PRECLINICAL AND COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUGS **"RAAJAMAARTHANDHA ILAGAM**(INTERNALLY) AND **VAATHAKAJAKESARI THYLAM** (EXTERNALLY) IN THE TREATMENT OF **VATHASTHAMBAM (SCIATICA)** WITH AND WITH OUT **VARMAM** THERAPY**"**

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CHENNAI – 47.

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "Pre clinical and comparative clinical trial of Siddha drugs ***Raajamaarthandha Ilagam*** (Internally) and ***Vaathakajakesari Thylam*** (Externally) in the treatment of ***Vathasthambam*** (Sciatica) with and without ***Varmam therapy***" is a bonafide and genuine research work carried out by me under the guidance of **Dr.M.V.Mahadevan, M.D(s), Ph.D.,** Lecturer**,** 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.K.Aarthy**

BONAFIED CERTIFICATE

Certified that I have gone through the dissertation submitted by **Dr.K.Aarthy, (Reg.No:32161301)** 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

மறுப்ப துடல்நோய் மருந்தென லாகும்
மறுப்ப துளநோய் மருந்தெனச் சாலும்
மறுப்ப தினிநோய் வாரா திருக்க
மறுப்பது சாவை மருந்தெனலாமே

– திருமூலர் திருமந்திரம்

The ancient Siddha system of medicine is a life science of wellbeing practiced in southern part of India, particularly in Tamilnadu. This system was bestowed by the great Siddhars, after attaining spiritual knowledge through physical perfection and spiritual salvation, explained by the saint *Yugi* in the following verse:

அடைவான ஆயிள்வே தந்தன் நைத்தான்
ஐயருமே அம்மைதனக் கருளி செய்ய
நடைவான அம்மைதனக் கருளிச் செய்ய
நந்நியுமே சீடர்களுக் கருளிச் செய்ய
தடைவான தன்வந்திரி அசுவி னிக்குச்
சமரசமாம் அகத்தியமுனி தேரை யர்க்கு
நடைவான ரிஷிடேவர் சொன்னநூலின்
நேர்மையெல்லாம்விவரமாய் நிகழ்த்தி னேனே.

These works were passed on from lord *Siva* to his consort and then to *Nandi*, narrated these works to *Agathiya*r.

Siddhars not only contributed medicine but also the knowledge of eternity, alchemy and yogic living. According to Siddha medicine the human body is made up of a combination of 5 *poothangal* (five universal elements such as Earth, water, fire, wind and space). These elements regulate the 3*thadhukkal* (three Vital humours named *Vatham, Pitham and Kabam*) in relation to *arusuvai* (six taste) and 2 *veeriyam* (hot and cold potency). Their interaction produces various pathological states.

As per *AgathiyarRathinaChurukkam*, diseases are classified through pulse (*Naadi*) as 4,448 in numbers as follows.

“நாளடா நாற்பத்து நாலு நூறு
நயமுடனே நாற்பத்து எட்டு ரோகம்”

In Siddha text, ***YugiVaithiyaChindhamani****Vatham* disease is classified into 80 types, ***Vathasthambam***is one among them. As per *Yugi* text, the signs and symptoms of *Vathasthambam* may be correlated with **Sciatica** in modern medicine. As per the verse given below, the symptoms of *Vathasthambam* are,

- Radiating pain in legs
- Burning sensation
- Swelling
- Numbness
- Generalized tiredness

Vathasthambam is correlated to sciatica having the symptoms of pain in legs, burning sensation and numbness.

