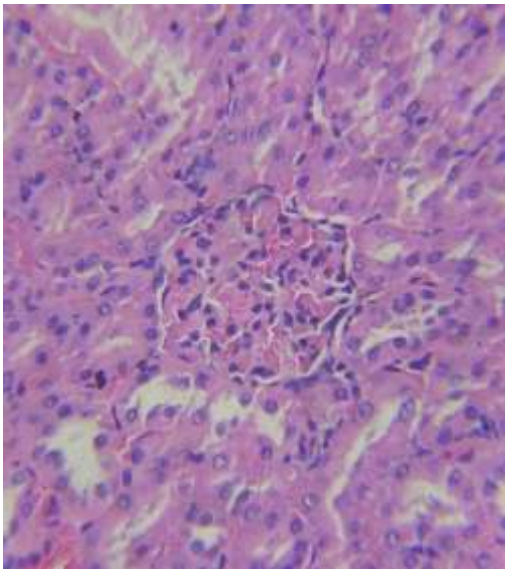


Histopathology of Kidney

Low Power Magnification 10X

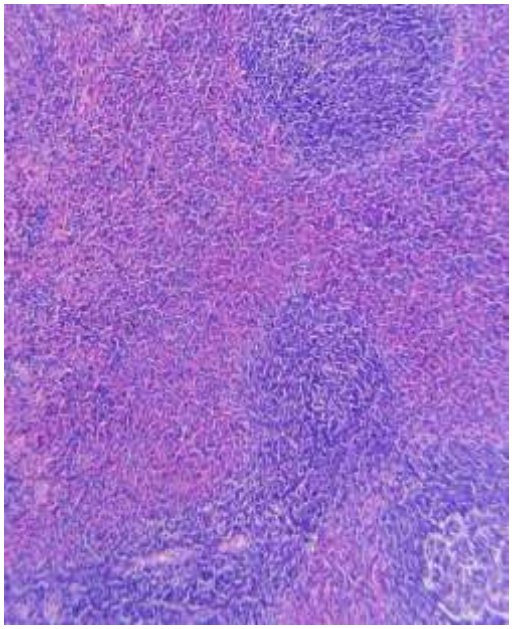


High Power Magnification 40X

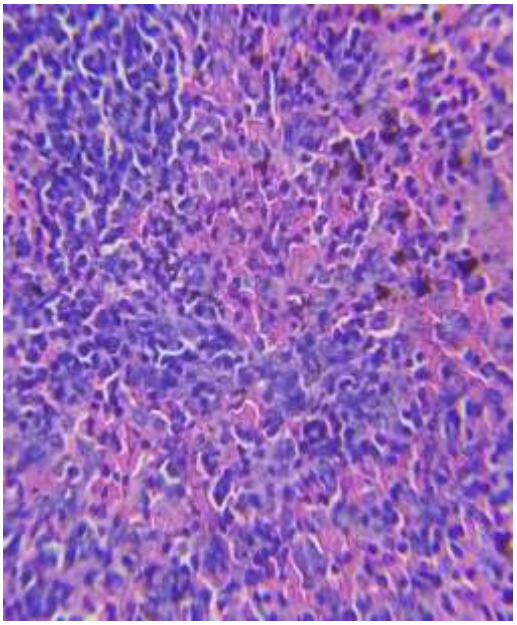


Histopathology of Spleen

Low Power Magnification 10X

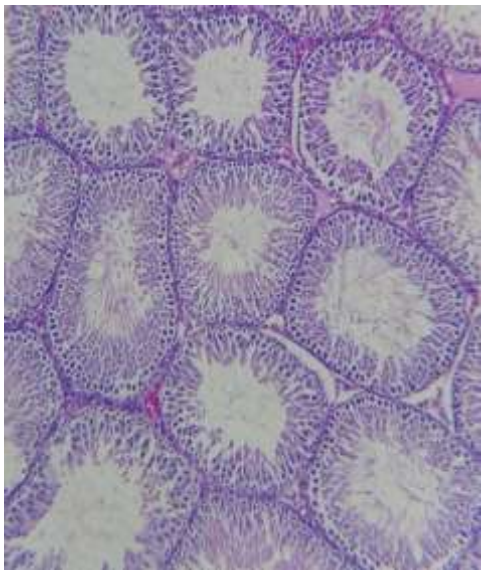


High Power Magnification 40X

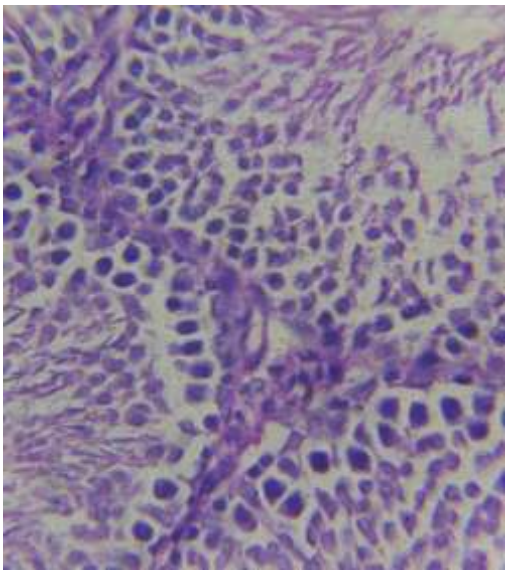


Histopathology of Testes

Low Power Magnification 10X



High Power Magnification 40X



Pathology Report

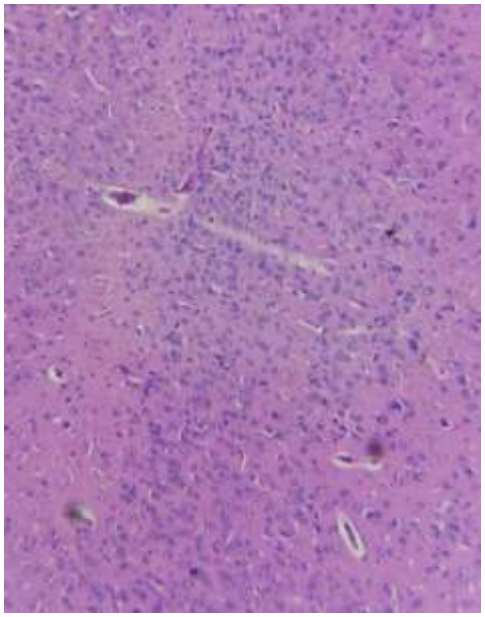
Sample ID: SMC- HM

Brain	Morphology of neurons in CA1, CA2 and CA3 zones are normal
Heart	Normal histology of myocardial fibres with no evident of necrotic fibres evident
Lung	Normal alveoli with equidistant arrangement and prominent histology
Stomach	Normal stomach cyto architecture with no signs of ulceration and infiltration
Liver	Hepatic cords appears normal with radiating morphology
Spleen	Morphology of capsule, nodes, red and white pulp appears normal
Kidney	Appearance of proximal and distal convolutes tubules was normal with no evidence of atrophy
Testes	Section of testis of showing normal interstitial connective tissue with ovoid or polygonal leydig cells and flat myoid cells

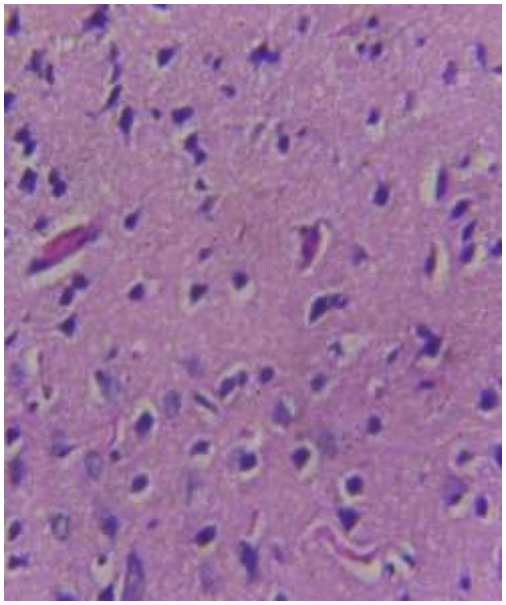
Sample ID: SMC- HF

Histopathology of Brain

Low Power Magnification 10X

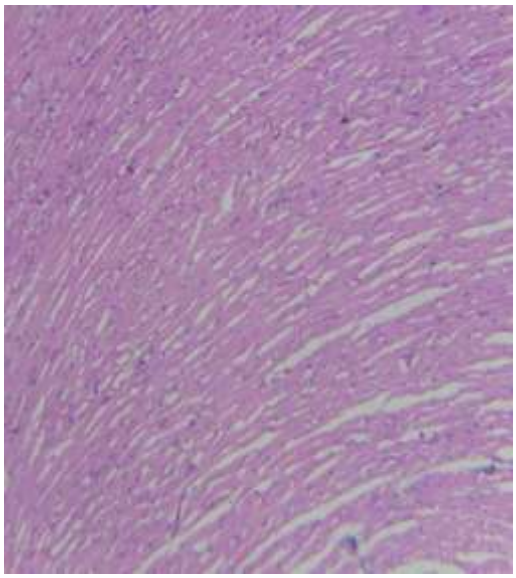


High Power Magnification 40X

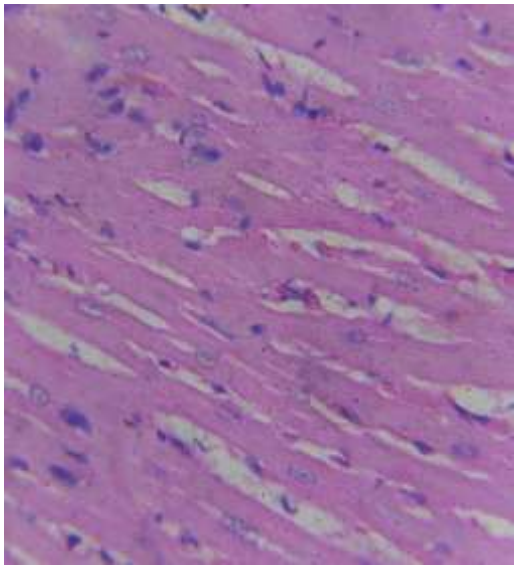


Histopathology of Heart

Low Power Magnification 10X

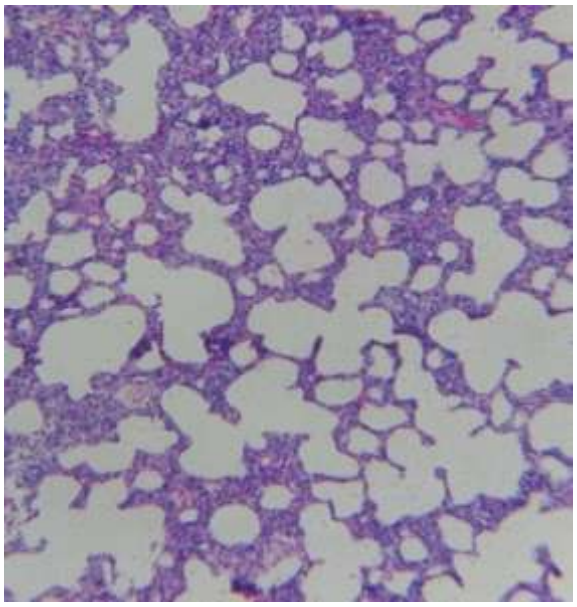


High Power Magnification 40X

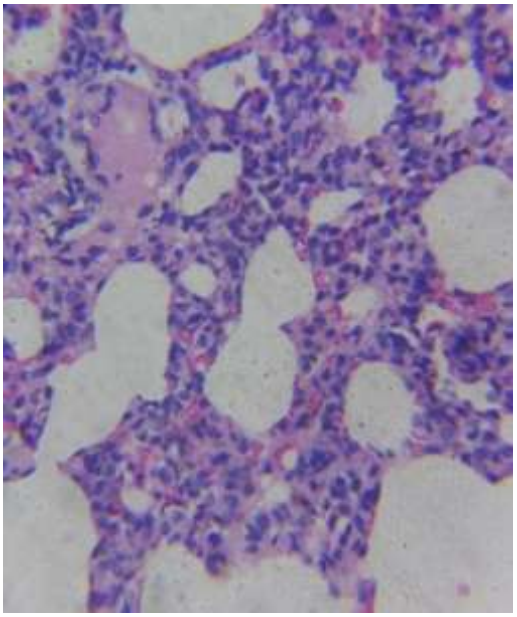


Histopathology of Lung

Low Power Magnification 10X

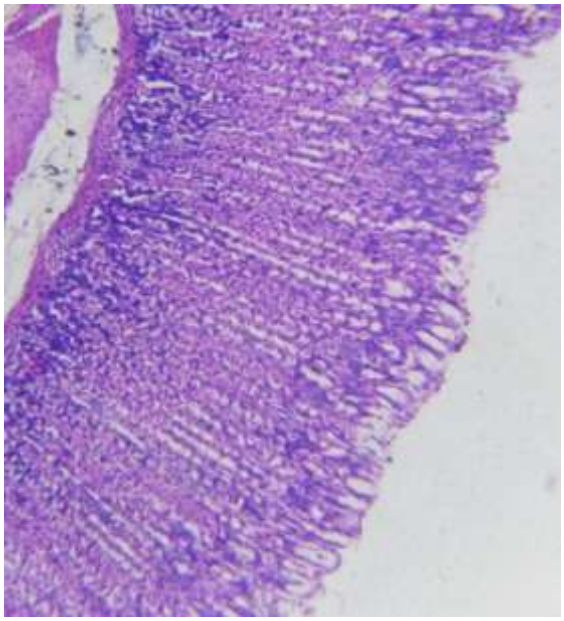


High Power Magnification 40X

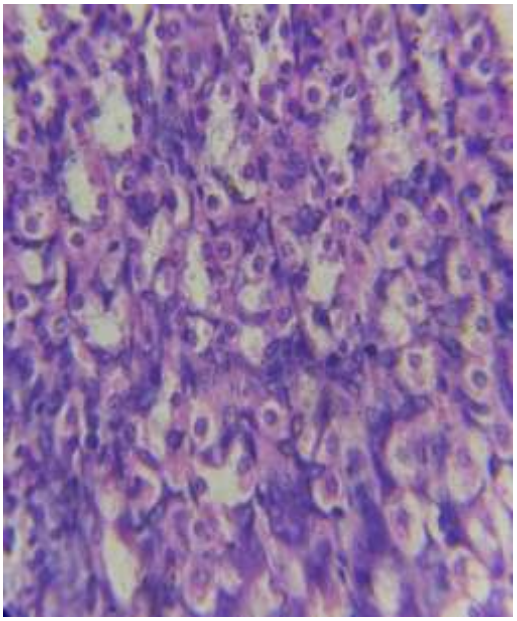


Histopathology of Stomach

Low Power Magnification 10X

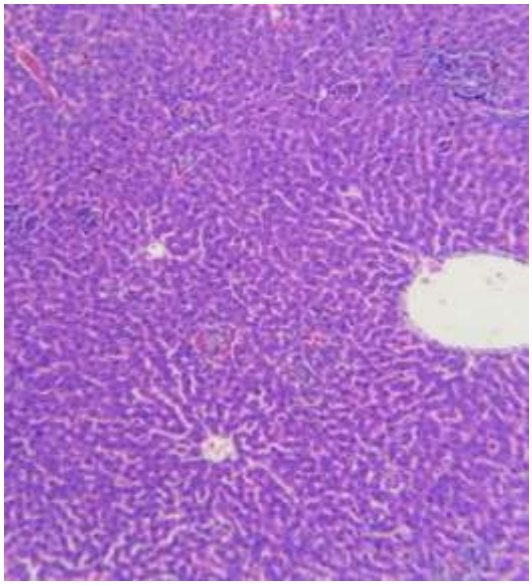


High Power Magnification 40X

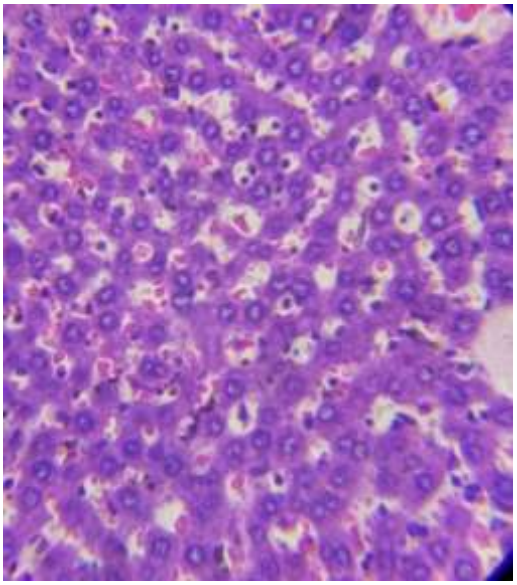


Histopathology of Liver

Low Power Magnification 10X

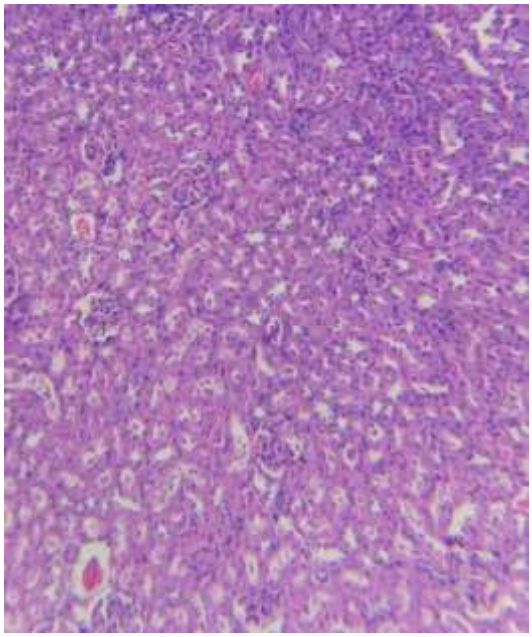


High Power Magnification 40X



Histopathology of Kidney

Low Power Magnification 10X



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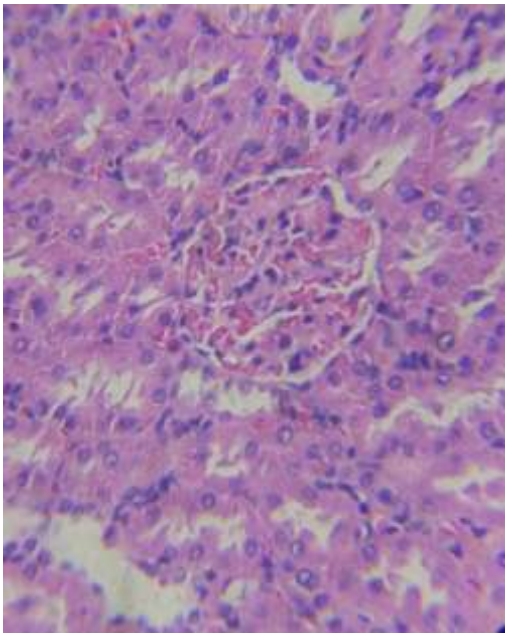
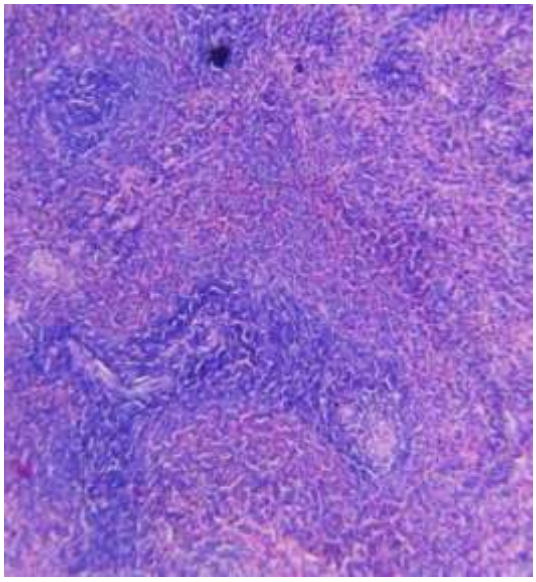
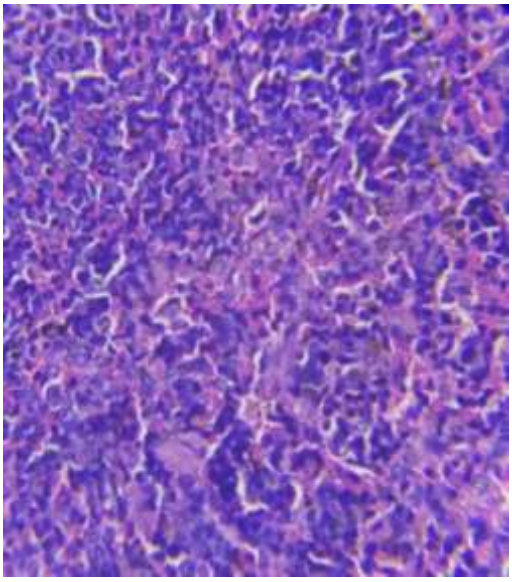