When *Vatham* is vitiated, it leads to Pain, dryness of the throat and Irritation. *Vatham* disease can also be produced by food items which contain more astringent than sour taste. In Siddha text ***NoinadalNoimudhalNadhalThirattu*** it is mention as,

"புளிதுவர் விஞ்சுகறியால்பூரிக்கும் வாதம்"

According to modern era, due to Life style, occupation, obesity etc., a greaternumber of peoples are suffering from low back ache. On the basis of high prevalence of sciatica and the cases reported at APH of NIS is increased day by day. With this background the author has chosen *Vathasthambam* (Sciatica) for her clinical study with ***Raajamaar thandailagam*** **(Internal Medicine)** mentioned in **Pranarakshamirtha sindhu** which is indicated for *Vatham* diseases and ***Vaathakajakesari thylam*** **(Externalmedicine)** mentioned in **Kannusamyparambarai vaidhyam**, also indicated for*Vatham* diseases.

AIM AND OBJECTIVES

AIM:

A preclinical and comparative clinical trial of Siddha drugs **"*Raajamaarthanda Ilagam*"** (Internally) and "***Vaathakajakesari Thylam*"** (Externally) in the treatment of **"*Vathasthambam*"(sciatica)** with and without "***varmam***".

OBJECTIVE:

PRIMARY OBJECTIVE:

To evaluate the efficacy of Siddha drugs ***Raajamaarthanda Ilagam*** (Internally) and ***Vaathakajakesari Thylam*** (Externally) in reducing the symptoms of ***Vathasthambam*** (sciatica) through clinical study with and without *Varmam therapy.*

SECONDARY OBJECTIVE:

To evaluate the safety of the trail drug.

To study the Siddha basic principle like *envagaithervu, udalthathu* etc in *Vathasthambam* patients treated with trial drugs and *varmam*.

To evaluate the biochemical analysis of the trial drug.

SIDDHA ASPECTS

VATHASTHAMBAM:

In the text *YugiVaithyaChinthaamani*, *Yugimunivar* has classified the *Vatham* diseases as 80 types and "*Vathasthambam*" is one among them. In *Yugi* as per the text the signs and symptoms of *Vathasthambam*may be correlated with Sciatica in Modern medicine.

வாதக்குற்றம் அதிகமாகி காலின்புறவடிகள் குடைந்து, வீக்கத்துடன் பளபளத்துக் காணப்படும். தேகம் எங்கும் உடல் நொந்து திமிருண்டாம். வில்போல் வளைய வைக்கும். நேர்கொண்டு நடக்கும் மனிதர்களை குறுகி நடக்கச் செய்யும்.

வாதத்தம்பம் - வாதம்+தம்பம்.

Vatham - is a clinical condition characterized by pain, swelling, pricking sensation and loss of function due to vitiated *Vatham*, which is the principle humour of the body.

- T.V. Sambasivam Pillai Dictionary

வாதத்தின் இருப்பிடம்,

"நாமென்ற வாதத்துக் கிருப்பிடமே கேளாய்

நாடிக்குக் கீழென்று நவிலலாகும்"

Vatham generally lives in:

1. Hip region
2. Bones
3. Joints
4. Nerves
5. Muscles
6. Skin
7. Hair follicles

8. Abanan
9. Edakalai
10. Below the umbilicus
11. Stools

Natural properties of *Vatham*:

- Giving briskness
- Respiration
- Mental function
- Regulation of fourteen physiological reflexes
- Uniformity in functioning of the seven elements
- Strengthening the five sensory organs

AETIOLOGY OF VATHAM DISEASES:

1. **According to *YugiVaithyaChinthamani***

"என்னவே வாதந்தானெண்ப தாகும்

இகத்திலே மனிதர்களுக் கெய்யுமாறு

பின்னவே பெண்தனையே சோரஞ் செய்து

பெரியோர்கள் பிராமணரைத் தூஷ ணித்தும்

வன்னவேவச்சொத்திற் சோரஞ் செய்து

மாதாபிதா குருவைம றந்து பேர்க்கும்

கன்னவே வேதத்தை நிந்தைசெய்த பேர்க்குங்

காயத்திற் கலந்திடுமே வாதந் தானே”