Histopathology of Spleen

Low Power Magnification 10X

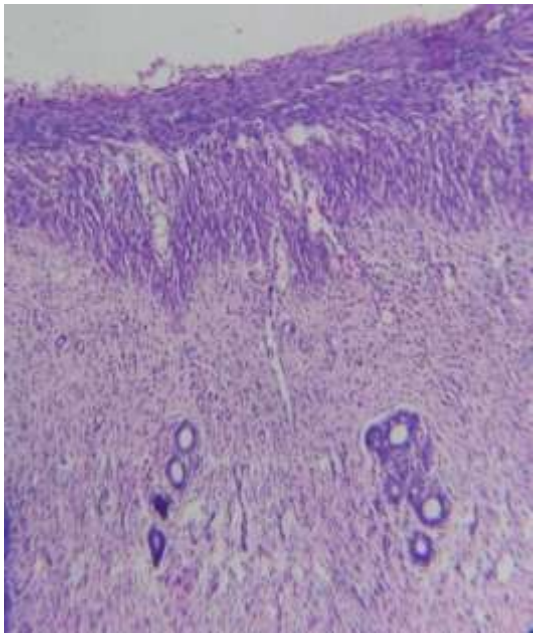


High Power Magnification 40X

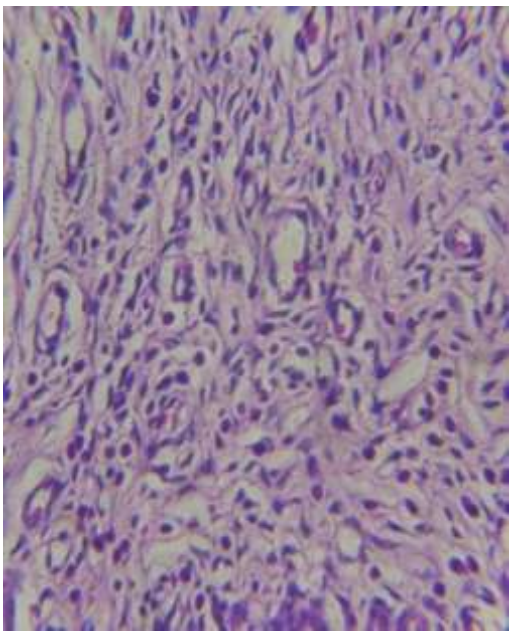


Histopathology of Uterus

Low Power Magnification 10X

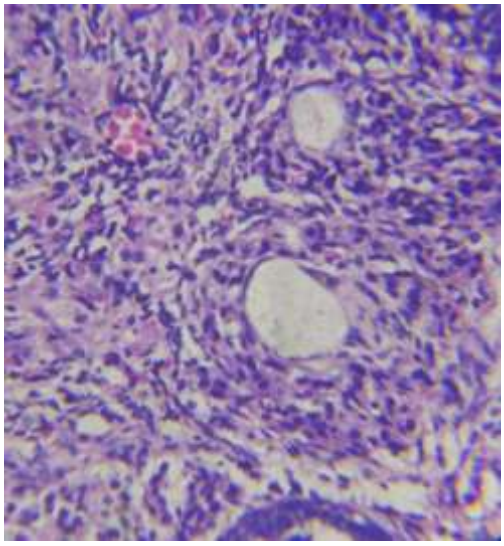


High Power Magnification 40X

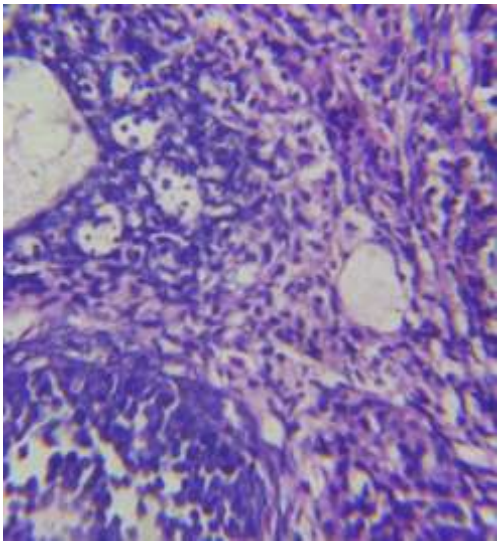


Histopathology of Ovary

Low Power Magnification 10X



High Power Magnification 40X



Pathology Report

Sample ID: SMC- HF

Brain	Regular marginal alignment on the neurons with promising histology were observed
Heart	Myocardial fibres appears normal elongated and rod shaped
Lung	Perivascular region appears normal, Alveolar septa and wall appeared widen and normal
Stomach	Appearance of Sub-mucosa and gastric glands appear normal
Liver	Cytoplasm appears normal with widen portal tract
Spleen	Regular appearance of red pulp is composed of a three dimensional meshwork of splenic cords and venous sinuses were observed
Kidney	No evidence of interstitial inflammation and lymphocyte accumulation
Uterus	Normal cyto architecture of uterine layers and glands were observed
Ovary	Sequential arrangement of granulosa cells around oocyte was normal and regular

OBSERVATIONS AND RESULTS

1). Age

2).Gender

3).Gunam

4).Bodyconstitution

5).Paruvakaalangal

6).Thinai

7). Socio economic status

8).Diet

9).Occupation

10).Duration of illness

11).Onset of illness

12).Distribution of Vatham

13).Distribution of Pitham

14).Distribution of Kabham

15).Neikkuri analysis

16).Analysis of UdalThathukal

17).Analysis of Kanmenthiriyam

18). Analysis of Naadi

19).Analysis of Envagaithervu

20).Clinical features

21).Outcome measures

22).Result of treatment

1.DISTRIBUTION OF CASES BY AGE :

Table.1

AGE	NO. OF CASES	PERCENTAGE%
20-30	1	2.5%
31-40	8	20%
41-50	20	50%
51-60	11	27.5%
TOTAL	40	100%

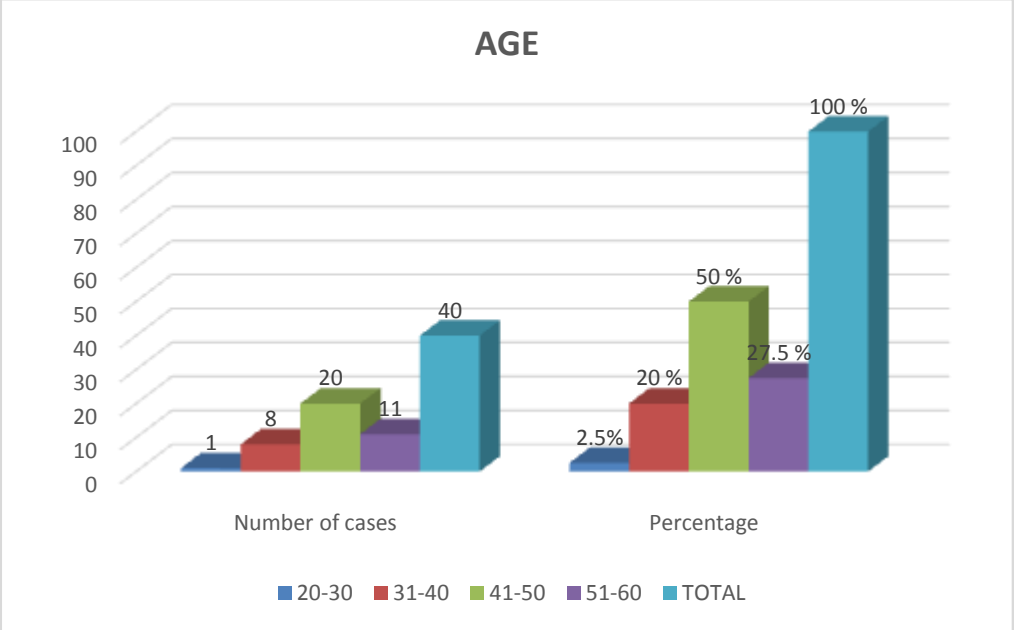


Fig :1

Inference:

Among 40 cases, the disease was found to be higher in the age group of 41-50 years, 20 cases (50%).

2.DISTRIBUTION OF CASES BY GENDER:

Table :2

S.NO	GENDER	NO. OF CASES	PERCENTAGE%
1.	Male	15	37.5%
2.	Female	25	62.5%

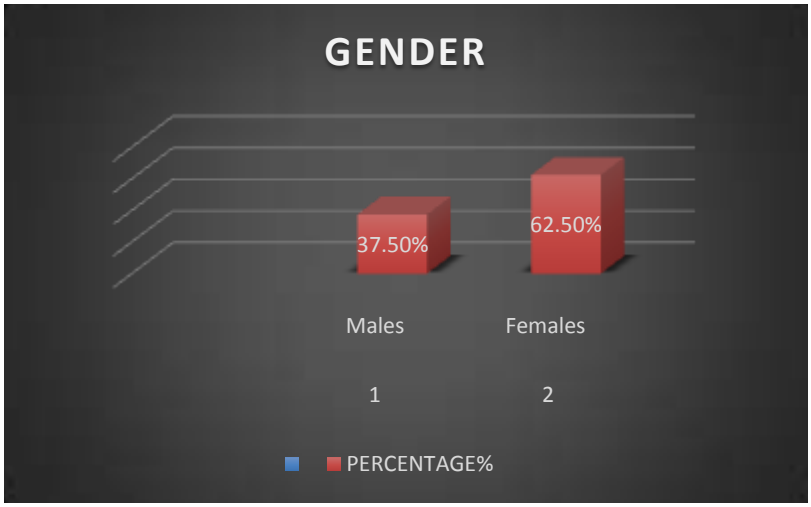


Fig.2

Inference:

Among 40 cases, 62.5% (25) females and 37.5% (15) males are affected.

3.DISTRIBUTION OF CASES BY GUNAM:

Table 3 :

GUNAM	NO.OFCASES	PERCENTAGE%
Sathuvagunam	0	0%
Rasathagunam	40	100%
Thamogunam	0	0%
Total	40	100%

Inference:

Among 40 cases, all of them were comes under *Rasatha gunam.*

4.DISTRIBUTION OF CASES BY BODY CONSTITUTION:

Table 4:

BODY CONSTITUTION	NO.OF CASES	PERCENTAGE%
Vaathapitha thegi	20	50%
Piththavathathegi	15	37.5%
Kabavathathegi	05	12.5%
Total	40	100%

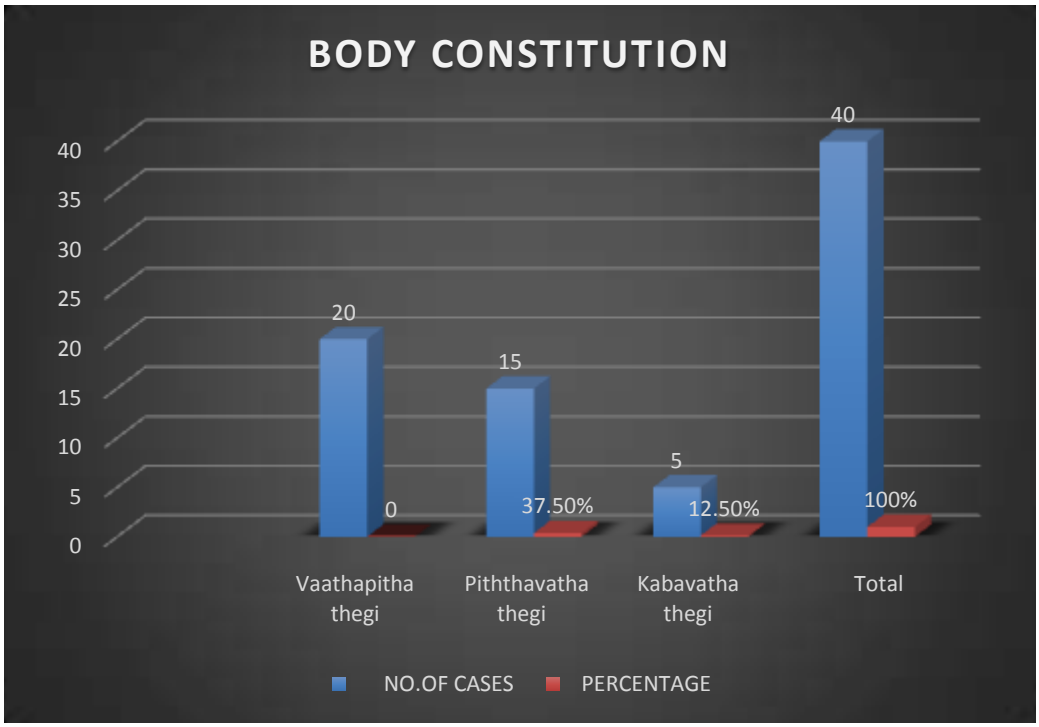


Fig.3

Inference:

Among 40 cases,Vathapitha Thegi 20 (50%), Pithavatha Thegi 15 (37.5%), Kabavatha Thegi 05 (12.5%).

5.DISTRIBUTION OF CASES BY KAALANGAL:

PARUVAKAALAM	NO.OF PATIENTS	PERCENTAGE%
Munpanikaalam (Dec17-Feb 12)	20	50%
Pinpanikaalam (Feb 13-Apr13)	18	45%
Elavenilkaalam (Apr 14-Jun 14)	02	5%
Total	40	100%

Table.5

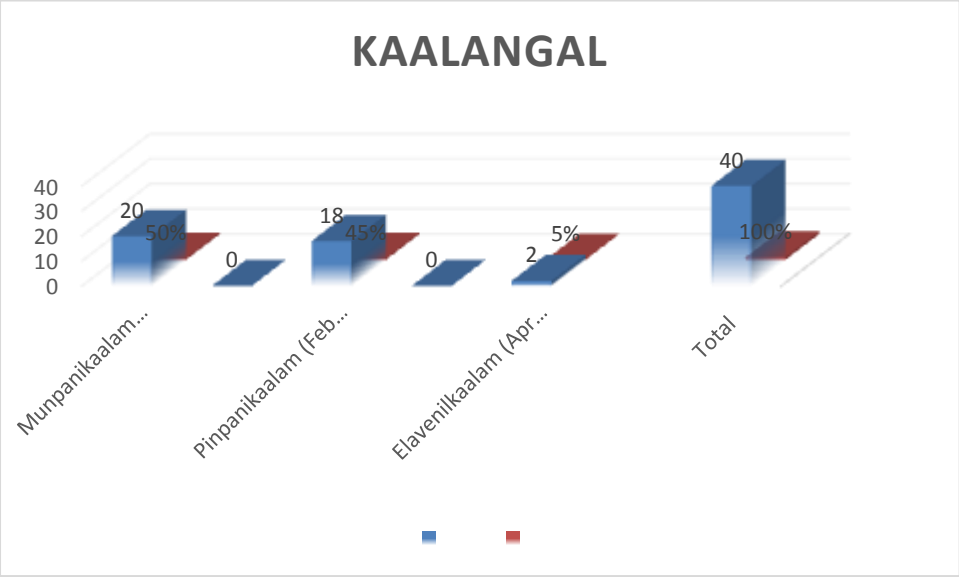


Fig.4

Inference:

Among 40 cases, most of the cases 20 (50%) were recruited in Munpanikalam 18 (45%) in Pinpanikalam,2 (5%) in Elavaenirkalam.

6.DISRTIBUTION OF CASES BY THINAI (LAND):

Table :6

S.NO	THINAI (LAND)	NO. OF CASES	PERCENTAGE(%)
1.	Kurinchi (Hill)	02	5%
2.	Mullai (Forest)	0	0%
3.	Marutham (Fertile)	02	5%
4.	Neithal (Coastal)	36	90%
5.	Paalai (Dessert)	0	0 %
	Total	40	100%

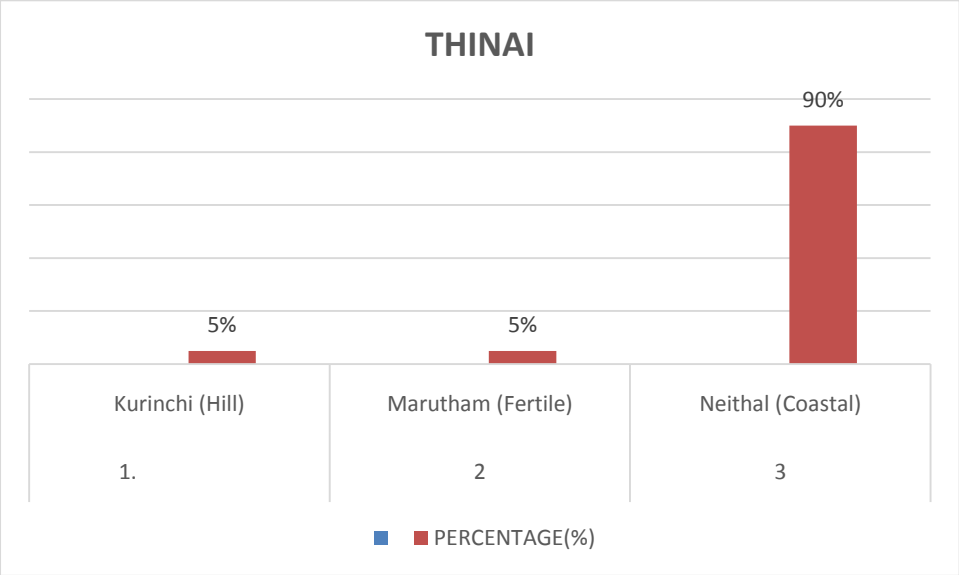


Fig :5

Inference :

Among 40 cases, 36 (90%) cases were from ***Neithal*** (Coastal), 2(5%) cases from kurinchi (Hill), 2 (5%) cases from Marutham (fertile)

7.DISRTIBUTION OF CASES BY SOCIO ECONOMIC STATUS:

Table.7

SOCIO ECONOMIC STATUS	NO.OF CASES	PERCENTAGE%
LowEconomicStatus	30	75%
ModerateEconomicstatus	10	25%
HighEconomicStatus	0	0%
Total	40	100%

Fig:6

Inference:

Among 40 cases 30 (75%) were belongs to low economic status, 10 (25%) were belongs to middle economic status.

8. DISTRIBUTION OF CASES BY DIETARY HABITS:

Table :8

DIET	NO.OF CASES	PERCENTAGE%
Vegetarian	02	5%
Non-vegetarian	38	95%
Total	40	100%

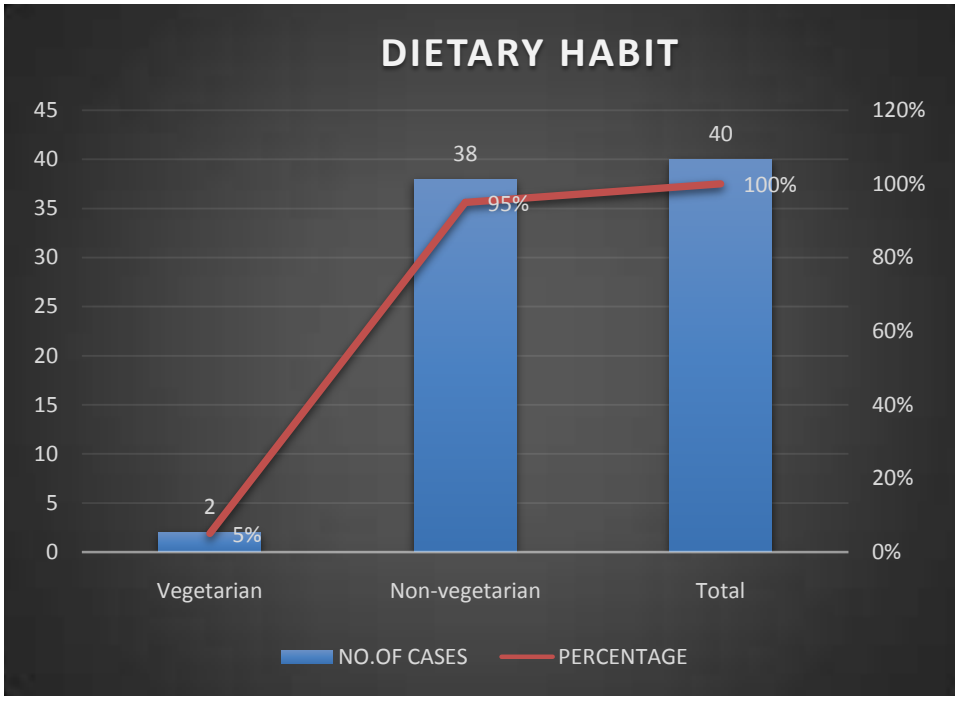


Fig.7

Inference:

Among 40 cases 2(5%) were vegetarian ,38 (95%) were non-vegetarian.