"தானென்ற கசப்போடுதுவர்ப்புறைப்பு

சாதகமாய் மிஞ்சுகினுஞ் சமைத்த வன்னம்

ஆனென்ற வாறினது பொசித்த லாலும்

ஆகாத் தேறலது குடித்த லாலும்

பானென்றபகலுறக்க மிராவி ழிப்பு

பட்டினியே மிகவுறுதல் பார மெய்தல்

தேனென்ற மொழியாற் மேற் சிந்தை யாகில்

சீக்கிரமாய் வாதமது செனிக்குந் தானே”

"ஆணான வரன்றனெளயே மதியா மாந்தர்

அகதிபர தேசியர்கட் கன்ன மீயார்

பானென்றபகலுறக்க மிராவி ழிப்பு

பட்டினியே மிகவுருதல் பார மெய்தல்

கோனான குரமொழியை மறந்த பேர்கள்

கொலைகளவு பொய்காமங் குறித்த பேர்க்கு

ஊனான சடந்தன்னில் வாதம் வந்து

உற்பவிக்கும் வேதத்தி லுண்மை தானே."

According to the text, those who disrespect the parents, teachers, insulting the elders, cursing the Holy books, daytime sleep and sleeplessness at night will get *Vatham* diseases. Increased consumption of bitter taste, astringent and sour foods, increased intake of cold water, excessive starvation, Sexual indulgence will lead to *Vatham* diseases.

2. **As per *konganavarVathakaviyam***

"ஆச்சப்பா யிதன்கூறை நலதாய்ச்சொன்னோம்
ஆகாகா யிந்நூல்தான் காவியகாண்டத்தில்

வாச்சப்பா வாதத்தின் கூறைச்சொன்னோம்

வாதமதின் வாயுநிலை மயங்கிப்போகும்

காச்சப்பா கலங்கியது தியங்கிப்போகும்

கண்மனியே வதுக்குமத்திபந்தான் கேளு

மாச்சப்பா மக்கினிதான் மதுவோடொக்க

மார்க்கமதாய் கூடிவிளை யாடும்பாரே"

3. **According to the text *'Pararasasekaram'***

Excessive intake of acrid, bitter, pungent taste foods, intake of more grains, day time sleep. Increased food intake, frequent starvation, sexual indulgence, excessive fear, anger, sadness, and higher exposure to air, changes in diet timings should produce *Vatham related* diseases.

4. **According to the text *SarabenthirarVaithiyaMuraigal- VathaRokhaSikitchai***

- ✓ Consumption of excessive intake of food
- ✓ Sexual indulgence
- ✓ Deprived sleep
- ✓ Excessive purgation or emesis.
- ✓ Excessive loss of blood during bloodletting therapy.
- ✓ Doing heavy work
- ✓ Control of reflexes like micturition and defaecation

- ✓ Conversion of indigested food juices into toxic substances (¬Áõ)
- ✓ Trauma
- ✓ hungry

All these activities lead to the low level of *saaram* in ducts. So as to compensate this more of *vatham* were produced and affect one or more organs.

FACTORS THAT INFLUENCES THE *VATHAM* DISEASE :

A) Seasons which deranges *Vatham* :

In *Muthuvenilkaalam*, the solar radiation increases the evaporation of water content from the earth in turn produces dryness. Similarly, the dryness is produced in our body and causes *vatham* diseases.

B) Diets which deranges *Vatham*:

- **According to the text '*SababathiKaiyedu*'**

"வளி தரு காய்கிழங்கு வரைவிலா தமிலல் கோழை புளி தயிர் போன்மிகுக்கு முறையிலா வுண்டி கோடல் குளிர்தரு வளியிற் றேகங்குனிப்புற வுலவல் பெண்டிர் குளிதரு மயக்கம் பெற்றோர் கடிசெயல் கருவியாமல்."

Excessive intake of tuber, irregular timings in consumption of food, excess consumption of curd, sour food items, higher exposure to wind, living in higher attitudes, sexual indulgence, and increased exposure to chill weather will aggravate *Vatham* diseases.

C) Habitual characters derange *Vatham*:

- **In *Theraiyarvagadam*,**

"வெய்யிலில் நடக்கையாலும் மிகத்தண்ணீர் குடிக்கையாலும் செய்யிழை மகளினரைச் சேர்ந்தனுப விக்கையாலும் பையனே உண்மையாலும் பாகற்காய் தின்கையாலும் தையலே வாதரோகம் சனிக்குமென்றறிந்து கொள்ளே."

Walking in hot climate, excessive intake of water, sexual indulgence and intake of bitter guard leads to *Vatham* diseases.

- **In *aaviyalikkumamuthamuraisurukkam***

சொல்லவே வாதமது மீறிற்றானால்
சோர்வடைந்து வாயுவால் தேகமெங்கும்
மெல்லவே கைகாள்கள சதியுண்டாம்
மெய்முடங்கும் நிமிர வொண்ணா திமிருண்டாகும்
வெல்லவே உடல் பொருமுவயி றுளைக்கும்
விரும்பி யன்னஞ்செல்லாது விந்துநட்டம்
சொல்லவே நாப்புளிக்கும் கழிச்சலு ண்டாகும்
கூறினார் மலையமுனி கூறினாரே

- Pricking sensation all over the body
- Pain all over the joints
- Difficulty in flexion and extension
- Nausea
- Loss of appetite
- Constipation
- Incontinence of urine
- Diarrhoea

SEATS OF THE THREE HUMORS:

வளிமுதலா யெண்ணியமுக் குற்ற மெல்லாம்

வாழ்வதெனும் தேகமுற்றும் பம்பிப்பரந்து

தெளிவுறச் சாற்றும்நாபிக்குக்கீழ் வாதம்

தீயின்கூ றாமழலோ உந்தி யாவிக்...

(மருத்துவத் தனிப் பாடல்)

*Vatham, pitham*and*kabam* are the three humours which are the Life constitutes of the human body. But still there's predominant *Vatham*, below the

umbilicus, predominant *Pitham* in the abdomen and thorax region and predominant *Kabam* in the head and neck region.

GENERAL CHARACTERS OF VATHAM DISEASES

"வாதம் வந்துற்ற போது வயிறது பொருமிக் கொள்ளும்
தாதவிழ்ந்திடுப்பு கைகால் சந்துகள் கடுப்பு தோன்றும்
சீதொரு மலமு நீருந் சிறுத்துடன் கடுத்து விழ
மாதவமரை மேல் வந்த வாதத்தின் குணமிதாமே."

- YugiMunivarPerunoolKaaviyam

Vatham diseases are characterized by pain and swelling in joints, abdominal distension, constipation and burning micturition.

"வாதவீறு அன்னமிறங்காது கடுப்புண்டாம் வண்ணமுண்டாம்
மோதுகட்டு ரொகம் சுரமுண்டா மிருமலுமா முறங்காதேன்றும்
ஓது சூரிய வாத மனலாகு நடுக்க முண்டாம் போருள்களாய்த்
தீதனவே நரம்பிசித்து சந்துகள் தோறுங் கடுக்கும் தினமுந்தானே"

- TherayarVaagadam

Loss of appetite, pain and redness, fever, cough, insomnia, shivering and pain in all joints is the characteristic features of *vatham* diseases, which is mentioned in the text "*Therayarvaagadam*".

CLINICAL FEATURES:

- **According to *YugiVaithiyaChinthamani* the following clinical features were seen:**
    - ✓ Stiffness of the body
    - ✓ Sweating
    - ✓ Body pain
    - ✓ Paleness of the body

- **Accoding to *VathaNoiMaruthuvam*:**

"தண்டுவாதத்தின் குணத்தை சாற்றக்கேளாய் மடமயிலே

பண்டேதண்டுமிகஊதி பற்றிபொருமி கொண்டிருக்கும்

விண்டோம் சில போதுளைவுண்டாம் மிகுந்த வாட்டமுண்டாம்

கொண்டெ மனமும் தளர்ச்சியும் கோபமதிகம் காணும் என்றே."