9.DISRTIBUTION OF CASES BY OCCUPATION:

Table.9

OCCUPATION	NO.OF CASES	PERCENTAGE%
Agriculture	1	2.5%
Home maker	14	35%
I.T sector	5	12.5%
Train driver	1	2.5%
Welder	2	5%
Machinery work	1	2.5%
Tailor	8	20%
Export company labor	2	5%
Security	3	7.5%
Supervisor	3	7.5%
Total	40	100%

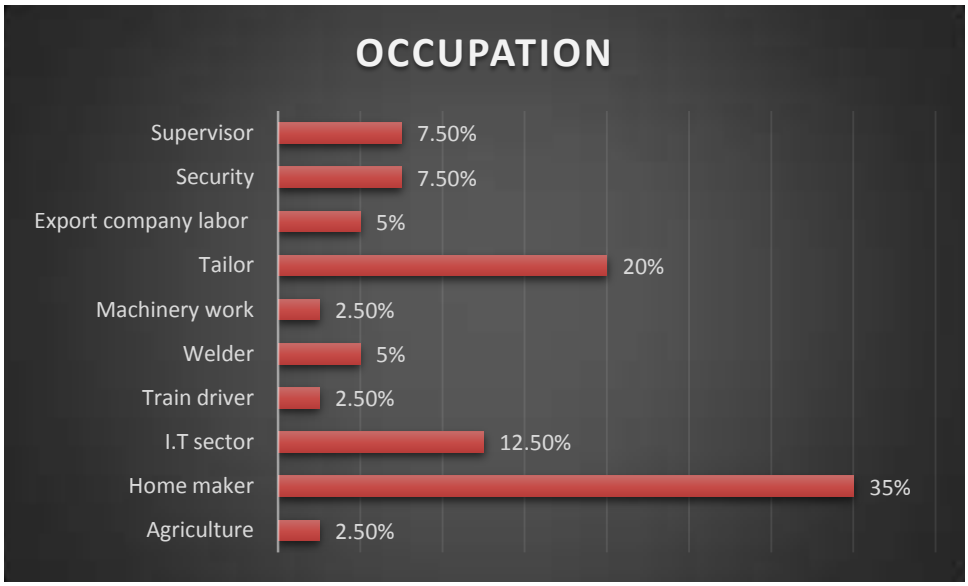


Fig.8

Inference :

The majority of patients 14 (35%) in this study were home maker.

10. DISRTIBUTION OF CASES BY DURATION OF ILLNESS:

Table. 10

DURATION	NO.OF CASES	PERCENTAGE%
Within a year	10	25%
1-2Years	10	25%
2-5Years	20	50%
5-10years	0	0%
Morethan10years	0	0%

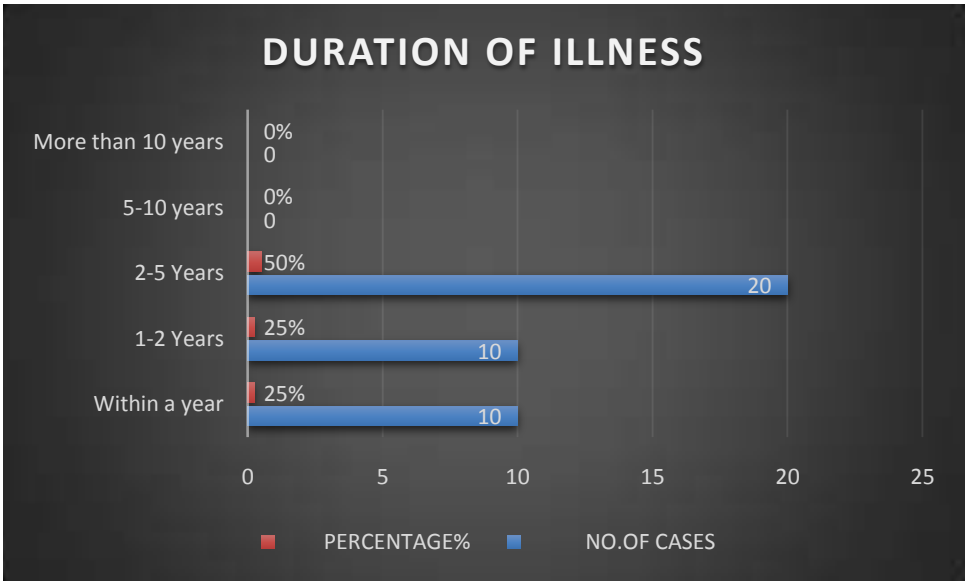


Fig.9

Inference:

Among 40 cases, the prevalence was more in 20 cases (50%) for 2-5 years, 10 cases suffered for (25%) 1-2 years, 10 cases (25%) suffered within a year.

11.DISTRIBUTION OF CASES BY ONSET OF DISEASE:

Table :11

ONSET	NO.OF CASES	PERCENTAGE
Sudden	0	0
Gradual	40	100
Total	40	100

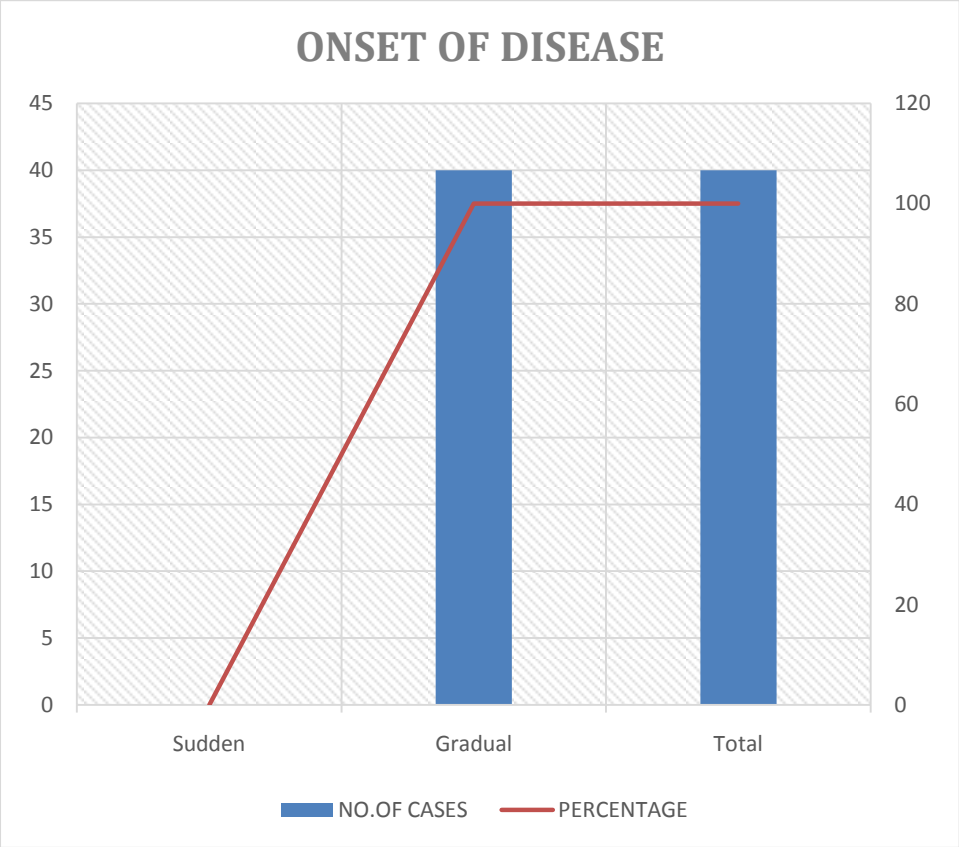


Fig.10

Inference :

Among 40 cases, all the cases belongs to gradual onset.

12.DISTRIBUTION OF CASES BY VATHAM:

Table.12

VATHAM	NO.OF CASES	PERCENTAGE
Praanan	0	0%
Abaanan	0	0%
Viyaanan	40	100%
Uthaanan	0	0%
Samaanan	40	100%
Nagan	0	0%
Koorman	0	0%
Kirukaran	0	0%
Devadhathan	0	0%
Dhananjayan	-	-

Inference:

Among the 40 cases, it is observed that all the 40 cases (100%) were affected by Viyanan and samanan.

13. DISTRIBUTION OF CASES BY PITHAM:

Table.13

PITHAM	NO.OF CASES	PERCENTAGE
Analagam	0	0%
Ranjagam	0	0%
Saathagam	40	100%
Prasagam	0	0%
Alosagam	0	0%
Total	40	100%

Inference:

Among 40cases, Saathagam was affected in all the cases.

14. DISTRIBUTION OF CASES BY KABHAM:

Table.14

KABHAM	NO.OF CASES	PERCENTAGE%
Avalambagam	0	0%
Kilethagam	0	0%
Pothagam	0	0%
Tharpagam	0	0%
Santhigam	40	100%

Inference:

Among 40 cases Santhigam was affected 40 (100%)

15.DISTRIBUTION OF CASES BY UDAL THATHUKAL:

Table.15

UDALTHATHUKAL	NO OF PATIENTS	PERCENTAGE%
Saaram	40	100%
Senneer	0	0%
Oon	40	100%
Kozhuppu	23	57.5%
Enbu	40	100%
Moolai	0	0%
Sukilam / Suronitham	0	0%

Inference:

Among the 40 cases, Saaram 40 (100%), Senneer 40 (100%), Oon 40 (100%), Kozhuppu 23 (57.5%), Enbu 40 (100%).

16.DISTRUBUTION OF CASES BY KANMAENTHIRIYAM:

Table.16

KANMAENTHIRIYAM	NO OF PATIENTS	PERCENTAGE%
Kai	40	100%
Kaal	0	0%
Vaai	0	0%
Karuvai	0	0%
Eruvai	0	0%

Inference:

Among 40 cases, kai was affected in 40 cases (100%).

17.ANALYSIS OF CASES BY NAADI:

Table17:

NAADI	BEFORE		AFTER	
	NO. OF CASES	**%**	**NO. OF CASES**	**%**
Vathapitham	20	50%	19	47.5%
vathakabam	-	-	1	2.5%
Pithavatham	19	47.5%	20	50%
Pithakabam	1	2.5%	1	2.5%
Kabavatham	-	-	-	-
Kabapitham	-	-	-	-
Total	40	100%	40	100%

Inference:

Among 40 cases, Before treatment vathapitham naadi were found in 20 (50%) cases, pithavatha naadi were found in 19 (47.5%) cases, pithakaba naadi were found in 1 (2.5%). After treatment vathapitha naadi were found in 19 (47.5%) cases, vathakaba naadi were found in 1(2.5%) case, pithavatha naadi were found in 20 (50%), pithakaba naadi were found in 1(2.5%) case.

18.ANALYSIS OF CASES BY ENVAGAITHERVUGAL:

Table.18

ENVAGAITHERVUGAL	NO.OFCASES	PERCENTAGE%
Naa	10	25%
Niram	0	0%
Mozhi	0	0%
Vizhi	0	0%
Sparisam	0	0%
Malam	0	0%
Moothiram	0	0%

Inference:

Among 40 cases, Naa 10 cases (25%) was affected.

19. ANALYSIS OF CASES BY NEIKURI:

Table.19

PATTERN	BEFORE		AFTER	
	NO. OF CASES	%	NO. OF CASES	%
Aravenaneendathu– Vaathaneer	11	27.5%	13	32.5%
Aazhipolparaviyadhu– Piththaneer	17	42.5%	10	25%
Muthothunindrathu– Kabaneer	12	30%	17	42.5%

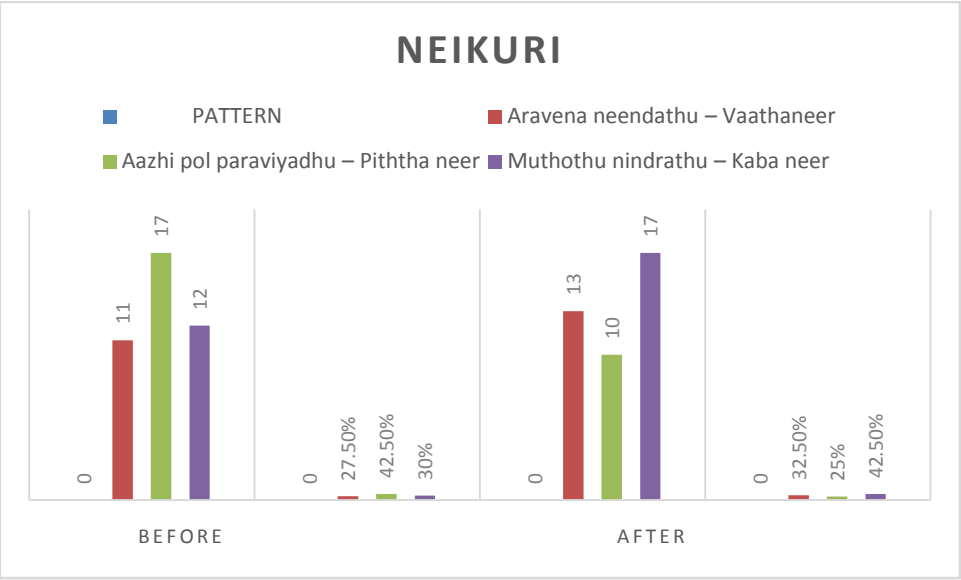


Fig.11

Inference:

Among 40 cases Vaatha Neer were found in 11 cases (21.5%), Piththa Neer were found in 17 cases (42.5%), Kabha Neer were found in 12 cases (30)

20.DISTRIBUTION CASES BY CLINICAL FEATURES:

Table.20

SYMPTOMS	NO. OF CASES		PERCENTAGE %	
	BT	AT	BT	AT
Radiating pain to upper limb	40	05	100%	12.5%
Tenderness	27	05	67.5%	12.5%
Stiffness of cervical spine	40	04	100%	10%
Numbness&paraesthesia	26	04	65%	10%

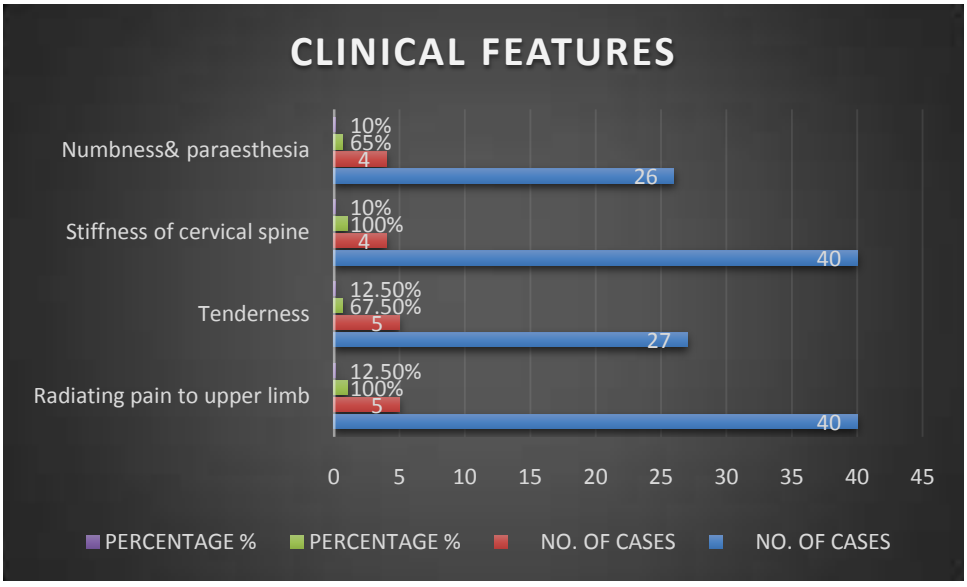


Fig.12

Inference:

Among 40 cases, Before treatment radiating pain and stiffness were present 40 (100%) cases, tenderness present in 27 cases (67.5%), Numbness and paresthesia 26(65%). After treatment 05 cases (12.5%) had radiating pain to upper limbs, 05 cases (12.5%) had tenderness in cervical region, 04 cases (10%) had stiffness of cervical spine, 04 cases (10%) had numbness & paraesthesia.

PAIN SCORE TRAIL DRUG (GROUP A)

S.NO	OP.NO	NAME	A/S	PAIN		RADIATING PAIN		ROM		NUMBNESS	
				BT	AT	BT	AT	BT	AT	BT	AT
1.	**I53772**	Mr.S.Jayakumar	22/M	7	2	+	_	G3	G1	-	-
2.	**I53772**	Mrs.N.Dhanalakshmi	42/F	7	2	+	-	G3	G2	-	-
3.	**K63027**	Mrs.B.Ashadevi	39/F	7	1	+	-	G3	G1	-	-
4.	**K81868**	Mrs.S.Subbulakshmi	54/F	6	2	+	-	G3	G1	-	-
5.	**K97733**	Mrs.M.Shawarbanu	46/F	8	1	+	-	G3	G1	+	+
6.	**K73022**	Mrs.K.Sulochana	34/F	7	1	+	-	G3	G1	+	-
7.	**K81635**	Mrs.R.Suganthi	54/F	7	2	+	-	G3	G1	+	-
8.	**J75907**	Mrs.V.Rani	43/F	8	3	+	+	G2	G1	+	+
9.	**K96363**	Mrs.R.Dhanalakshmi	42/F	7	2	+	-	G3	G1	+	-
10.	**L03490**	Mrs.R.Kalavathy	50/F	8	4	+	+	G2	G1	+	-
11.	**K92700**	Mrs.M.Madhuladevi	55/F	7	2	+	-	G2	G1	-	-
12.	**I30336**	Mr.R.Jayashankar	42/M	6	2	+	-	G3	G1	-	-
13.	**L10556**	Mrs.M..Banu	57/F	7	4	+	-	G3	G2	-	-
14.	**L03476**	Mr.K.Mohanasundaram	49/M	8	2	+	+	G3	G1	+	-
15.	**J94001**	Mrs.L.Judith	34/F	8	1	+	+	G3	G1	+	-
16.	**L03046**	Mr.E.Ramesh	38/M	8	4	+	+	G3	G1	+	-
17.	**L30335**	Mrs.G.Jayanthi	46/F	8	1	+	-	G3	G1	+	-
18.	**K75867**	Mrs.U.Shakila	38/F	7	2	+	-	G2	G2	+	-
19.	**L11182**	Mr.Egambaram Eswaran	41/M	7	1	+	-	G3	G2	+	-
20	**I38337**	Mrs.S.Vanitha	34/F	8	2	+	-	G3	G2	-	-

PAIN SCORE TRAIL DRUG WITH VARMAM (GROUP B)

S.NO	OP.NO	NAME	A/S	PAIN		RADIATING PAIN		ROM		NUMBNESS	
				BT	AT	BT	AT	BT	AT	BT	AT
1.	**K02822**	Mrs.R.Rajeshwari	50/F	8	0	+	-	G2	G1	-	-
2.	**K68058**	Mrs.K.Sathya	41/F	9	5	+	-	G2	G1	+	-
3.	**K91986**	Mrs.R.Malar	44/F	8	1	+	-	G2	G1	+	-
4.	**F30722**	Mrs.R.Renuka	47/M	8	0	+	-	G3	G2	+	-
5.	**K77777**	Mr.V.Umapathy	44/F	9	1	+	-	G3	G2	+	+
6.	**K91634**	Mrs.P.Bhavani	49/F	7	0	+	-	G3	G1	+	-
7.	**I01928**	Mr.G.Harihara Subramaniyam	49/M	9	2	+	-	G2	G1	+	-
8.	**J61956**	Ms.J.Sasikala	37/F	6	0	+	-	G3	G1	-	-
9.	**K77778**	Mr.T.M.Kumar	58/M	8	0	+	-	G3	G2	+	-
10.	**K96012**	Mr.N.Ravindar	43/M	8	1	+	-	G3	G1	+	-
11.	**K84007**	Mr.C.Velmurugan	39/M	8	1	+	-	G3	G1	+	-
12.	**K74748**	Mrs.S.Malarkodi	52/F	7	2	+	-	G2	G1	+	-
13.	**1849-18**	Mrs. V.Suganya	48/F	7	1	+	-	G3	G2	+	-
14.	**1864-18**	Mrs.K.Hemavathy	42/F	8	1	+	-	G2	G1	+	-
15.	**1863-18**	Mrs.S.Kumudha	60/F	8	1	+	-	G3	G2	+	-
16.	**J76413**	Mr.B.V.Katheresan	42/M	9	2	+	-	G3	G1	+	+
17.	**L08360**	Mr.D.Dilli	53/M	7	0	+	-	G3	G2	-	-
18.	**K68865**	Mr.D.Design	49/M	7	0	+	-	G2	G1	-	-
19.	**L03496**	Mr.G.Venkatesan	59/M	8	0	+	-	G3	G1	-	-
20	**H25446**	Mr.R.Ganasekaran	59/M	7	2	+	-	G3	G1	-	-

21.OUTCOME MEASURES:

RESTRICTED MOVEMENT ASSESMENT SCALE:

Table.21

	BEFORE TREATMENT		AFTER TREATMENT		
GRADING	**NO OF CASES**	**%**	**GRADING**	**NO OF CASES**	**%**
GRADE I	0	0%	G3 -G1	19	47.5%
			G2 – G1	10	25%
GRADE II	11	27.5%	G3 -G2	10	25%
			G2 -G2	1	2.5%
GRADE III	29	72.5%			
GRADE IV	0	0%			
TOTAL	40	100%		40	100%

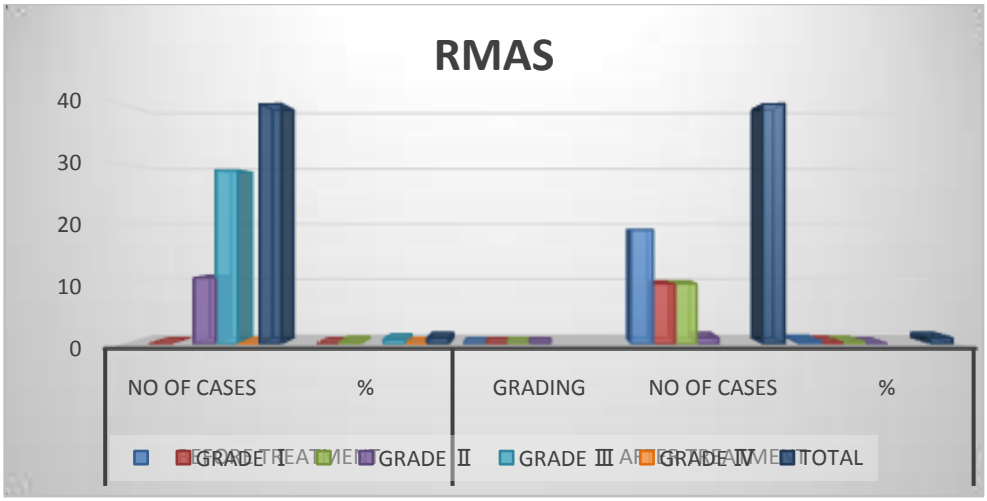


Fig.13

Inference:

Among 40 cases, movement restriction was reduced in 29 cases (72.5%) Grade1, Mild restriction was found in 11 cases (27.5%).

23.A.DISTRIBUTION OF CASES BY PAIN ASSSEMENT SCALE IN TRAIL DRUG SIGAMANI CHOORANAM (INTERNAL) WITH ARKASHEERATHY THYLAM (EXTERNAL).

Table.23 (GROUP A)

PAIN ASSESSMENT WITH TRAIL DRUG	BEFORE		AFTER	
	NO. OFCASES	%	NO. OF CASES	%
No pain	0	0%	0	0%
Mild	0	0%	17	85%
Moderate	2	10%	03	15%
Severe	18	90%	0	0%
Total	20	100%	20	100%

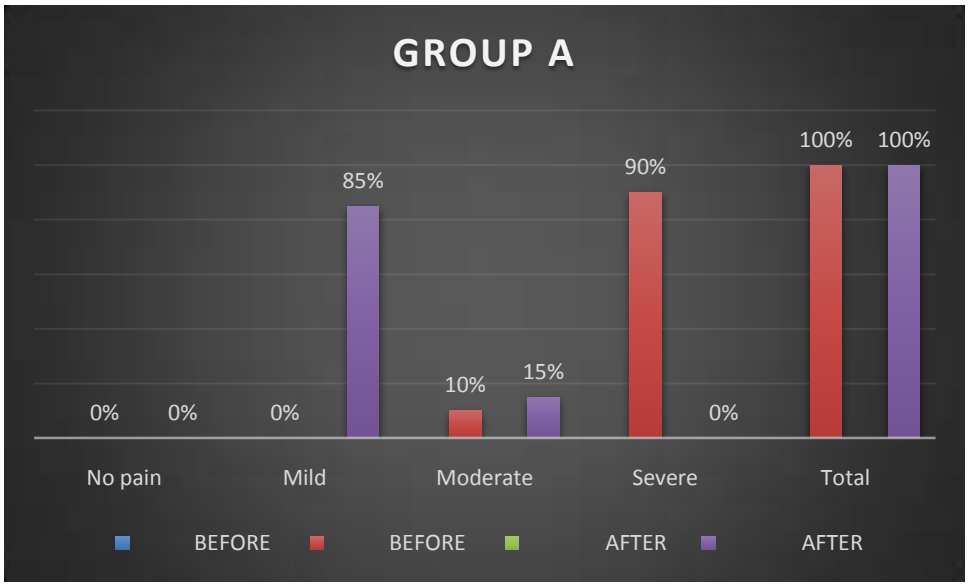


Fig.14

Inference:

Among 20 cases, before treatment severe pain were present in 18 cases (90%), moderate pain present in 2 case (10%). After treatment mild pain present in 17 cases (85%), moderate pain present in 3 cases (15%).

23.B.DISTRIBUTION OF CASES BY PAIN ASSSEMENT SCALE IN (TRAIL DRUG WITH VARMAM):

Table.24 (GROUP-B)

PAIN ASSESSMENT (TRAIL DRUG + VARMAM)	BEFORE		AFTER	
	NO. OFCASES	%	NO. OF CASES	%
No pain	0	0%	08	40%
Mild	0	0%	11	55%
Moderate	1	5%	1	5%
Severe	19	95%	0	0%
Total	20	100%	20	100%

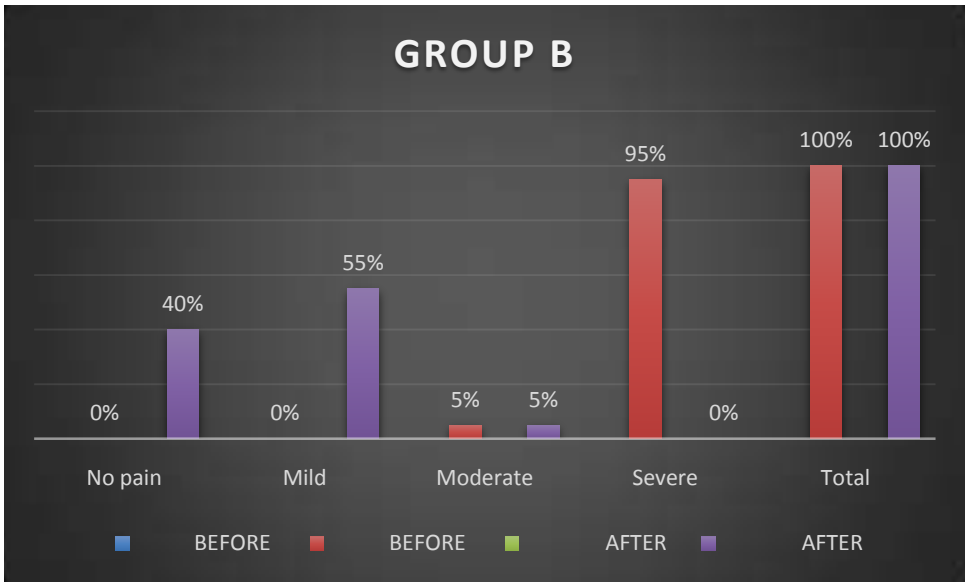


Fig.15

Inference:

Among 20 cases, before treatment severe pain present in 19 cases (95%), moderate pain present in 1 case (5%). After treatment pain nil in 8 cases (40%), mild pain present in 11cases (55%), moderate pain present in 1 cases (5%).

24. QUETIONNAIRE OUTCOME WITH PAIN ASSESSEMENT OUTCOME:

Table.25

BOTH GROUP	BEFORE		AFTER	
	NO. OFCASES	%	NO. OF CASES	%
No pain	0	0%	08	20%
Mild	0	0%	28	70%
Moderate	3	7.5%	4	10%
Severe	37	92.5%	0	0%
Total	40	100%	40	100%

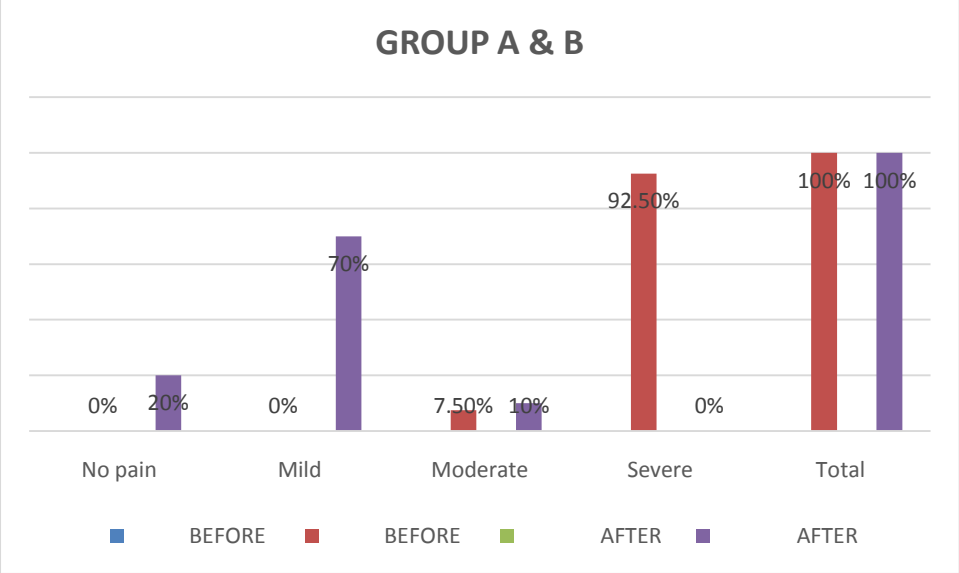


fig:16

Inference:

Among 40 cases, before treatment severe pain present in 37 cases (92.5%), moderate pain present in 3 case (7.5%). After treatment No pain in 08 cases (20%), mild pain present in 28 cases (70%), moderate pain present in 4 cases (10%).

25. RESULT:

Table.26

PAIN ASSESSMENT	TRAIL DRUG				TRAIL DRUG +VARMAM			
	BEFORE TREATMENT		**AFTER TREATMENT**		**BEFORE TREATMENT**		**AFTER TREATMENT**	
	NO.OF CASES	**%**	**NO.OF CASES**	**%**	**NO.OF CASES**	**%**	**NO.OF CASES**	**%**
No Pain	0	0%	0	0%	0	0%	08	40%
Mild	0	0%	17	85%	0	0%	11	55%
Moderate	2	10%	03	15%	1	5%	01	5%
Severe	18	90%	0	0%	19	95%	0	0%
Total	20	100%	20	100%	20	100%	20	100%

26.IMPROVEMENT OF CASES:

Table.27

PAIN ASSESSEMENT	NO OF CASES	PERCENTAGE %
Sever – No pain	06	15%
Severe – Mild pain	26	65%
Severe – Moderate pain	04	10%
Moderate – No pain	02	5%
Moderate – Mild pain	02	5%
Total	40	100%

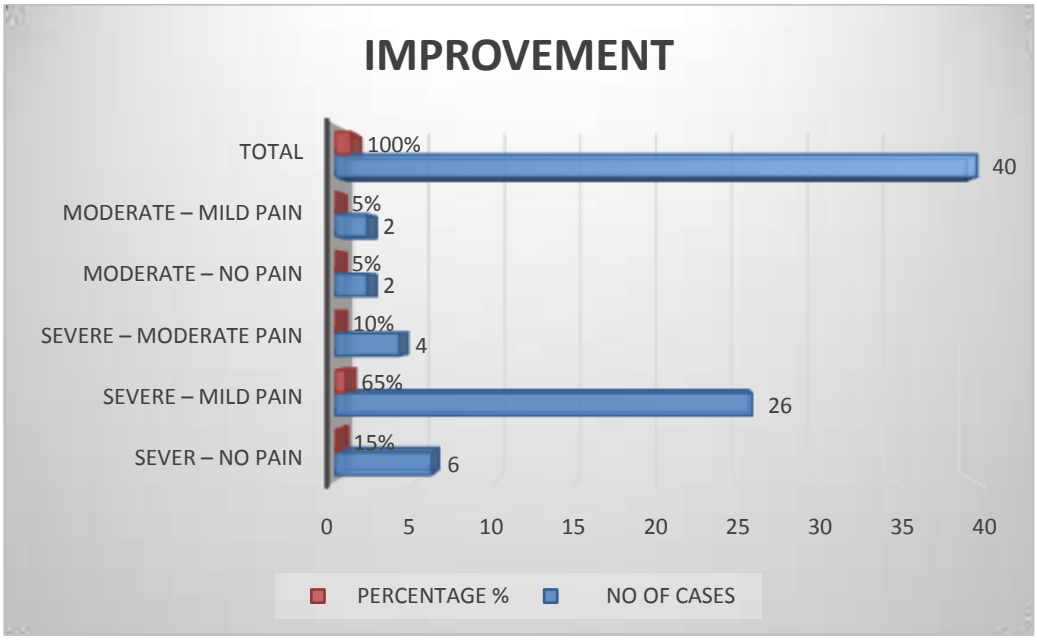


fig:17

Inference :

Among 40 cases, severe – no pain in 06 cases(15%), severe -mild pain in 27 cases (67.5%), severe – moderate pain in 03 cases (7.5%), Moderate- no pain in 02 cases (5%), moderate -mild pain in 02 cases (5%).

STASTICAL ANALYSIS:

All collected data were entered into MS Excel software using different columns as variables and rows as patients.SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross tabulations were performed.The quantity variables were expressed as Mean±Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired 't' test was performed for determining the significance between before and after treatment.

PAIN ASSESSMENT SCALE BEFORE AND AFTER TREATMENT

Painscale	Samplesize	Mean	standard deviation	95% confidence interval	Significant
Beforetreatment	40	7.55	0.78	7.31-7.39	p<0.0001
Aftertreatment	40	1.52	1.21	1.15-1.9	

PAINASSESSMENTATSTARTOFTREATMENTBETWEENTWOGROUPS:

	Sample Size	Mean		Standard Deviation		't'value		'p'value	
		BT	AT	BT	AT	BT	AT	BT	AT
Without Varmam	20	7.3	2.05	0.65	0.99	2.121	3.004	0.2953	0.3895
With Varmam	20	7.8	1.0	0.83	1.21				

There is mild significant difference between with and without varmam treatment.

LAB INVESTIGATIONS TRAIL DRUG ONLY (GROUP A)

S. NO	IP / OP.NO	NAME	AGE / SEX	HB (gm/dl)		T.RBC (million Cells/cu.mm)		ESR (mm/ Hours)		T.WBC (cells/cu.mm)		DIFFERANTIAL COUNT (%)			
												P		L	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**I53772**	Mr.S.Jayakumar	22/M	15.2	15.1	$5.7\ 10^6$	$5.6\ 10^6$	08	08	6500	6400	63	62	34	34
2	**I53772**	Mrs.N.Dhanalakshmi	42/F	12.6`	12.7	$4.7\ 10^6$	$4.6\ 10^6$	34	34	8800	8700	65	65	34	33
3	**K63027**	Mrs.B.Ashadevi	39/F	12.7	12.8	$4.4\ 10^6$	$4.1\ 10^6$	10	11	9200	8000	57	55	38	36
4	**K81868**	Mrs.S.Subbulakshmi	54/F	13.0	13.1	$4.1\ 10^6$	$4.4\ 10^6$	22	20	6100	6100	58	60	40	42
5	**K97733**	Mrs.M.Shawarbanu	46/F	12.4	12.8	$4.7\ 10^6$	$5.0\ 10^6$	8	10	8600	7300	65	62	31	34
6	**K73022**	Mrs.K.Sulochana	34/F	12.2	12.2	3.910^6	$4.0\ 10^6$	34	16	7600	7900	65	56	30	41
7	**K81635**	Mrs.R.Suganthi	54/F	10.4	10.7	$4.3\ 10^6$	$4.3\ 10^6$	80	34	8000	7300	70	70	27	28
8	**J75907**	Mrs.V.Rani	43/F	12.7	13.2	$4.6\ 10^6$	$4.7\ 10^6$	52	12	7500	7000	60	50	35	43
9	**K96363**	Mrs.R.Dhanalakshmi	42/F	7.5	8.8	$4.10\ 10^6$	4.510^6	46	46	8100	7900	82	75	17	15
10	**L03490**	Mrs.R.Kalavathy	50/F	12	12	$3.7\ 10^6$	$4.2\ 10^6$	35	16	7600	7900	65	54	31	40
11	**K92700**	Mrs.M.Madhuladevi	55/F	14.5	14.5	$5.0\ 10^6$	$5.1\ 10^6$	14	25	9900	8600	62	51	35	46
12	**I30336**	Mr.R.Jayashankar	42/M	12.5	12.5	$5.5\ 10^6$	$5.5\ 10^6$	22	22	10200	10900	60	72	30	20
13	**L10556**	Mrs.M..Banu	57/F	12.0	12.1	$4.4\ 10^6$	$4.4\ 10^6$	12	24	6700	6800	60	55	35	41
14	**L03476**	Mr.K.Mohanasundaram	49/M	13.3	13.8	$4.7\ 10^6$	$4.9\ 10^6$	36	26	7000	6600	65	61	30	36
15	**J94001**	Mrs.L.Judith	34/F	11.8	12.7	$4.4\ 10^6$	$4.5\ 10^6$	42	41	6800	6900	65	64	30	30
16	**L03046**	Mr.E.Ramesh	38/M	14.1	13.5	$5.9\ 10^6$	$5.3\ 10^6$	16	12	5900	5100	60	57	33	38
17	**L30335**	Mrs.G.Jayanthi	46/F	12.7	12.8	$4.4\ 10^6$	$4.1\ 10^6$	$9\ 10^6$	11	9200	8000	57	55	38	36
18	**K75867**	Mrs.U.Shakila	38/F	14.7	14.7	$5.1\ 10^6$	$5.2\ 10^6$	16	26	9900	8600	62	50	36	45-
19	**L11182**	Mr.EgambaramEswaran	41/M	16.3	15.8	$5.7\ 10^6$	$5.5\ 10^6$	10	22	7900	8400	65	63	30	30
20	**I38337**	Mrs.S.Vanitha	34/F	12.9	12.9	$5.1\ 10^6$	$5.0\ 10^6$	34	34	9300	9200	60	61	37	38