- ***VathaNoiMaruthuvam***

There will be inflammation of spine. Generalized tiredness, mental depression and excessive anger.

இடுப்பு வாதம்

"இடுப்பது கடுத்து உளைந்து இடைவிடா வலித்துக் கொள்ளும்
முடுக்கமாய் குனியவே தான் முடுகியே நிமிரவொட்டாது
துடுக்கென வந்து அடரும சுரமது அற்பம் அற்பம்
சடக்கென இடுப்பைச்சுற்றி சார்ந்திடும் வாதம்தானே
நடப்பெனபோது மெத்த நய்யவேவலிக்குமென்ன
கெடப்பேனபோதும் சற்றே குணமென தோன்றுமாகில்
படுப்பென போதும்யாமம் பாகியால் வாதமுண்டாம்
இடுப்பென சேரும் வாதத்தியலிது எண்ணுவீரே"

- VathaNoiMaruthuvam

The clinical features are,

- Continuous pain in the low back region.
- Difficulty in bending forward and standing erect from that position.
- Sudden onset of fever.
- Warmth around the low back region.
- Pain increases on walking and reduced by rest.

KINDS OF VATHAM:

"முறைமையாம் பிராணனோடபானன் வியானன்

மூர்க்கமா முதானனொடு சமான னாகன்

திறமையாங் கூர்மனோடு கிருக ரன்றான்

தேவதத்த னொடுதனஞ்சயனு மாகும்"

(யுகிமுனி சிந்தாமணி 800)

Even though the *vatham* seems to be the same, it has got ten different forms and actions.

1. ***PRANAN*: (AIR OF LIFE)**

   - It corresponds to cardiac plexus and it refers to the chest.
   - It maintains the action of the heart
   - It regulates the respiration and digestion.
   - It is otherwise called as "*Uyirkkaal*". For one*nazhigai* i.e. 24 minutes, there will be 360 inspirations. So, there will be 21,600 inhalations for a day. Out of these 14,400 inspirations goes inside the body and be useful and the rest go waste.

2. ***ABAANAN*: (FLATUS AIR)**

   - It corresponds to the Pelvic plexus and controls the excretion.
   - It has the tendency to travel downwards. It starts from*Swathittanam* and descends down and is responsible for excretion of urine and faces. It contracts the anus.
   - It helps to take the essence of the digested food to the different parts of the body.

3. ***VIYANAN*: (SPREADS ALL OVER BODY)**

   - It corresponds to the naso ciliary Plexus at the root of the nose and base of the skull and controls the will.

- *Viyanan* arises from the skin and go through all the 72,000 nerve and thus activate voluntary and involuntary movements of the body and thus make them to extend or contract.
- This appreciates the sense of touch helps to take the essence of the food to the strategic points of the body and guards the body.
- It also transports the nutrients and blood throughout theentire body; hence it is known as *Paravukal*.

4. *UDHANAN*: (UPWARD AIR)

It corresponds to the pharyngeal plexus in the throat region and controls the speech and breathing. *Udhanan* starts from the umbilical region (*Udarakkini*) and takes the essence of food and stasis it in appropriate places. It helps in digestion and assimilation of food.

5. *SAMANAN*: (BALANCING FORCE) (Nadukkal)

It corresponds to the navel region and controls the digestion. *Samanan* starts from the umbilical cord and spread out up to the lower limb. This is responsible for the balance of the other four Vatha. It equalises the six tastes, water, food etc. and helps in assimilation.

6. *NAGAN:* (INTELLECTUAL AIR)

Nagan is responsible for higher intellectual functions, hearing, thinking etc. It causes closing and opening of the eye lids.