S. NO	IP / OP.NO	NAME	AGE / SEX	BLOOD GLUCOSE (FASTING)		BLOOD GLUCOSE (PP)		SERUM CHOLESTROL		LIPID PROFILE HDL		LIPID PROFILE LDL		LIPID PROFILE VLDL	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**I53772**	Mr.S.Jayakumar	22/M	109	90	100	120	187	190	39	40	102	103	84	285
2	**I53772**	Mrs.N.Dhanalakshmi	42/F	82	83	116	115	214	150	58	42	117	110	19	18
3	**K63027**	Mrs.B.Ashadevi	39/F	87	88	132	120	195	160	68	40	100	98	16	15
4	**K81868**	Mrs.S.Subbulakshmi	54/F	100	94	120	121	2`13	210	63	60	115	110	24	20
5	**K97733**	Mrs.M.Shawarbanu	46/F	100	99	134	109	209	220	64	58	109	115	26	21
6	**K73022**	Mrs.K.Sulochana	34/F	87	85	94	92	229	220	59	58	127	126	17	18
7	**K81635**	Mrs.R.Suganthi	54/F	156	143	210	255	284	160	60	50	168	72	51	21
8	**J75907**	Mrs.V.Rani	43/F	96	90	105	88	181	181	60	47	93	75	15	24
9	**K96363**	Mrs.R.Dhanalakshmi	42/F	92	70	133	120	174	167	55	44	90	82	24	36
10	**L03490**	Mrs.R.Kalavathy	50/F	94	89	162	120	237	211	55	53	124	114	19	22
11	**K92700**	Mrs.M.Madhuladevi	55/F	87	90	100	114	189	172	37	60	93.5	91	15	22
12	**I30336**	Mr.R.Jayashankar	42/M	99	98	131	137	201	231	57	66	106	116	19	27
13	**L10556**	Mrs.M..Banu	57/F	98	97	130	110	210	184	55	55	105	94	29	21
14	**L03476**	Mr.K.Mohanasundaram	49/M	96	90	105	88	181	181	60	47	93	75	15	24
15	**J94001**	Mrs.L.Judith	34/F	93	90	110	111	270	210	73	72	134	130	74	70
16	**L03046**	Mr.E.Ramesh	38/M	74	75	67	97	174	171	47	51	83	89	14	14
17	**L30335**	Mrs.G.Jayanthi	46/F	87	88	132	120	195	160	68	40	100	98	16	15
18	**K75867**	Mrs.U.Shakila	38/F	80	82	100	112	194	224	49	46	97	126	29	51
19	**L11182**	Mr.Egambarameswaran	41/M	94	89	162	120	237	211	55	53	124	114	19	22
20	**I38337**	Mrs.S.Vanitha	34/F	86	86	120	110	199	198	48	40	115	110	21	20

S. NO	IP / OP.NO	NAME	AGE / SEX	LIPID PROFILE (TGL)		RFT mg/dl BLOOD UREA		SERUM CREATININE		TOTAL BILIRUBINE		DIRECT BILIRUBINE		INDIRECT BILIRUBINE	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**I53772**	Mr.S.Jayakumar	22/M	420	150	16	15	1.0	1.1	0.5	0.2	0.2	0.1	0.3	0.2
2	**I53772**	Mrs.N.Dhanalakshmi	42/F	96	90	17	15	0.9	0.8	0.6	0.5	0.1	0.1	0.5	0.5
3	**K63027**	Mrs.B.Ashadevi	39/F	79	70	27	27	0.9	0.9	0.8	0.7	0.3	0.3	0.5	0.5
4	**K81868**	Mrs.S.Subbulakshmi	54/F	119	110	15	14	0.8	0.7	0.3	0.4	0.1	0.1	0.3	0.2
5	**K97733**	Mrs.M.Shawarbanu	46/F	130	107	17	17	0.9	0.9	0.3	0.3	0.1	0.1	0.2	0.2
6	**K73022**	Mrs.K.Sulochana	34/F	85	90	18	20	0.9	0.8	0.6	0.4	0.2	0.2	0.4	0.2
7	**K81635**	Mrs.R.Suganthi	54/F	256	104	19	19	0.8	0.9	0.7	0.2	0.2	0.1	0.5	0.1
8	**J75907**	Mrs.V.Rani	43/F	76	120	15	14	0.8	0.8	0.5	0.4	0.2	0.2	0.3	0.2
9	**K96363**	Mrs.R.Dhanalakshmi	42/F	121	180	18	11	0.8	0.8	0.7	04	0.2	0.2	0.5	0.2
10	**L03490**	Mrs.R.Kalavathy	50/F	85	83	11	12	0.9	0.9	0.4	0.3	0.1	0.2	0.2	0.2
11	**K92700**	Mrs.M.Madhuladevi	55/F	88	92	19	18	0.8	0.8	0.4	0.4	0.1	0.1	0.3	0.3
12	**I30336**	Mr.R.Jayashankar	42/M	94	138	21	19	1.1	1.0	0.8	0.5	0.3	0.2	0.5	0.3
13	**L10556**	Mrs.M..Banu	57/F	96	90	17	15	0.9	0.8	0.6	0.5	0.1	0.1	0.5	0.5
14	**L03476**	Mr.K.Mohanasundaram	49/M	79	70	27	27	0.9	0.9	0.8	0.7	0.3	0.3	0.5	0.5
15	**J94001**	Mrs.L.Judith	34/F	37	120	19	17	0.8	0.7	0.3	0.2	0.1	0.2	0.2	0.2
16	**L03046**	Mr.E.Ramesh	38/M	72	68	14	13	1.0	0.9	0.8	1.2	0.3	0.5	0.5	0.7
17	**L30335**	Mrs.G.Jayanthi	46/F	97	112	22	29	1.1	1.0	0.7	0.8	0.3	0.3	0.4	0.5
18	**K75867**	Mrs.U.Shakila	38/F	146	254	10	17	0.9	0.8	0.7	0.5	0.2	0.2	0.5	0.3
19	**L11182**	Mr.Egambarameswaran	41/M	97	112	22	29	1.1	1.0	0.7	0.8	0.3	0.3	0.4	0.5
20	**I38337**	Mrs.S.Vanitha	34/F	109	110	11	12	0.7	0.6	0.5	0.4	0.2	0.1	0.4	0.3

S. NO	IP / OP.NO	NAME	AGE / SEX	LFT (mg/dl) TOTAL PROTEIN		SERUM ALBUMIN		SERUM GLOBULIN		SGOT		SGPT		ALP	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**I53772**	Mr.S.Jayakumar	22/M	7.2	7.1	4.2	4.1	3.0	3.1	22	21	95	89	9.7	9.8
2	**I53772**	Mrs.N.Dhanalakshmi	42/F	6.8	6.7	3.7	3.6	3.1	3.0	17	17	14	14	82	81
3	**K63027**	Mrs.B.Ashadevi	39/F	6.7	6.6	3.7	3.3	3.0	3.0	15	16	13	12	59	60
4	**K81868**	Mrs.S.Subbulakshmi	54/F	6.9	7.0	4.0	4.1	2.9	2.9	23	24	23	23	68	69
5	**K97733**	Mrs.M.Shawarbanu	46/F	7.3	7.3	3.9	3.8	3.4	3.5	24	28	26	33	103	106
6	**K73022**	Mrs.K.Sulochana	34/F	6.7	6.8	3.7	3.8	3.0	3.0	15	17	07	16	89	91
7	**K81635**	Mrs.R.Suganthi	54/F	6.7	6.8	3.9	3.8	2.9	2.9	18	16	13	14	105	88
8	**J75907**	Mrs.V.Rani	43/F	7.4	7.4	3.9	3.8	3.5	3.7	13	16	14	17	120	125
9	**K96363**	Mrs.R.Dhanalakshmi	42/F	7.4	7.3	3.9	3.8	3.5	3.5	09	20	12	22	69	70
10	**L03490**	Mrs.R.Kalavathy	50/F	7.1	7.2	3.6	3.6	3.5	3.6	08	12	05	18	87	95
11	**K92700**	Mrs.M.Madhuladevi	55/F	6.6	6.6	3.9	3.9	2.7	2.8	13	17	06	15	112	119
12	**I30336**	Mr.R.Jayashankar	42/M	7.3	7.4	4.2	4.0	3.1	3.4	20	18	18	17	81	87
13	**L10556**	Mrs.M..Banu	57/F	7.3	7.2	3.9	3.8	3.4	3.2	10.1	10.1	16	16	70	72
14	**L03476**	Mr.K.Mohanasundaram	49/M	6.6	6.6	3.9	3.9	2.7	2.8	13	17	06	15	112	119
15	**J94001**	Mrs.L.Judith	34/F	6.7	6.5	3.8	3.7	2.9	2.8	15	14	20	20	74	73
16	**L03046**	Mr.E.Ramesh	38/M	7.3	7.2	4.0	3.9	3.3	3.3	17	17	18	14	74	64
17	**L30335**	Mrs.G.Jayanthi	46/F	6.8	6.7	3.7	3.6	3.1	3.0	17	17	14	14	82	81
18	**K75867**	Mrs.U.Shakila	38/F	7.6	7.8	4.2	4.0	3.4	3.8	20	15	21	61	61	66
19	**L11182**	Mr.Egambarameswaran	41/M	7.1	7.3	4.0	4.0	3.1	3.3	22	19	27	23	97	93
20	**I38337**	Mrs.S.Vanitha	34/F	7.3	7.2	3.9	3.8	3.4	3.2	10.1	10.1	16	16	70	72

S. NO	IP / OP.NO	NAME	AGE / SEX	SERUM CALCIUM		SERUM PHOSPHORUS		SERUM URIC ACID		CRP		ASO TITRE		RA FACTOR	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**I53772**	Mr.S.Jayakumar	22/M	9.7	9.8	-	-	7.3	7.1	Neg	Neg	Neg	Neg	Neg	Neg
2	**I53772**	Mrs.N.Dhanalakshmi	42/F	9.9	9.8	-	-	3.6	3.5	Neg	Neg	POS	Neg	Neg	Neg
3	**K63027**	Mrs.B.Ashadevi	39/F	9.5	9.9	-	-	4.4	4.3	Neg	Neg	Neg	Neg	Neg	Neg
4	**K81868**	Mrs.S.Subbulakshmi	54/F	9.1	9.0	-	-	4.3	4.4	Neg	Neg	Neg	Neg	Neg	Neg
5	**K97733**	Mrs.M.Shawarbanu	46/F	9.9	9.7	-	-	3.4	3.7	Neg	Neg	Neg	Neg	Neg	Neg
6	**K73022**	Mrs.K.Sulochana	34/F	8.7	8.6	-	-	4.5	4.7	Neg	Neg	Neg	Neg	Neg	Neg
7	**K81635**	Mrs.R.Suganthi	54/F	9.5`	9.7	-	-	5.4	3.3	Neg	Neg	Neg	Neg	Neg	Neg
8	**J75907**	Mrs.V.Rani	43/F	9.4	9.7	-	-	3.6	4.2	Neg	Neg	Neg	Neg	Neg	Neg
9	**K96363**	Mrs.R.Dhanalakshmi	42/F	9.9	9.6	-	-	4.1	4.3	Neg	Neg	Neg	Neg	Neg	Neg
10	**L03490**	Mrs.R.Kalavathy	50/F	9.5	9.5	-	-	3.6	4.2	Neg	Neg	Neg	Neg	Neg	Neg
11	**K92700**	Mrs.M.Madhuladevi	55/F	9.5	9.7	-	-	4.7	4.7	Neg	Neg	Neg	Neg	Neg	Neg
12	**I30336**	Mr.R.Jayashankar	42/M	9.3	8.4	-	-	5.3	4.3	Neg	Neg	Neg	Neg	Neg	Neg
13	**L10556**	Mrs.M..Banu	57/F	8.7	8.6	-	-	4.5	4.7	Neg	Neg	Neg	Neg	Neg	Neg
14	**L03476**	Mr.K.Mohanasundaram	49/M	9.5`	9.7	-	-	5.4	3.3	Neg	Neg	Neg	Neg	Neg	Neg
15	**J94001**	Mrs.L.Judith	34/F	8.7	8.6	-	-	3.9	4.0	Neg	Neg	Neg	Neg	Neg	Neg
16	**L03046**	Mr.E.Ramesh	38/M	9.8	8.3	-	-	5.2	4.7	Neg	Neg	POS	POS	Neg	Neg
17	**L30335**	Mrs.G.Jayanthi	46/F	8.7	7.4	-	-	5.9	5.0	Neg	Neg	Neg	Neg	Neg	Neg
18	**K75867**	Mrs.U.Shakila	38/F	9.9	8.3	-	-	3.5	3.6	Neg	Neg	Neg	Neg	Neg	Neg
19	**L11182**	Mr.Egambarameswaran	41/M	8.7	7.4	-	-	5.9	5.0	Neg	Neg	Neg	Neg	Neg	Neg
20	**I38337**	Mrs.S.Vanitha	34/F	9.2	9.1	-	-	2.4	2.4	Neg	Neg	Neg	Neg	Neg	Neg

S. NO	IP / OP.NO	NAME	AGE / SEX	URINE INVESTIGATION (ALBUMIN)		SUGAR (F)		SUGAR(PP)		DEPOSITS		BILE SALTS		BILE PIGMENTS	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**I53772**	Mr.S.Jayakumar	22/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	1-2 epi	Nil	Nil	Nil	Nil
2	**I53772**	Mrs.N.Dhanalakshmi	42/F	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	2-3 epi	Nil	Nil	Nil	Nil
3	**K63027**	Mrs.B.Ashadevi	39/F	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	1-2 epi	Nil	Nil	Nil	Nil
4	**K81868**	Mrs.S.Subbulakshmi	54/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
5	**K97733**	Mrs.M.Shawarbanu	46/F	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	1-2 epi	Nil	Nil	Nil	Nil
6	**K73022**	Mrs.K.Sulochana	34/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
7	**K81635**	Mrs.R.Suganthi	54/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
8	**J75907**	Mrs.V.Rani	43/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
9	**K96363**	Mrs.R.Dhanalakshmi	42/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
10	**L03490**	Mrs.R.Kalavathy	50/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
11	**K92700**	Mrs.M.Madhuladevi	55/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-5 epi	Nil	Nil	Nil	Nil
12	**I30336**	Mr.R.Jayashankar	42/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
13	**L10556**	Mrs.M..Banu	57/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
14	**L03476**	Mr.K.Mohanasundaram	49/M	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	1-2 epi	Nil	Nil	Nil	Nil
15	**J94001**	Mrs.L.Judith	34/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
16	**L03046**	Mr.E.Ramesh	38/M	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-5 epi	Nil	Nil	Nil	Nil
17	**L30335**	Mrs.G.Jayanthi	46/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
18	**K75867**	Mrs.U.Shakila	38/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
19	**L11182**	Mr.Egambarameswaran	41/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
20	**I38337**	Mrs.S.Vanitha	34/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil

LAB INVESTIGATIONS TRAIL DRUG WITH VARMAM (GROUP B)

S. NO	IP / OP.NO	NAME	AGE / SEX	HB (gm/dl)		T.RBC (million Cells/cu.mm)		ESR (mm/ Hours)		T.WBC (cells/cu.mm)		DIFFERANTIAL COUNT (%)			
												P		L	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**K02822**	Mrs.R.Rajeshwari	50/F	13.2	14.18	$4.4\ 10^6$	$4.7\ 10^6$	22	22	6600	7300	69	72	30	24
2	**K68058**	Mrs.K.Sathya	41/F	11.4	10.7	$4.7\ 10^6$	$4.6\ 10^6$	26	44	6300	6400	64	60	31	35
3	**K91986**	Mrs.R.Malar	44/F	12.6	12.7	$4.8\ 10^6$	$4.7\ 10^6$	40	80	8300	8000	66	60	28	37
4	**F30722**	Mrs.R.Renuka	47/M	12.6	13.8	$4.1\ 10^6$	$4.4\ 10^6$	42	70	9100	7400	63	60	34	35
5	**K77777**	Mr.V.Umapathy	44/F	14.1	14.1	$5.1\ 10^6$	$5.1\ 10^6$	8	12	5800	6200	69	65	26	30
6	**K91634**	Mrs.P.Bhavani	49/F	12.0	12.1	$4.4\ 10^6$	$4.4\ 10^6$	12	24	6700	6800	60	55	35	41
7	**I01928**	Mr.G.Harihara Subramaniyam	49/M	14.6	14.2	$5.0\ 10^6$	$4.8\ 10^6$	50	20	6700	6100	60	63	35	33
8	**J61956**	Ms.J.Sasikala	37/F	8.8	10.0	$4.9\ 10^6$	$5.0\ 10^6$	100	40	12,400	8600	65	64	30	33
9	**K77778**	Mr.T.M.Kumar	58/M	14.6	15.1	$5.0\ 10^6$	$5.2\ 10^6$	10	20	5300	6000	65	70	30	25
10	**K96012**	Mr.N.Ravindar	43/M	13.3	13.4	$4.7\ 10^6$	$4.6\ 10^6$	20	20	7500	7600	70	72	25	20
11	**K84007**	Mr.C.Velmurugan	39/M	15.5	15.9	$5.2\ 10^6$	$5.5\ 10^6$	8	12	10200	11100	70	66	24	30
12	**K74748**	Mrs.S.Malarkodi	52/F	11.6	11.5	$5.1\ 10^6$	$5.1\ 10^6$	16	16	8600	8700	52	50	45	42
13	**1849-18**	Mrs. V.Suganya	48/F	12.6	12.0	$4.2\ 10^6$	$4.0\ 10^6$	60	44	7000	5400	76	75	22	22
14	**1864-18**	Mrs.K.Hemavathy	42/F	15.2	14.3	$5.1\ 10^6$	$4.7\ 10^6$	08	10	9000	9600	60	62	35	37
15	**1863-18**	Mrs.S.Kumudha	60/F	13.3	13.8	$4.7\ 10^6$	$4.9\ 10^6$	36	26	7000	6600	65	61	30	36
16	**J76413**	Mr.B.V.Katheresan	42/M	14.3	14	$4.8\ 10^6$	$4.6\ 10^6$	22	44	7800	7900	55	56	43	44
17	**L08360**	Mr.D.Dilli	53/M	15.2	14.3	$5.1\ 10^6$	$4.7\ 10^6$	08	10	9000	9600	60	62	35	37
18	**K68865**	Mr.D.Design	49/M	15.4	15.4	$5.5\ 10^6$	$5.5\ 10^6$	22	22	10400	10400	69	68	27	26
19	**L03496**	Mr.G.Venkatesan	59/M	16	15.5	$5.6\ 10^6$	$5.5\ 10^6$	08	08	6900	6000	65	67	33	27
20	**H25446**	Mr.R.Ganasekaran	59/M	17.8	16.1	$5.7\ 10^6$	$5.7\ 10^6$	12	32	10100	8700	65	60	30	36

S. NO	IP / OP.NO	NAME	AGE / SEX	BLOOD GLUCOSE (FASTING)		BLOOD GLUCOSE (PP)		SERUM CHOLESTROL		LIPID PROFILE HDL		LIPID PROFILE LDL		LIPID PROFILE VLDL	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**K02822**	Mrs.R.Rajeshwari	50/F	101	82	100	126	273	260	73	74	152	156	31	21
2	**K68058**	Mrs.K.Sathya	41/F	95	96	103	97	180	174	59	49	92	82	19	25
3	**K91986**	Mrs.R.Malar	44/F	99	106	140	131	293	254	81	63	161	129	15	13
4	**F30722**	Mrs.R.Renuka	47/M	96	97	100	149	239	236	66	54	128	119	25	20
5	**K77777**	Mr.V.Umapathy	44/F	88	82	109	133	166	186	52	44	89	94	14	14
6	**K91634**	Mrs.P.Bhavani	49/F	94	90	100	101	184	195	48	46	101	101	27	23
7	**I01928**	Mr.G.Harihara Subramaniyam	49/M	96	93	93	70	205	207	57	47	110	100	24	17
8	**J61956**	Ms.J.Sasikala	37/F	84	84	90	135	189	206	56	52	103	102	17	16
9	**K77778**	Mr.T.M.Kumar	58/M	99	94	146	137	212	225	53	46	120	122	15	29
10	**K96012**	Mr.N.Ravindar	43/M	120	110	160	150	150	152	37	36	83	82	22	20
11	**K84007**	Mr.C.Velmurugan	39/M	96	98	130	128	196	202	45	35	110	100	31	34
12	**K74748**	Mrs.S.Malarkodi	52/F	152	100	196	185	206	195	41	30	111	110	39	36
13	**1849-18**	Mrs. V.Suganya	48/F	87	90	100	114	189	172	37	60	93.5	91	15	22
14	**1864-18**	Mrs.K.Hemavathy	42/F	99	94	146	137	212	225	53	46	120	122	15	29
15	**1863-18**	Mrs.S.Kumudha	60/F	101.3	93	93	126	206	185	50.5	50	107	89	17.8	18
16	**J76413**	Mr.B.V.Katheresan	42/M	91	100	90	128	170	169	42	41	84	89	26	30
17	**L08360**	Mr.D.Dilli	53/M	100	98	130	121	200	193	61	53	141	101	42	44
18	**K68865**	Mr.D.Design	49/M	105	90	141	164	243	243	46	44	127	128	27	36
19	**L03496**	Mr.G.Venkatesan	59/M	98	97	130	110	210	184	55	55	105	94	29	21
20	**H25446**	Mr.R.Ganasekaran	59/M	140	139	220	210	259	236	45	40	144	130	42	31

S. NO	IP / OP.NO	NAME	AGE / SEX	LIPID PROFILE (TGL)		RFT mg/dl BLOOD UREA		SERUM CREATININE		TOTAL BILIRUBINE		DIRECT BILIRUBINE		INDIRECT BILIRUBINE	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**K02822**	Mrs.R.Rajeshwari	50/F	158	105	18	21	0.8	0.9	0.4	0.6	0.2	0.3	0.2	0.3
2	**K68058**	Mrs.K.Sathya	41/F	93	123	19	20	1.0	1.0	0.3	0.3	0.1	0.1	0.2	0.2
3	**K91986**	Mrs.R.Malar	44/F	73	65	20	22	0.8	0.8	0.6	0.5	0.2	0.2	0.4	0.3
4	**F30722**	Mrs.R.Renuka	47/M	126	100	15	16	0.8	0.8	0.3	0.3	0.1	0.1	0.2	0.2
5	**K77777**	Mr.V.Umapathy	44/F	69	73	13	18	0.9	0.9	0.9	0.7	0.4	0.3	0.5	0.4
6	**K91634**	Mrs.P.Bhavani	49/F	134	116	13	20	0.8	0.8	0.5	0.5	0.2	0.2	0.3	0.3
7	**I01928**	Mr.G.Harihara Subramaniyam	49/M	121	85	23	20	1.1	1.1	0.6	0.7	0.2	0.3	0.4	0.4
8	**J61956**	Ms.J.Sasikala	37/F	85	83	11	12	0.9	0.9	0.4	0.3	0.1	0.2	0.2	0.2
9	**K77778**	Mr.T.M.Kumar	58/M	78	143	12	14	1.0	0.9	0.9	0.8	0.3	0.3	0.6	0.5
10	**K96012**	Mr.N.Ravindar	43/M	109	101	12	11	1.1	1.1	1.3	1.3	0.4	0.4	0.9	0.9
11	**K84007**	Mr.C.Velmurugan	39/M	154	170	17	18	1.1	1.1	0.9	0.4	0.3	0.2	0.6	0.2
12	**K74748**	Mrs.S.Malarkodi	52/F	160	141	22	21	1.1	1.0	0.7	0.7	0.2	0.1	0.5	0.2
13	**1849-18**	Mrs. V.Suganya	48/F	75.2	112	16.6	19	0.9	0.9	0.5	0.5	0.24	0.2	0.3	0.3
14	**1864-18**	Mrs.K.Hemavathy	42/F	85	83	11	12	0.9	0.9	0.4	0.3	0.1	0.2	0.2	0.2
15	**1863-18**	Mrs.S.Kumudha	60/F	88	92	19	18	0.8	0.8	0.4	0.4	0.1	0.1	0.3	0.3
16	**J76413**	Mr.B.V.Katheresan	42/M	128	141	18	22	1.2	1.0	0.9	0.6	0.3	0.2	0.6	0.4
17	**L08360**	Mr.D.Dilli	53/M	161	170	16	17	1.0	1.0	0.9	0.9	0.3	0.3	0.6	0.6
18	**K68865**	Mr.D.Design	49/M	134	179	23	31	1.0	0.9	0.5	0.5	0.2	0.2	0.3	0.3
19	**L03496**	Mr.G.Venkatesan	59/M	143	105	14	17	1.2	1.0	0.5	0.6	0.2	0.3	0.3	0.3
20	**H25446**	Mr.R.Ganasekaran	59/M	210	155	23	33	1.0	0.9	0.8	0.9	0.4	0.3	0.4	0.6

S. NO	IP / OP.NO	NAME	AGE / SEX	LFT (mg/dl) TOTAL PROTEIN		SERUM ALBUMIN		SERUM GLOBULIN		SGOT		SGPT		ALP	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**K02822**	Mrs.R.Rajeshwari	50/F	6.9	7.1	3.7	3.9	3.2	3.3	16	24	04	23	118	107
2	**K68058**	Mrs.K.Sathya	41/F	7.2	7.2	3.8	3.4	3.6	3.8	17	16	12	03	63	67
3	**K91986**	Mrs.R.Malar	44/F	7.6	7.3	4.0	3.9	3.6	3.4	40	22	96	27	90	91
4	**F30722**	Mrs.R.Renuka	47/M	7.2	7.5	3.8	3.8	3.4	3.7	16	17	13	24	76	74
5	**K77777**	Mr.V.Umapathy	44/F	7.0	6.9	4.0	3.0	3.0	3.0	19	19	19	24	79	84
6	**K91634**	Mrs.P.Bhavani	49/F	6.7	6.8	3.9	3.8	2.8	3.0	18	15	17	17	69	70
7	**I01928**	Mr.G.Harihara Subramaniyam	49/M	7.1	6.9	4.0	3.9	3.1`	3.0	14	18	15	23	52	55
8	**J61956**	Ms.J.Sasikala	37/F	7.1	7.2	3.6	3.6	3.5	3.6	08	12	05	18	87	95
9	**K77778**	Mr.T.M.Kumar	58/M	6.6	6.6	3.9	3.9	2.7	2.8	13	17	06	15	112	119
10	**K96012**	Mr.N.Ravindar	43/M	6.6	6.7	4.0	4.1	2.6	2.5	16	15	15	14	63	64
11	**K84007**	Mr.C.Velmurugan	39/M	7.4	7.4	4.0	3.8	3.4	3.6	19	28	37	40	139	146
12	**K74748**	Mrs.S.Malarkodi	52/F	7.9	7.9	4.2	4.1	3.6	3.4	47	36	44	63	106	105
13	**1849-18**	Mrs. V.Suganya	48/F	7.19	7.3	3.94	3.8	3.3	3.5	16	17	16.4	15	92	92
14	**1864-18**	Mrs.K.Hemavathy	42/F	6.7	6.8	3.9	3.8	2.8	3.0	18	15	17	17	69	70
15	**1863-18**	Mrs.S.Kumudha	60/F	7.5	7.2	3.9	3.8	3.7	3.4	23	26	20	25	108	108
16	**J76413**	Mr.B.V.Katheresan	42/M	6.9	6.7	4.0	4.1	2.9	2.8	18	16	17	10	76	88
17	**L08360**	Mr.D.Dilli	53/M	6.9	6.5	4.1	3.6	2.8	2.9	12	14	14	14	70	63
18	**K68865**	Mr.D.Design	49/M	6.9	7.0	3.7	3.8	3.2	3.2	15	14	14	22	109	111
19	**L03496**	Mr.G.Venkatesan	59/M	7.1	7.2	4.1	3.9	3.1	3.3	22	20	31	16	87	79
20	**H25446**	Mr.R.Ganasekaran	59/M	7.2	6.4	4.4	3.9	2.8	3.2	24	15	37	23	113	100

S. NO	IP / OP.NO	NAME	AGE / SEX	SERUM CALCIUM		SERUM PHOSPHORUS		SERUM URIC ACID		CRP		ASO TITRE		RA FACTOR	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**K02822**	Mrs.R.Rajeshwari	50/F	8.7	10.1	-	-	4.9	4.8	Neg	Neg	Neg	Neg	Neg	Neg
2	**K68058**	Mrs.K.Sathya	41/F	8.5	8.9	-	-	4.2	4.1	Neg	Neg	Neg	Neg	Neg	Neg
3	**K91986**	Mrs.R.Malar	44/F	8.6	9.0	-	-	5.9	6.0	Neg	Neg	Neg	Neg	Neg	Neg
4	**F30722**	Mrs.R.Renuka	47/M	8.8	8.7	-	-	3.3	3.8	Neg	Neg	Neg	Neg	Neg	Neg
5	**K77777**	Mr.V.Umapathy	44/F	8.6	9.1	-	-	4.3	5.8	Neg	Neg	Neg	Neg	Neg	Neg
6	**K91634**	Mrs.P.Bhavani	49/F	9.7	8.7	-	-	4.2	4.1	Neg	Neg	Neg	Neg	Neg	Neg
7	**I01928**	Mr.G.Harihara Subramaniyam	49/M	9.7	8.9	-	-	6.1	6.2	Neg	Neg	Neg	Neg	Neg	Neg
8	**J61956**	Ms.J.Sasikala	37/F	9.5	9.5	-	-	3.6	4.2	Neg	Neg	Neg	Neg	Neg	Neg
9	**K77778**	Mr.T.M.Kumar	58/M	9.5	9.7	-	-	4.7	4.7	Neg	Neg	Neg	Neg	Neg	Neg
10	**K96012**	Mr.N.Ravindar	43/M	9.4	9.7	-	-	5.3	5.1	Pos	Neg	Neg	Neg	Neg	Neg
11	**K84007**	Mr.C.Velmurugan	39/M	9.5	9.4	-	-	4.1	3.9	Neg	Neg	Neg	Neg	Neg	Neg
12	**K74748**	Mrs.S.Malarkodi	52/F	9.8	9.7	-	-	4.4	4.2	Neg	Neg	pos	Neg	Neg	Neg
13	**1849-18**	Mrs. V.Suganya	48/F	8.6	9.1	-	-	4.7	4.1	Neg	Neg	Neg	Neg	Neg	Neg
14	**1864-18**	Mrs.K.Hemavathy	42/F	8.8	9.2	-	-	5.2	5.1	Neg	Neg	Neg	Neg	Neg	Neg
15	**1863-18**	Mrs.S.Kumudha	60/F	9.0	9.2	-	-	3.7	3.4	Neg	Neg	Neg	Neg	Neg	Neg
16	**J76413**	Mr.B.V.Katheresan	42/M	8.8	9.2	-	-	5.2	5.1	Neg	Neg	Neg	Neg	Neg	Neg
17	**L08360**	Mr.D.Dilli	53/M	11.1	11	-	-	3.5	2.9	Neg	Neg	Neg	Neg	Neg	Neg
18	**K68865**	Mr.D.Design	49/M	8.5	9.2	-	-	4.8	4.4	Neg	Neg	Neg	Neg	Neg	Neg
19	**L03496**	Mr.G.Venkatesan	59/M	9.5	9.7	-	-	6.7	7.0	Neg	Neg	Neg	Neg	Neg	Neg
20	**H25446**	Mr.R.Ganasekaran	59/M	9.8	8.2	-	-	5.3	5.8	Neg	Neg	Neg	Neg	Neg	Neg

S. NO	IP / OP.NO	NAME	AGE / SEX	URINE INVESTIGATION (ALBUMIN)		SUGAR (F)		SUGAR(PP)		DEPOSITS		BILE SALTS		BILE PIGMENTS	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	**K02822**	Mrs.R.Rajeshwari	50/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	1-2 epi	Nil	Nil	Nil	Nil
2	**K68058**	Mrs.K.Sathya	41/F	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	2-3 epi	Nil	Nil	Nil	Nil
3	**K91986**	Mrs.R.Malar	44/F	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	1-2 epi	Nil	Nil	Nil	Nil
4	**F30722**	Mrs.R.Renuka	47/M	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
5	**K77777**	Mr.V.Umapathy	44/F	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	1-2 epi	Nil	Nil	Nil	Nil
6	**K91634**	Mrs.P.Bhavani	49/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
7	**I01928**	Mr.G.Harihara Subramaniyam	49/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
8	**J61956**	Ms.J.Sasikala	37/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
9	**K77778**	Mr.T.M.Kumar	58/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
10	**K96012**	Mr.N.Ravindar	43/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
11	**K84007**	Mr.C.Velmurugan	39/M	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-5 epi	Nil	Nil	Nil	Nil
12	**K74748**	Mrs.S.Malarkodi	52/F	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
13	**1849-18**	Mrs. V.Suganya	48/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
14	**1864-18**	Mrs.K.Hemavathy	42/F	Nil	Nil	Nil	Nil	Nil	Nil	2-3epi	1-2 epi	Nil	Nil	Nil	Nil
15	**1863-18**	Mrs.S.Kumudha	60/F	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-3 epi	Nil	Nil	Nil	Nil
16	**J76413**	Mr.B.V.Katheresan	42/M	Nil	Nil	Nil	Nil	Nil	Nil	2-4epi	2-5 epi	Nil	Nil	Nil	Nil
17	**L08360**	Mr.D.Dilli	53/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
18	**K68865**	Mr.D.Design	49/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
19	**L03496**	Mr.G.Venkatesan	59/M	Nil	Nil	Nil	Nil	Nil	Nil	1-2epi	2-4 epi	Nil	Nil	Nil	Nil
20	**H25446**	Mr.R.Ganasekaran	59/M	Nil	Nil	Nil	Nil	++	++	1-2epi	2-4 epi	Nil	Nil	Nil	Nil

DISCUSSION

The main aim of the treatment was to study the safety and therapeutic Efficacy of the drug ***Sigamani Chooranam*** to reduce pain, stiffness, restriction of movements and other clinical symptoms in the disease ***Cagana vaatham***.

The clinical features of ***Cagana vaatham*** can be correlated with Cervical Spondylosis in modern science. It is characterised by degeneration of the intervertebral disc and osteophyte formation. Such "wear and tear" is extremely common and radiological changes are frequently found in asymptomatic individuals over the age of 50. Spondylosis may be associated with neurological dysfunction. In order of frequency, the C5/C6, C6/C7 & C4/C5 vertebra levels affect C6,C7 & C5 roots, respectively.

The drugs which possess anti-Vaatha property as mentioned in Siddha literature were selected and the trial drugs were prepared by the Author in the Gunapadam practical laboratory of National Institute of Siddha, after getting proper authentication of raw drugs from the Medicinal botany department at NIS, Chennai 47, under the supervision of the members of the teaching faculty and guided by the Head of the Department of Sirappu Maruthuvam of the National Institute of Siddha, Chennai - 47. The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

The safety of the trial drug usage and standardization of the trial drug through biochemical analysis were also ensured during the study.

The sub-acute toxicity studies for the above said trial drug was conducted at National Institute of Siddha after getting the proper acceptance and Permission from the Institutional Animal Ethical Committee. The trial drug was proved to be safe for human beings from the observations made from the study.

The Biochemical qualitative and quantitative analysis were done at the Biochemistry lab of National Institiute of Siddha,Chennai. It revealed the presence of effective minerals and the existence of the drug molecules at micro level.

The clinical study was conducted with a defined protocol and a proper proforma after the approval of the Institutional Ethical Committee. After screening patients reporting at the OPD of department of Sirappu Maruthuvam, 40 cases were selected for

induction to the trial. Before enrolment into the trial the informed consent was obtained from the patients.40 patients of both genders were recruited for this study. Among the 40 patients 20 patients received medicine only and 20 patients received Varmam treatment along with the trial drugs.

The treatment was aimed at normalizing the vitiated humours and providing relief from symptoms. By giving purgation we can normalize the vitiated Vaatham.

"விரேசனத்தால் வாதந் தாழும்"

Before treating with trail drug the patients were advised to take *Agathiyar kuzhambu- 130 mg* with hot water in early morning for purgation. The patient was advised to take rest without internal medicine.

The patients were treated with trial drugs ***Sigamani Chooranam*** (internal) twice a day with Hot waterand ***Arkkasheerathy Thylam*** (external) for 48 days. Patients were instructed to take the medicines regularly advised to follow Pathiyam (avoid tamarind, tubers, etc) and advised to avoid cold exposure. Out-Patients were asked to visit the hospital once in 7 days. For Out- Patients the drugs were given for 48 days and the clinical assessment was done on 1st day, 8th day, 15th day, 22nd day, 29th day, 36th day, 43rd day and 49th day.

Among 40 patients, 20 patients the drugs were given for 48 days and the clinical assessment was done daily. 20 Patients were given *Varmam* treatment along with trial drugs. Varmam therapy is given for 3 alternative days in a week.

After the treatment, the patients were advised to visit the Out-Patient ward of Department of Sirappu Maruthuvam for another 2 months for follow-up. The results observed during the study period were discussed by the author below.

OBSERVATION:

- ✓ Among 40 cases the disease was found to be higher in the age group of 41-50 years, 20 cases (50%).
- ✓ The majority affected sex 63% (25) females and 37% (15) males are affected. The common cause for this may bedepletion of calcium, nutritional deficiency and increased house hold works. History taking reveals the above reasons for female predominance.

- ✓ In this study, 36 (90%)cases were reported from *Neithal* land, 2 (5%) cases from kurinchi(Hill), 2 (5%) cases from Marutham(fertile).In Siddha literatures, it was mentioned that Neithal, which is responsible for Vaatha diseases. This study also emphasized the same.
- ✓ Among40 cases,all of them were belongs to 40(100%)*Rasathagunam*.
- ✓ Among40 cases, Vathapitha thegi 20 (50%), Pithavatha thegi 15 (37.5%), Kabavatha thegi 05 (12.5%).
- ✓ The incidence of cases 20 (50%) were recruited in *Munpanikalam* 18 (45%) in *Pinpanikalam*, 2 (5%) in *Elavaenirkalam.*
- ✓ Among 40 cases 30 (75%) were belongs to low economic status, 10 (25%) were belongs to middle economic status.
- ✓ Among 40 cases 2(5%) were belongs to vegetarian, 38 (95%) were belongs to non-vegetarian.
- ✓ Most of the cases shows 100% gradual onset of disease.
- ✓ *Viyanan, Samanan* were affected in all 40 cases.
- ✓ In all the cases the *Sathaga pitham* were affected.
- ✓ *Santhigam* were affected in all the 40 cases. *Santhiga kabam* mainly lives in joints and so it was affected in all the cases.
- ✓ Among 40 cases, *kai* were affected in 40 cases 100%.
- ✓ Pulse reading *(Naadi)* was observed in all patients. Among 40 cases, Before treatment vathapitham naadi were found in 20 (50%) cases, pithavatha naadi were found in 19 (47.5%) cases, pithakaba naadi were found in 1 (2.5%). After treatment vathapitha naadi were found in 19 (47.5%) cases, vathakaba naadi were found in 1(2.5%) case, pithavatha naadi were found in 20 (50%), pithakaba naadi were found in 1(2.5%) case.
- ✓ In *NeikuriVaatha Neer* was found in 11 cases (21.5%), *Piththa Neer* was found in 17 cases (42.5%), *Kabha Neer* was found in 12 cases (30%).

OCCUPATIONAL REFERENCES:

Among 40 cases, 14 cases were homemaker (35%), and 8 cases were in (20%) tailoring occupation. Hence the study reveals that the disease is more prevelance in Homemaker may be due to those who have lack of exercise.

CLINICAL MANIFESTATIONS:

Among 40 cases, Before treatment radiating pain and stiffness were present 40 (100%) cases, tenderness present in 27 cases (67.5%), Numbness and paresthesia 26(65%). After treatment 05 cases (12.5%) had radiating pain to upper limbs, 05 cases (12.5%) had tenderness in cervical region, 04 cases (10%) had stiffness of cervical spine, 04 cases (10%) had numbness & paraesthesia.

RESTRICTED MOVEMENT ASSESMENT SCALE:

Among 40 cases, before treatment grade 2 present in 11 cases (27.5%), grade 3 present in 29 case (72.5%). After treatment grade 1 in 29 cases (72.5%), grade 2 present in 11 cases (27.5%).

QUETIONNAIRE OUTCOME WITH PAIN ASSESSEMENT OUTCOME:

Among 40 cases, before treatment severe pain present in 37 cases (92.5%), moderate pain present in 3 case (7.5%). After treatment No pain in 08 cases (20%), mild pain present in 28 cases (70%), moderate pain present in 4 cases (10%).

LABORATORY INVESTIGATIONS:

- By laboratory investigation ESR was found raised in early stages but after treatment it was found to be reduced.
- At the same time Total WBC counts, T.RBC were increased in 5 patients.
- Total cholesterol and LDL levels showed no changes in this study
- Blood Urea and Serum Creatinine levels showed no changes in this study.
- The radiographic studies showed narrowed joint space and presence of Osteophytes. The trial drug showed improvement in prognosis of the disease clinically rather than in radiographic changes.

EFFECT OF TREATMENT:

Among 40 cases,20 patients are treated with medicines before treatment severe pain were present in 18 cases (90%), moderate pain present in 2 case (10%). After treatment mild pain present in 17 cases (85%), moderate pain present in 3 cases (15%).

The mean pain score before treatment patients who treated without *Varmam* was 7.3± 0.65 and after treatment it was reduced to 2.05± 0.99

EFFECT OF VARMAM WITH MEDICINE :

Among 40 cases,20 patients are treated with medicines along with *Varmam* before treatment severe pain present in 19 cases (95%), moderate pain present in 1 case (5%). After treatment pain nil in 8 cases (40%), mild pain present in 11cases (55%), moderate pain present in 1 cases (5%). In this clinical trial, patients who treated with *Varmam* showed good result in the marked reduction of pain.