7. *KOORMAN:* (VISUAL AIR)

Koorman starts from the mind and causes wrinkling of the eyelids, yawning and closure of mouth. It gives strength and helps to visualise things and causes lacrimal and salivary secretion.

8. *KIRUKARAN*: (SECRETORY AIR)

Kirukaran lies in the tongue & causes nasal and salivary secretions. It includes hunger; It makes to concentrate on one thing. Sneezing and cough are attributed to *kirukaran*.

9. *DEVADATHTHAN*: (TIRESOME AIR)

Laziness, lassitude, arguing, is attributed to *Devadaththan*. Ocular movements & human passions are attributed to this *vatham*. It stays either at the anus or at urinary orifice.

10. *DHANAJAYAN:* (INTRACRANIAL AIR)

Dhanajayan functions from the nose & it is responsible for the bloating of the body after death. It leaves from the body after 3rd day of death by blowing up the cranium.

SIDDHA PATHOPHYSIOLOGY:

Changes in lifestyle, occupation, food and other habits lead to development of this disease by causing derangement of Vital humors. Improper food habits alter the elemental composition directly while the other causes lead to derangement of these elements indirectly.

When the elemental composition is altered, the *uyirthaathukkal* or the three humours

get deranged. This simultaneously leads to derangement of seven *udalthaathukkal*, which produces symptoms of the disease *Vathasthambam.*

DIAGNOSIS

Diagnosis of*Vathasthambam*in Siddha is based on *Envagaithervugal* and also on the other factors like

1. *Uyirthaathukkal*
2. *Udalthaathukkal*
3. *Gnanenthiriyam*
4. *Kanmenthiriyam*

THREE UYIR THAATHUKKAL

1.*Vatham*

In **Vathasthambam** patients among the ten types of *vatham*; the following three types are affected and causing symptoms accordingly.

1. *Viyaanan* - Affected (producing restriction of joint movements)
2. *Samaanan* - Affected (deranging the other four types of vatham)

2. Pitham

Among the Five types of *pitham (Analaagam, Ranjagam, Pirasagam, Alosagam*and*Saathagam*) *Saathagapiththam* only affected in *Vathasthambam* patients and causing difficulty in walking, sitting and bending forward postures.

3.*Kabam*

In the five types of *Kabam (Avalambagam, Kilethagam, Pothagam, Tharpagam*and*Santhigam) Avalambagam*and*Santhigam*affected in *Vathasthambam*patients and causing pain in low back region and restriction of movements in the lumbo sacral junctions.

SEVEN *UDAL THAATHUKKAL:*

Among the seven *UdalThaathukkal (Saaram, Senneer, Oon, Kozhuppu, Enbu, Moolai and Sukkilam/Suronitham*) the following four are commonly affected in *Vathasthambam* patients.

1. *Saaram* - Tiredness and weakness
2. *Oon* - Muscular pain, muscle spasm
3. *Kozhuppu* - Restriction of movements.
4. *Enbu* - Pain present in low back region

GNANENTHIRIYAM

The *Vathasthambam*patients are having the clinical features of pain, numbness and burning sensation especially in lower limbs. These are felt through *Mei*.

KANMENTHIRIYAM

In *Vathasthambam* patients, *Kaal* is affected. This is due to radiating pain, difficulty in walking etc.

***NOI KANIPPU VIVADHAM* (DIFFERENTIAL DIAGNOSIS)**

Some types of *Vatha*diseases are mimicking like *Vathasthambam*. Careful and clear history taking and examination will reveal the correct diagnosis.They are:

1. Vathakarshanam
2. Aasuvathambavatham.

வாதகர்ஷணம்:

பார்க்கின்ற பாதவுள்ள டியிற் சாணி
பதித்து வைத்ததுபோலப் பாரமெங்கும்
கோர்க்கின்ற குதிநரம்புங் கால்க ளெங்கும்
கொடிதான பாரமாய்த்தி மிர்ப்புண் டாகி
வார்க்கின்ற வார்த்தைகள்தான் மிகவே செய்து
வாறுகினி நிமிருகினும்வசங்கொ டாமல்
ஏர்க்கின்ற காலுளைக்கும் வாதகர் ஷணம்
ஈதலற மில்லாதார்க் கெய்துங் காணே

The clinical features of vathakarshanam,

- Feeling sensory disturbance in foot
- Heaviness and numbness in legs and foot
- difficulty in forward and backward bending
- pain in legs
- blabbering

ஆசுவதம்ப வாதம்

"வாதமா யுடல்வெளுத்து வடிவெல் லாநோம்
மயக்கமோ டிருமலா மீளையுண்டாம்
நேதமாய் நெஞ்சடைத்துப் பொறிக லங்கும்
நெருப்பாக உடல்காணு நெடுமூச் சுண்டாம்
கோதுதான் மயக்கத்தில் மருத்தி னீட்டால்
குளிர்ச்சியாய்க் கோபிக்குங்கூச்ச லுண்டாம்

-YugiVaithiyaChinthamani.

The clinical features are: -

- Paleness of the body.
- Cough.
- Heaviness in the chest.
- Numbness of both feet.
- Sexual indulgence, long walking, exposure to chill weather, eating curd, tubers etc will worsen the disease.

LINE OF TREATMENT

The main goal of the treatment was not only healing the disease but also the prevention of disease and rejuvenation of *udalkattugal*.

These were as follows:

1) **Neekkam(Treatment)**
2) **Niraivu(Restoration)**
3) **Kaappu(Prevention)**

1. NEEKKAM (TREATMENT)

In the text, ***Siddha MaruthuvangaChurukkam,*** the deranged Vatham can be balanced by purgation hence to start with…….

விரேசனத்தால் வாதந் தாழும்"

Followed by usage of Internal and external drugs.

On first day: - Purgation:

Meganathakulaigai -2 with hotwater (early morning)

- **Internal drug:**

Raajamaarthandhailagam- Kottaipaakalavu (6 gms, twice a day).

- **External drug:**

Vaathakajakesarithylam- is given for external application over the affected area.

- **Varmam treatment:**

Mudichu-4
Nanganapoottu
Komberi kalam
Kudhikalvarmam
Viruthi kalam
Ullangalvellai

2.NIRAIVU(RESTORATION)

The diet and yogam should be advised to the patients for normalize the Vatha and also strengthen the body.

DIETARY REGIMENS:

-According to 'Siddha MaruthuvangaChurukkam'

மருந்து தின்றிடின் பத்தியம்
வகுத்திடா விடினும்
அருந்த வாகிடாப் பொருள்களை
அகற்றவே வேண்டும்
பொருந்திடாது பெண் போகமோர்
மருந்துக்கும்புவியில்
வருந்து வோருட லறிந்துபத்
தியந்தனை வகுப்பாய்

பத்தியங் கொண்ட பேர்கள்
பகற்றுயில் கொண்ட காலைச்
நித்திர பானு வெப்பஞ்
செப்பிடு மருந்தின் வெப்பம்
பத்தியச் செயலின் வெப்பம்
பகருநித் திரையின் வெப்பம்
இத்தனை வெப்பங் கூடி
னியலுநோய்க் களவின் றென்னை.

The heat produced by excessive sleep, day time sleep, hot sun, and medicines cause the disease.

-According to 'Siddha MaruthuvangaChurukkam'

செங்கழு நீர்கோஷ்டந் தேன்மிளகு நல்லெண்ணெய்
தங்குபெருங் காயந் தழுதாழை– எங்கெங்கும்
கூட்டுசிறு முத்துநெய் கோதில் உழுந்திவைகள்
வாட்டுமனி லத்தை மதி

- ✓ Senkazhuneer
- ✓ Crepe ginge
- ✓ Honey
- ✓ Pepper
- ✓ Gingely oil
- ✓ Asofotedia
- ✓ Hog weed
- ✓ Castor oil

These were the food items for the Vatham diseased patients.