The mean pain score before treatment was 7.8± 0.83 and after treatment it was reduced to 1.0 ± 1.21.

EVALUATION OF MEDICINES:

- The extract prepared from the given sample ***Sigamani Chooranam*** contains Chloride, Tannic Acid, Unsaturated Compounds, Reducing Sugar and Amino Acids.
- Sub-Acute oral toxicity study conducted for 28 days and the drug did not exhibit significant changes in blood counts.
- All other observations were found to be normal before and after the study. In Necropsy, the organs of the animal such as, Liver, Heart, Lungs, Pancreas, Spleen, Stomach, Intestine, Kidney, Urinary bladder, Uterus all appeared normal.

SUMMARY

The 40 cases of ***Cagana vaatham*** were diagnosed clinically and treated with the trial drugs in Department of Sirappu Maruthuvam in Ayothidoss Pandithar Hospital attached to National Institute of Siddha, Tambaraam Sanatoruim, Chennai-47.

The study Protocol was approved by Institutional Ethics Committee(NIS). Before initiating the clinical trial, it was registered in Clinical Trials Registry of India and Ref. No Is: CTRI/2018/10/016011.

Among 40 cases, 20 patients were treated with trail drug only and 40 patients were treated with trail drug along with varmam.

The various Siddha methods of examination of the disease were carried out and the data were recorded in the prescribed Proforma for the 20 Cases.

Initially in the first Day of treatment Purgation was given by administering ***Agasthiyar kuzhambu-200mg*** with ginger juice in early morning with empty stomach to bring the thirithodam to equilibrium.

From the second day onwards **"*Sigamani Chooranam" 1gm*** (twice a day) alomg with water was given internally and **"*Arkkasheerathy thylam"*** for external use were given to the patients.

Laboratory Investigations were done for all the cases before and after treatment and radiological investigations were done for all the cases before treatment.

The observations made during the clinical study showed that internal drug and external drugs were effective in relieving pain in Cagana vaatham patients. During the study period, there was no adverse event reported. As per the Siddha Literature and recent research articles, the ingredients of the trial drugs was found to have Anti- inflammatory, analgesic properties owing to the disease manifestations.

The mean pain score before treatment is 7.55 after treatment it is reduced to1.52. Hence this study reveals that the patients treated with trial drugs and Varmam showed Good improvement when compared to those who are treated only with trial drugs. Statistical analysis showed significant reduction in the pain score.

The outcome of the trial medicine was assessed by universal pain assessement scale and the results were as follows:

The improvement of cases such as severe – no pain in 06 cases(15%), severe - mild pain in 27 cases (67.5%), severe – moderate pain in 03 cases (7.5%), Moderate- no pain in 02 cases (5%), moderate -mild pain in 02 cases (5%).

CONCLUSION

The dissertation is a comparative study on safety and efficacy of **"*Sigamani chooranam*"**and "*Varmam*"therapy in ***CaganaVaatham.***

The study results showed that the improvement of cases such as severe – no pain in 06 cases(15%), severe -mild pain in 27 cases (67.5%), severe – moderate pain in 03 cases (7.5%), Moderate- no pain in 02 cases (5%), moderate -mild pain in 02 cases (5%).

Varmam treatment along with the trial drugs showed good improvement when comparedto patients treated only with trial drugs.

Repeated 28 days oral toxicity study in Wistar albino rats revealed that the drug was safe. Histo-pathological studies have shown that the drug has no toxic effects in the vital organs.

Clinically, no adverse effects were reported during the trial. The laboratory investigations shows ESR were found raised in early stages but after treatment it was found to be reduced, at the same time Total WBC counts, T.RBC were increased in 5 patients & other laboratory investigations were also within normal limits. So, the drug is assumed to be safe for human beings.

Hence the study concludes that, the trial drugs were clinically effective in reduction ofpain, swelling, restriction of movements.

However further work with large number of patients should be carried out towards finding the ideal dose response.

BIOCHEMICAL ANALYSIS OF SIGAMANI CHOORANAM ANALYSED AT NATIONAL INSTITUTE OF SIDDHA

S.No	EXPERIMENT	OBSERVATION	INFERENCE
1.	Appearance of the sample	Brown in color	
2.	**Solubility:** a. A little (500mg) of the sample is shaken well with distilled water. b. A little (500mg) of the sample is shaken well with con. HCl/ Con. H2So4	Sparingly soluble	Presence of Silicate
3.	**Action of Heat:** A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.	White fumes not evolved	Absence of Carbonate
4.	**Flame Test:** A small amount (500mg) of the sample is made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.	No Bluish green flame appeared.	Absence of Copper
5.	**Ash Test:** A filter paper is soaked into a mixture of sample and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited.	No Yellow colored flame	Absence of sodium

Preparation of Extract:

5gm of **"*SIGAMANI CHOORANAM*"** was weighed accurately and placed 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.

S..No	Procedure	Observation	Inference
1.	**Test for Calcium:** 2 ml of extract is taken in a clean test tube. To this add 2 ml of 4% ammonium oxide solution.	white precipitate is formed	Absence of calcium
2.	**Test for Sulphate**: 2 ml of the extract is added to 5 % barium chloride solution.	No white precipitate is formed	Absence of Sulphate
3.	**Test for Chloride**: The extract is treated with Silver nitrate solution	White precipitate is formed	Presence of Chloride
4.	**Test for carbonate**: The substance is treated with Conc. HCl.	No effervescence is formed	Absence of carbonate
5.	**Test for Starch**: The extract is added with weak iodine solution	No blue colour is formed	Absence of starch
6.	**Test for Iron (Ferric)**: The extract is treated with glacial acetic acid and potassium ferrocyanide	No blue colour is formed	Absence of Ferric iron
7.	**Test for Iron (Ferrous)**: The extract is treated with Conc. HNO3 and ammonium thiocyanate.	Blood red colour is formed	Presence of Ferrous iron.
8.	**Test for phosphate**: The extract is treated with ammonium molybdate and conc. HNO3	Yellow precipitate is formed.	Absence of phosphate
9.	**Test for Tannic acid**: The extract is treated with Ferric chloride	No Black precipitate is formed	presence of Tannic acid

10.	**Test For Albumin:** the extract is treated with Esbatch's reagent.	No yellow precipitate is formed	Absence of Albumin
10.	**Test for Unsaturation**: 1ml of Potassium permanganate solution is added to the extract.	It get decolourized.	Presence of unsaturated compound
11.	**Test for saponins**: Dilute extract+ 1ml of distilled water shake well.	No Froth formation	Absence of saponins
12.	**Test for sugars**: **Benedict method**: 5ml of Benedict solution heated gently then add 8 drops of diluted extract then heated in a boiling water bath. **Molisch test**: Dilute extract+2 drops of Molisch+3ml conc.H2SO4.	colour change occurred. No Reddish violet zones appeared.	Indicates the Absence of Sugar Absence of carbohydrate.
13.	**Test for steroids:** Liberman Burchard test Dilute extract +2 ml acetic anhydride+ conc.H2SO4	No Formation of red colour	Absence of steroids
14.	**Test for amino acids**: One or two drops of the extract is placed on a filter paper and dried well. After drying, 1% Nihydrin is sprayed over the same and dried well.	Formation of violet colour	Presence of amino acids
15.	**Test for zinc:** The extract is treated with potassium ferrocyanide	No white precipitate is formed	Absence of zinc

INFERENCE: The extract prepared from the given sample ***"SIGAMANI CHOORANAM"*** contains Chloride, Tannic Acid, Unsaturated Compounds, Reducing Sugar and Amino Acids.

NATIONAL INSTITUTE OF SIDDHA

राष्ट्रीय सिद्ध संस्थान -
Ministry of AYUSH - आयुष मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियम चेन्नई -600 047
दूरभाष\Tele : 044-22411611 फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in वेब www.nischennai.org

F.No.NIS/6-20/Res/IEC/17-18 Date: 28-12-2017

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.L.Nilopher, M.D(S) – II year, Department of Sirappu Maruthuvam - Dissertation –	
Protocol title: Preclinical and Comparative clinical trial of Siddha formulations ***Sigamani Chooranam*** internally and ***Arkka Sheerathi Thylam*** *externally* in the treatment of ***Cegana Vaatham*** (Cervical Spondylosis) with and without varmam therapy.	
Documents filed	1) Protocol, 2) Data Collection forms 3) Patient Information Sheet 4) Consent form 5) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	**Yes**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/13-IEC/2017-1-04/ 22-11-2017**

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, Review periodically, any SAE occurring in the course of the study, any changes in the protocol and submission of final report

Chairman

NATIONAL INSTITUTE OF SIDDHA CHENNAI-600 047

09/01/18

CERTIFICATE

This is certify that the project title "To evaluate the safety profile of *Sigamani chooranam* (Sub acute oral toxicity study) in the treatment of *Caganavaatham*" has been approved by the IAEC.

Total No: animal sanctioned: 40 Rats (20M + 20F)

IAEC Approval NO: NIS/IAEC-VI/24042018/10

Prof.Dr.V.Banumathi — **Chairman/ IAEC**

Prof.Dr.K.Nachimuthu — **CPCSEA nominee**

Signature with date:

V. Banumathi

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.L.Nilopher, II year PG scholar

Name of the Department : Sirappu Maruthuvam Department.

Name of the Guide : Dr.N.J.Muthukumar MD(S),
Associate professor,HOD,
Sirappu Maruthuvam Department,
National Institute of Siddha.

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Sigamani chooranam"** (Internal) and **"Arkkasheerathy Thylam"** (External) taken up for Post Graduation Dissertation studies by **Dr.I.Nilopher** M.D(S). II year, Department of Sirappu Maruthuvam, 2018, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Cynodon dactylon (Linn.) Pers. (Poaceae), Root
Azima tetracantha Lam. (Salvadoraceae), Root
Azadirachta indica A. Juss. (Meliaceae), Bark
Zingiber officinale Rosc. (Zingiberaceae), Dried rhizome
Piper nigrum Linn. (Piperaceae), Fruit
Piper longum Linn. (Piperaceae), Fruit
Carum copticum Benth & Hook. f. (Apiacea), Fruit
Cuminum cyminum Linn. (Apiaceae), Fruit
Kaempferia galanga Linn. (Zingiberaceae), Rhizome
Alpinia galanga Willd. (Zingiberaceae), Rhizome
Piper cubeba Linn. f. (Piperaceae), Fruit
Embelia ribes Burm. f. (Myrsinaceae), Fruit
Smilax china Linn. (Liliaceae), Root
Hyoscyamus niger Linn. (Solanaceae), Seed
Picrorhiza scrophulariiflora Royle ex Benth. (Scrophulariaceae), Root
Anacyclus pyrethrum DC. (Asteraceae), Root
Clerodendrum serratum (Linn.) Moon (Verbenaceae), Root
Syzygium aromaticum (Linn.) Merr. & L.M. Perry (Myrtaceae), Flower bud
Myristica fragrans Houtt. (Myristicaceae), Nut & aril
Nigella sativa Linn. (Ranunculaceae), Seed
Cinnamomum verum Presl. (Lauraceae), Stem Bark

CERTIFICATE

NATIONAL INSTITUTE OF SIDDHA

Ministry of AYUSH, Government of India

Tambaram Sanatorium, Chennai - 600 047.

WORKSHOP ON

RESEARCH METHODOLOGY & BIOSTATISTICS

This is to certify that

Dr. L. NILOPHER

has participated in the above Workshop held from 16.04.2018 to 20.04.2018 conducted by the Dept. of Noi Naadal, at National Institute of Siddha, Tambaram Sanatorium, Chennai-600 047.

Dr. G.J. Christian
Coordinator
HoD, Dept. of Noi Naadal
National Institute of Siddha

Prof.Dr.V.Banumathi
Director
National Institute of Siddha
Chennai - 600 047

NATIONAL INSTITUTE OF SIDDHA

An Autonomous Body under Ministry of AYUSH
Govt. of India

Workshop on

Laboratory Animal Care and Basic Research Techniques

(12-16 February, 2018)

CERTIFICATE

This is to certify that Dr. L. NILOPHER has participated as Trainee / ~~Resource Person~~ / ~~organizing committee member~~ in the workshop on **"Laboratory Animal Care and Basic Research Techniques"** held on 12 - 16 February, 2018 at National Institute of Siddha, Chennai, Tamil Nadu.

Dr. V. Suba
Organizing Secretary

Prof.Dr.V.Banumathi
Director

Clinical Trial Details (PDF Generation Date :- Fri, 19 Jul 2019 12:58:33 GMT)

CTRI Number	CTRI/2018/10/016011 [Registered on: 12/10/2018] - **Trial Registered Prospectively**
Last Modified On	10/10/2018
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug Siddha Other (Specify) [varmam]
Study Design	Other
Public Title of Study	Treatment for cervical spondylosis through siddha system of medicines along with varmam therapy.
Scientific Title of Study	Preclinical and comparative clinical trial of siddha formulations Sigamani chooranam internally and Arkkasheerathy thylam externally in the treatment of Cegana vaatham (cervical spondylosis) with and without varmam therapy.

Secondary IDs if Any

Secondary ID	Identifier
NIL	Other

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

Details of Principal Investigator	
Name	Dr L Nilopher
Designation	PG Scholar
Affiliation	National Institute of Siddha
Address	National Institute of Siddha Tambaram sanatorium Chennai-47 - Kancheepuram TAMIL NADU 600047 India
Phone	8508627786
Fax	-
Email	nilochill@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr N J Muthukumar
Designation	Head of the Department i/c
Affiliation	National Institute of Siddha
Address	National Institute of Siddha Tambaram sanatorium Chennai-47 - Kancheepuram TAMIL NADU 600047 India
Phone	9962006843
Fax	-
Email	njmuthu@hotmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr L Nilopher
Designation	PG Scholar
Affiliation	National Institute of Siddha
Address	National Institute of Siddha Tambaram sanatorium Chennai-47 - Kancheepuram TAMIL NADU 600047 India
Phone	8505627786

	Fax	-
	Email	nilochill@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Self

Primary Sponsor

Primary Sponsor Details	
Name	Dr L Nilopher
Address	National Institute of Siddha Tambaram sanatorium Chennai-47
Type of Sponsor	Other []

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 L Nilopher	Ayothidoss pandithar hospital	Op no - 3 Dept of Sirappu Maruthuvam National Institute of Siddha Tambaram sanatorium Chennai 47 Kancheepuram TAMIL NADU	8508627786 - nilochill@gmail.com

Details of Ethics Committee

Name of Committee	**Approval Status**	**Date of Approval**	**Is Independent Ethics Committee?**
Institutional Ethical Committee	Approved	22/11/2017	No

Regulatory Clearance Status from DCGI

Status	**Date**
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	**Condition**
Patients	Spondylopathies

Intervention / Comparator Agent

Type	**Name**	**Details**
Intervention	Sigamani Chooranam Arkkasheerathi Thylam varmam therapy	Sigamani Chooranam (internally) 1g,twice a day for 20days Arkkasheerathi Thylam (externally) for 45 days varmam therapy
Comparator Agent	-	-

Inclusion Criteria

Inclusion Criteria	
Age From	20.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	Pain in the neck radiating to the shoulder blades, top of the shoulder, upper arm and back of the head Numbness and paraesthesia Willing to attend OPD or admission in IPD for the trial Willingness for consent Willing to give specimen of blood for the investigation Willing to undergo radiological investigation YES/ NO

Exclusion Criteria

Exclusion Criteria

Clinical Trial Details (PDF Generation Date :- Fri, 19 Jul 2019 12:58:33 GMT)

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Scientific Title of Study	Preclinical and comparative clinical trial of siddha formulations Sigamani chooranam internally and Arkkasheerathy thylam externally in the treatment of Cegana vaatham (cervical spondylosis) with and without varmam therapy.

Secondary IDs if Any

Secondary ID	Identifier
NIL	Other

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

Details of Principal Investigator	
Name	Dr L Nilopher
Designation	PG Scholar
Affiliation	National Institute of Siddha
Address	National Institute of Siddha Tambaram sanatorium Chennai-47 - Kancheepuram TAMIL NADU 600047 India
Phone	8508627786
Fax	-
Email	nilochill@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr N J Muthukumar
Designation	Head of the Department i/c
Affiliation	National Institute of Siddha
Address	National Institute of Siddha Tambaram sanatorium Chennai-47 - Kancheepuram TAMIL NADU 600047 India
Phone	9962006843
Fax	-
Email	njmuthu@hotmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr L Nilopher
Designation	PG Scholar
Affiliation	National Institute of Siddha
Address	National Institute of Siddha Tambaram sanatorium Chennai-47 - Kancheepuram TAMIL NADU 600047 India
Phone	8505627786

NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"SIGAMANI CHOORANAM "*** (INTERNAL) AND ***"ARKKASHEERATHY THYLAM"*** (EXTERNAL) IN THE TREATMENT OF ***"CAGANA VAATHAM"*** (CERVICAL SPONDYLOSIS) WITH AND WITHOUT ***VARMAM*** THERAPY.

Principal Investigator: Dr.L.Nilopher

FORM I - SCREENING & SELECTION PROFORMA

1. SERIAL NO: **2. OP /IP NO:**
3. NAME: **4. AGE/GENDER:**
5. OCCUPATION: **6. INCOME:**

INCLUSION CRITERIA

- Whether age is between 20-60 YES/ NO
- Sex M /F/T
- Pain in the neck radiating to the shoulder blades, top of the shoulder, upper arm and back of the head YES/NO
- Numbness and paresthesia YES/NO
- Willing to attend OPD or admission in IPD for the trial YES/ NO
- Willingness for consent YES/ NO
- Willing to give specimen of blood for the investigation YES/ NO
- Willing to undergo radiological investigation YES/ NO

EXCLUSION CRITERIA

- Spondylolisthesis YES/NO
- Rheumatoid arthritis YES/NO
- Tuberculous arthritis YES/NO
- Cervical myelopathy YES/NO
- Cervical rib YES/NO
- Torticollis (wry neck) YES/NO
- Pyogenic bone infection YES/NO
- Compression fracture YES/NO
- Tumor in vertebral body YES/NO

- Osteochondritis YES/NO
- Metabolic bone disease YES/NO
- Ankylosing spondylitis YES/NO
- Spinal deformity YES/NO
- Sexually transmitted disease YES/NO

ADMITTED TO TRAIL

YES	☐	NO	☐
If Yes, OPD	☐	IPD	☐
		Serial NO:	☐

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 SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"SIGAMANI CHOORANAM"*** (INTERNAL) AND ***"ARKKASHEERATHY THYLAM"*** (EXTERNAL) IN THE TREATMENT OF ***"CAGANA VAATHAM"*** (CERVICAL SPONDYLOSIS) WITH AND WITHOUT ***VARMAM*** THERAPY.

Principal Investigator: Dr.L.Nilopher

STUDY NO : **OP / IP NO :**
NAME : **AGE / GENDER :**
ADDRESS : **CONTACT NO :**
RELIGION : H / C / M / O.
INCOME :

OCCUPATION:
MARITAL STATUS : 1. Married 2. Unmarried

DATE OF INTIAL ASSESSMENT:

COMPLAINTS & DURATION:

FORM II-A – HISTORY TAKING PROFORMA

PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES SPECIFY DURATION	AMOUNT/Qty
Smoking				
Tobacco Chewing				
Alcohol				
Narcotic Drug Addiction				

HISTORY OF PREVIOUS ILLNESS AND TREATMENT TAKEN:
FAMILY HISTORY:

Whether this problem runs in family? 1. Yes 2. No
If yes, mention the relationship of affected person(s) 1._____

2._____

DIETARY STYLE: 1. Vegetarian 2. Non-vegetarian

MENSTURAL AND OBSTETRIC HISTORY:

FORM –II B

GENERAL EXAMINATION:

1.Body weight [Kg]	:	
2.Height [cms]	:	
3.Body Temperature [F]	:	
4.Blood Pressure (mm/Hg)	:	
5.Pulse Rate /min.	:	
6.Heart Rate / min.	:	
7.Respiratory Rate /min.	:	

		Yes	**No**
8.Pallor	:	☐	☐
9.Jaundice	:	☐	☐
10.Clubbing	:	☐	☐
11.Cyanosis	:	☐	☐
12.Pedal Oedema	:	☐	☐
13.Lymphadenopathy		☐	☐
14.Jugular venous pulsation		☐	☐

SYSTEMIC EXAMINATION

Cardiovascular system	:
Respiratory system	:
Gastro-intestinal system	:
Central Nervous system	:
Urogenital system	:
Endocrine system	:

SIDDHA SYSTEM OF EXAMINATION

1. THEGI (BODY CONSTITUTION):

1. Vatha udal ☐
2. Pitha udal ☐
3. Kaba udal ☐
4. Thontha udal ☐

2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

1. Kurinji (Hilly terrain) ☐
2. Mullai (Forest range) ☐
3. Marutham (Plains) ☐
4. Neithal (Coastal belt) ☐
5. Paalai (Aridregion) ☐

3. KAALAM:

1. Kaar kaalam (Aavani-Purattasi) ☐
2. Koothir kaalam (Ippasi-Kaarthigai) ☐
3. Munpani kaalam (Maargazhi-Thai) ☐
4. Pinpani kaalam (Maasi-Panguni) ☐
5. Ilavenil kaalam (Chithirai-Vaigasi) ☐
6. Muthuvenil kaalam (Aani-Aadi) ☐

4. GUNAM:

1. Sathuvam ☐
2. Rasatham ☐
3. Thamasam ☐

5. PORIPULANGAL (SENSORY ORGANS):

	Before treatment	**After treatment**
Mei (Skin)	Normal / Affected	Normal / Affected
Vai (Tongue)	Normal / Affected	Normal / Affected
Kann (Eye)	Normal / Affected	Normal / Affected
Mooku (Nose)	Normal / Affected	Normal / Affected
Sevi (Ear)	Normal / Affected	Normal / Affected

6.KANMENDRIYAM (MOTOR ORGANS) :

	Before treatment	**After treatment**
Kai(Upper limb)	Normal /Affected	Normal /Affected
Kaal (Lower limb)	Normal /Affected	Normal /Affected
Vai (Oral cavity)	Normal /Affected	Normal /Affected
Eruvai (Anal reg.)	Normal /Affected	Normal /Affected
Karuvai(Uro-genital region)	Normal /Affected	Normal /Affected

7.KOSANGAL (SHEATH):

	Before treatment	**After treatment**
Annamaya kosam	Normal /Affected	Normal /Affected
Pranamaya kosam	Normal /Affected	Normal /Affected
Manomaya kosam	Normal /Affected	Normal /Affected
Vignanamaya kosam	Normal /Affected	Normal /Affected
Ananthamaya kosam	Normal /Affected	Normal /Affected

8. SEVEN UDAL THAATHUKKAL (SEVEN SOMATIC COMPONENTS)

	Before treatment	**After treatment**
Saaram	Normal /Affected	Normal /Affected
Senneer	Normal /Affected	Normal /Affected
Oon	Normal /Affected	Normal /Affected
Kozhuppu	Normal /Affected	Normal /Affected
Enbu	Normal /Affected	Normal /Affected

Moolai	Normal /Affected	Normal /Affected
Sukkilam / Suronitham	Normal /Affected	Normal /Affected

9. UYIR THAATHUKKAL: **[THREE HUMORS] (VALI/ AZHAL/ IYYAM)**

A) VALI

	0th day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**
Praanan								
Abaanan								
Samaanan								
Udhaanan								
Viyaanan								
Naagan								
Koorman								
Kirukaran								
Devathathan								
Dhananjeyan								

B) AZHAL

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Analakam								
Ranjakam								
Saathakam								
Prasakam								
Aalosakam								

C) IYYAM

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Avalambagam								
Kilethagam								
Pothagam								
Tharpagam								
Santhigam								

10. ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

NAADI	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day

II. SPARISAM: [PALPATION]

Day	SPARISAM
0th day	
8th day	
15th day	
22nd day	
29th day	
36th day	
43rd day	
49th day	

III. NAA: [TONGUE]

NAA	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day

IV. NIRAM: [COMPLEXION]

1. Vadham ☐
2. Pitham ☐
3. Kabam ☐

V. MOZHI: [VOICE]

1. High Pitched ☐
2. Low Pitched ☐
3. Medium Pitched ☐

VI.VIZHI: [EYES]

VIZHI	**0th day**	**8th day**	**15thday**	**22ndday**	**29thday**	**36th day**	**43rdday**	**49thday**

VII. MALAM: [BOWEL HABITS / STOOLS]

	Before treatment	**After treatment**
Niram		
Irugal		
Ilagal		
Others		

VIII. MOOTHIRAM [URINE EXAMINATION]
NEERKKURI:

Neerkkuri	**Before treatment**	**After treatment**
Niram		
Manam		
Edai		
Nurai		
Enjal		

NEIKKURI:

Neikkuri	Before treatment	After treatment
Aravena neendathu/ Snake like pattern		
Azhipol paraviyathu Annular/Ringedpattern		
Muththothu ninrathu Pearlbeadepattern		
Other patterns		

CLINICAL EXAMINATION:

LOCOMOTOR SYSTEM:

CLINICAL SYMPTOMS:

pain and stiffness : ☐ ☐

(cervical region) YES NO

Radiating pain : Right arm Left arm

Numbness & paraesthesia YES NO

Onset: Sudden Gradual

CLINICAL EXAMINATION

I.INSPECTION:

	0^{th} day	8^{th} day	15^{th} day	22^{nd}day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
SWELLING								
STIFFNESS								

II.PALPATION:

	0^{th} day	8^{th} day	15^{th} day	22^{th} day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
Tenderness								
Local heat								

III. MOVEMENTS

	0^{th} day	8^{th} day	15^{th} day	22^{nd}day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
Flexion								
Extension								
Lateral flextion								
Rotation								

IV. JOINT MESUREMENT:

A. HEALTH ASSESSMENT QUESTIONNAIRE:

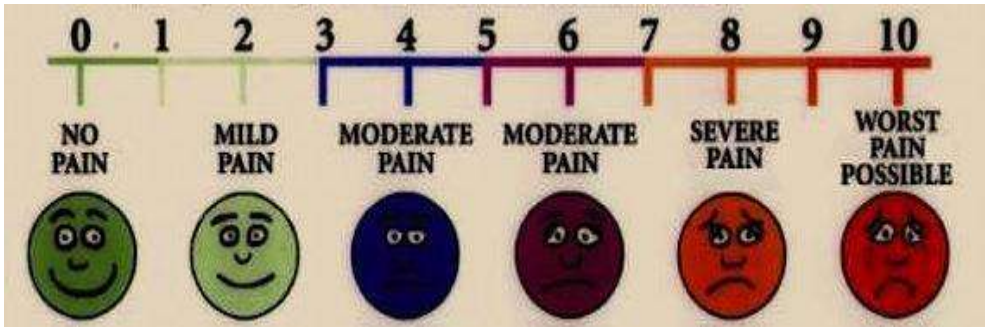
	0^{th} day	8^{th} day	15^{th} day	22^{nd}day	29^{th} day	36^{th} day	43^{rd}day	49^{th} day
PAIN A.Onset: Sudden/Gradual								
B. Early morning Stiffness (Present/absent)								
C. Nature of pain (Mild/ Moderate/ Severe)								
D. Aggravating factor- Movement (Yes/No)								
E. Relieving factor –Rest (Yes/No)								
G. Tenderness (Present/absent)								
RESTRICTION OF MOVEMENT (Fully/Partial/No)								

CLINICAL TEST:

	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day
Spurling's test								
Chin chest test								
Lateral flexion								
Shoulder abduction relief sign								

PAIN ASSESMENT SCALE:

1. UNIVERSAL PAIN ASSESMENT SCALE:



Grade 0 : No Pain

Grade 1-3 : Mild pain

(nagging, annoying, interfering little with ADLs)

Grade 4-6 : Moderate pain

(interfering significantly with ADLs)

Grade 7-10 : Severe pain

(disabling, unable to perform ADLs)

SCALE	0th day	8th day	15th day	22nd day	29th day	36th day	43rd day	49th day

OUTCOME:

0 - Good improvement

1-3 - Moderate improvement

4-6 - Mild improvement

7-10 - No improvement

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 SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRAIL OF SIDDHA DRUGS ***"SIGAMANI CHOORANAM"*** (INTERNAL) AND ***"ARKKASHEERATHY THYLAM"*** (EXTERNAL) IN THE TREATMENT OF ***"CAGANA VAATHAM"*** (CERVICAL SPONDYLOSIS) WITH AND WITHOUT **VARMAM** THERAPY.

Principal Investigator: Dr.L. Nilopher

1. SERIAL NO : **2. OP /IP NO :**
3. NAME : **4. AGE/GENDER :**

FORM -III - LABORATORY INVESTIGATIONS

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Hb(gm/dl)		M:13-18 W:11-16		
T.RBC(millions cells /Cu.mm)		M:4.5-6.5 W:3.5-5.5		
ESR (mm)	½ hr.	-		
	1 hr.	M:0-10 W:0-20		
T.WBC (Cells /Cu.mm)		4000-11000		
Differential Count (%)	Polymorphs	40-75		
	Lymphocytes	20-35		
	Monocytes	2-10		
	Eosinophils	1-6		
	Basophils	0-1		

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Blood glucose (mg/dl)	Fasting	70-110		
	PP	80-140		
Lipid profile (mg/dl)	Serum cholesterol	150-200		
	HDL	30-60		
	LDL	Up to 130		
	VLDL	40		
	TGL	Up to 160		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
LFT (mg/dl)	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-0.2		
	Indirect bilirubin	0.2-0.7		
	Total protein	6-8		
	Serum Albumin	3.5-5.5		
	Serum globulin	2-3.5		
	SGOT (IU/L)	0-40		
	SGPT (IU/L)	0-35		
	Alkaline	80-290		
	Serum calcium	9-11		
	Serum	2-5		
	Serum Uric acid	M:3-9 W: 2.5-7.5		
CRP				
ASO titre				
RA factor				

B.URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar (Fasting) **(PP)**		
Deposits		
Bile salts		
Bile pigments		

C.RADIOLOGICAL EXAMINATIONS

X- Ray: CERVICAL REGION

1. **Antero posterior**
2. **Lateral view**

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 SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRAIL OF SIDDHA DRUGS ***"SIGAMANI CHOORANAM"*** (INTERNAL) AND ***"ARKKASHEERATHY THYLAM"*** (EXTERNAL) IN THE TREATMENT OF ***"CAGANA VAATHAM"*** (CERVICAL SPONDYLYOSIS) WITH AND WITHOUT **VARMAM** THERAPY.

Name of Principal Investigator: Dr.L.Nilopher

FORM –IV- DRUG COMPLIANCE FORM

SERIAL NO:

NAME:

DRUG NAME:

On 1st day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 8th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 15th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 22th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 29th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 36th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)

Day	Date	Morning	Evening	Day	Date	Morning	Evening
Day 1				Day24			
Day2				Day25			
Day3				Day26			
Day4				Day27			
Day5				Day28			
Day6				Day29			
Day7				Day30			
Day8				Day31			
Day9				Day32			
Day10				Day33			
Day11				Day34			
Day12				Day35			
Day13				Day36			
Day14				Day37			
Day15				Day38			
Day16				Day39			
Day17				Day40			
Day18				Day41			
Day19				Day42			
Day20				Day43			
Day21				Day44			
Day22				Day45			
Day23				Day46			

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 SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRAIL OF SIDDHA DRUGS ***"SIGAMANI CHOORANAM"*** (INTERNAL) AND ***"ARKKASHEERATHY THYYLAM"*** (EXTERNAL) IN THE TREATMENT OF ***"CAGANA VAATHAM"*** (CERVICAL SPONDYLOSIS) WITH AND WITHOUT ***VARMAM*** THERAPY.

FORM-V– INFORMATION SHEET

Name of Principal Investigator **:** Dr .L.Nilopher
Name of the institute **:** National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL:

I, Dr.L.Nilopher Studying as M.D(Siddha) at National Institute of Siddha, Tambaram Sanatorium is doing a trial on the study of CAGANA VAATHAM(cervical spondylosis).cervical spondylosis is a most common persistent joint disease, occurring throughout the world. 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 can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree 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 internal medicine **"*sigamani chooranam*"** (Internal medicine-, Twice a Day with water for 20 days) and **"*Arakkasheerathy thylam*"** (External medicine), if you wish to stay in the In patient ward **"Varmam"** Treatment will be provided to you assuring that you will not be definitely hurt in any course of treatment.

The information I am collecting in this study will remain between you and the principal investigator (myself). If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact **Dr.L.Nilopher, PG Scholar,** cum principal investigator of this study, attached to National Institute of Siddha, Chennai-47. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, for rights and participation in the study.

FORM -V - தகவல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நோய்க்கான சித்த மருந்துகளின் சிகாமணி சூரணம் (உள் மருந்து) மற்றும் அர்க்கஷீராதி தைலம்(வெளிமருந்து) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர் : லி.நிலோபர்

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்
தாம்பரம் சானடோரியம்,சென்னை-47.

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர்: லி.நிலோபர்) சகன வாதம் என்னும் நோய்க்கான மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளை கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன். இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக சிகாமணி சூரணம் 1கிராம் 2 வேளை (காலை, மாலை) உணவுக்கு பின் 20 நாட்களுக்கு உட்கொள்ள வேண்டும். வெளிமருந்தாக அர்க்கஷீராதி தைலம் 45 நாட்களுக்கு நோயுள்ள இடங்களில் வெளியே தடவவேண்டும். வெளி நோயாளர் 7 நாட்களுக்கு ஒரு முறை மருத்துவமனைக்கு வரவேண்டும்.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கபடும் என உறுதிஅளிக்கிறேன். இதில் பயணப்படிவம் முதலிய எந்த உதவிதொகையும் வழங்கபடமாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறுபாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க மாற்று சிகிச்சை அளிக்கப்படும்.இந்த ஆராய்ச்சியில் தங்களை உட்படுத்தியபிறகு உங்களுக்கு விருப்பமில்லையெனில் எப்போது வேண்டுமாணலும் விலகிக் கொள்ள முழு உரிமை உள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மையை பற்றியும் முதன்மை ஆராய்ச்சியாளரான லி.நிலோபர் (பட்ட மேற்படிப்பாளர் மருத்துவ பிரிவு) அணுகவும். மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறப்பட்டுள்ளது.

தேதி: **கையொப்பம்** :

இடம்: **பெயர்** :

சாட்சிக்காரர் கையொப்பம் :

பெயர் :

உறவுமுறை :

விரிவுரையாளார் கையொப்பம்: **துறைத்தலைவர் கையொப்பம்** :

NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"SIGAMANI CHOORNAM"*** (INTERNAL) AND ***"ARKKASHEERATHY THYLAM"*** (EXTERNAL) IN THE TREATMENT OF ***"CAGANA VAATHAM"*** (CERVICAL SPONDYLOSIS) WITH AND WITHOUT ***VARMAM*** THERAPY.

Name of Principal Investigator: Dr.L.Nilopher

FORM-VI – CONSENT FORM

*"**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.***

***I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care**".*

"I have received a copy of the information sheet/consent form".

Date:
Signature of the participant
In case of illiterate participant

*"**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm individual has given consent freely**."*

Date:

Signature of a witness
(Selected by the participant bearing no connection with the survey team)

Left thumb Impression of the Participant

FORM –VI ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் சகனவாதம் என்னும் நோயின் ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வு காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும் தொடர்ந்து எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது, எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையைத் தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு சகனவாதம் நோய்க்கான சிகாமணிச் சூரணம் (உள் மருந்து) மற்றும் அர்க்கவீராதித் தைலம்(வெளி மருந்து) மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம்** :

இடம்: **பெயர்** :

சாட்சிக்காரர் கையொப்பம் :

பெயர் :

உறவுமுறை :

விரிவுரையாளார் கையொப்பம்:

துறைத்தலைவர் கையொப்பம் :

NATIONAL INSTITUTE OF SIDDHA
AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUG ***SIGAMANI CHOORANAM*** (INTERNAL) AND ***"ARKKASHEERATHY THYLAM"*** (EXTERNAL) IN THE TREATMENT OF ***"CAGANA VAATHAM"*****(CERVICAL SPONDYLOSIS)** WITH AND WITHOUT ***VARMAM*** THERAPY.

Name of Principal Investigator: Dr.L.Nilopher

FORM VII - WITHDRAWAL FORM

1. SERIAL NO OF THE CASE:

2. OP / IP NO:

3. NAME:

4. AGE:

5. GENDER:

6. DATE OF TRIAL COMMENCEMENT:

7. DATE OF WITHDRAWAL FROM TRIAL:

8. REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes/ No
Irregular treatment:	Yes/ No
Shift of locality:	Yes/No
Increase in severity of symptoms:	Yes/No
Development of severe adverse drug reactions:	Yes/No
Development of adverse event:	Yes/No

(If YES, give the details of adverse reaction in Form VII -B – Adverse Reaction Form / Pharmaco Vigilance Form)

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 SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"SIGAMANI CHOORANAM"*** (INTERNAL) AND **"*ARKKASHEERATHY THYLAM*"** (EXTERNAL) IN THE TREATMENT OF **"*CAGANA VAATHAM"***(CERVICAL SPONDYLOSIS) WITH AND WITHOUT VARMAM.

Name of Principal Investigator: Dr.L.Nilopher

FORM VII - A – ADVERSE REACTION FORM / PHARMACO VIGILANCE FORM

SERIAL NO:

OP/IP NO:

NAME: **AGE:** **GENDER:**

DATE OF TRIAL COMMENCEMENT:

DATE OF THE ADVERSE REACTION OCCUR:

DESCRIPTION OF ADVERSE REACTION:

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

FORM VII- PHARMACOVIGILANCE/WITHDRAWAL FORM

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

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: M / F 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)

Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:
Severe: Yes / No.	Reaction abated after drug stopped or dose reduced:			
	Reaction reappeared after re introduction:			

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 theRRC-ASU/ PPC-ASU

The Director
National Institute of Siddha,
(Pharmacovigilance Regional Centre For Siddha
icine),
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

What to Report?

Who Can Report?

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

⇒ All reactions, Drug interactions,

Confidentiality

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

⇒ Submission of report will be taken up for remedial measures only not for legal claim

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 SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRAIL OF SIDDHA DRUG *"**SIGAMANI CHOORANAM**"* (INTERNAL) AND *"**ARKKASHEERATHY THYLAM**"* (EXTERNAL) IN THE TREATMENT OF ***CEGANA VAATHAM*** (CERVICAL SPONDYLOSIS*)* WITH AND WITHOUT ***VARMAM*** THERAPY.
Principal Investigator: Dr.L.Nilopher

FORM - VIII DIETARY ADVICE FORM

சேர்க்க கூடிய உணவுகள்	தவிர்க்க வேண்டியவைகள்
காய்கள் (Vegetables): கத்தரிப்பிஞ்சு (Unripe brinjal) முருங்கைப்பிஞ்சு (Unripe drumstick) அவரைப்பிஞ்சு (Unripe Dolichos bean) **கீரைகள்(Greens):** பொன்னாங்கண்ணி (Sessile plant [*Alternanthera sessilis*]) மூக்கிரட்டை (Hog weed [*Boerhaavia diffusa*]) தூதுவேளை (Climbing brinjal [*Solanum trilobatum*]) முருங்கைக்கீரை (Leaves of Drumstick [*Moringa oleifera*]) கறிவேப்பிலை (Curry leaf [*Murraya koenigii*]) முடக்கறுத்தான் (Winter cherry [*Cardiospermum halicacabum*]) அறுகீரை (*Amaranthus tristis*) கரிசாலை (trailing eclipta [Eclipta prostrate]) **பழங்கள்(Fruits):** மாதுளை (Pomegranate) ஆப்பிள் (Apple) பப்பாளி (Papaya) ஆரஞ்சு (Orange) பேரீச்சை (Dates) அத்தி (Fig) நாவல் (Jambul [*Syzygium cumini*]) **அசைவம் (Non-vegetarian diet):** வெள்ளாட்டுக்கறி (Meat) காடை (Quail) , சிறு இறால்மீன் (Prawn)	சுரை (Bottle gourd) பூசணி (Pumpkin) வெள்ளரிக்காய் (Cucumber) புடலை (Snake gourd) பீர்க்கு (Ridged gourd) உளுந்து (Black gram) மொச்சை (Indian butter Bean) காராமணி (Cow gram) கொள்ளு (Horse gram) கடுகு (Mustard) எண்ணெய் (Gingelly oil) புளிப்பு (Sour) உப்பு (Salt) வாயுப் பொருட்கள் (Vatha diet) உருளைக் கிழங்கு (Potato) வாழைக் காய் (Plantain) புகையிலை (Tobacco) மது அருந்துதல் (Alcohol) பெண்போகம் (இச்சா பத்தியம்) [Sexual intercourse]

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