Tender vegetables:

- ✓ Avarai(*Dolichos lablab*)
- ✓ Aththi(*Ficusracemosus*)
- ✓ Murunkai(*Moringa oleifera*)
- ✓ Sundai(*Solanum torvum*)
- ✓ Mullangi(*Raphanus sativus*)
- ✓ Thoothuvelai(*Solanum trilobatum*)
- ✓ Pirandai(*Cissusquadrangularis*)
- ✓ Karunaikizhangu(*Colocasiaantiquarum*)
- ✓ Kathiri(*Solanum melongena*)

Greeens:

- ✓ Sirukeerai(*Amaranthus tricolor*)
- ✓ Mookkurattai(*Boerrhaviadiffusa*)
- ✓ Puliyaarai(*Hibiscus cannabinus*)
- ✓ Ponnankanni(*Alternanthera sessilis*)
- ✓ Manali(*Gisekiapharanaceoides*)
- ✓ Mudakkaruththaan(*Cardiospermumhalicacabum*)

Pulses:

- ✓ Ulunthu(*Vigna mungo*)
- ✓ Pottukkadalai(fried *Cajanuscajan*)

Dairy products:

- ✓ Cow's milk
- ✓ Butter milk

AVOID:

- ❖ Tubers except karunaikizhangu(*Colocasiaantiquorum*)
- ❖ Maaporulghal(Carbohydrates)
- ❖ Vaazhai(tender *Musa paradisiaca*)
- ❖ Kaaramani(*Vigna 19nguiculate*)
- ❖ Verkkadalai(*Arachis hypogea*)
- ❖ Pattaani(*Pisum sativum*)
- ❖ Mochai(*Lablab purpureus*)

- Kezhvaragu(*Eleusinecoracana*)
- Kambu(*Pennisetumtyphoideum*)
- Solum(*Sorghum vulgare*)
- Sour,astringent foods

YOGAM: (Union of mind and body)

*Yogam*is one of the divisions of siddha medicine, which was used to prevent and cure the disease. According to the patients age and severity of the disease the following asanam are advised for strengthens the muscles and ligaments.

Asanam:

Sitting position:

- ✓ **Relaxationexercise:** It is the technique used to relax all the major and minor joints.

  Toes: flexion and extension
  Ankle: dorsi flexion, plantar flexion, inversion, eversion, rotation
  Knee: flexion, extension
  Hip: flexion, extension, abduction, adduction
  Vertebra: flexion, extension, lateral rotation, lateral flexion
  Fingers: flexion, extension
  Wrist: flexion, extension, rotation
  Elbow: flexion, extension
  Shoulder: flexion, extension, abduction, adduction, rotation

Lying position:

- ✓ Ashthikaasanam
- ✓ Jadaraparivarthini
- ✓ Marjeriasanam
- ✓ Puliasanam
- ✓ Vishnuasanam
- ✓ Makarasanam
- ✓ Salabasanam

- ✓ Santhiasanam
- ✓ Bhujangasanam
- ✓ Sethubandhasanam

Sitting position:

- ✓ Vakrasanam
- ✓ Patchmothasanam
- ✓ Vajrasanam
- ✓ Mahamudraasanam
- ✓ Poorvattasanam
- ✓ Boominamaskaraasanam
- ✓ Arthaustrasanam

Standing position:

- ✓ Thadasanam
- ✓ Pathahasthasanam
- ✓ Arthachakkarasanam
- ✓ Kattichakkara
- ✓ Arthakattichakkarasanam
- ✓ UdhirthaThirikonasanam
- ✓ Parivarthathirikonasanam
- ✓ Pranayamam (vajrasanam / padmasanam / sugasanam)

Other advice:

- ✓ Advised to avoid lifting over weight
- ✓ Advised to avoid prolonged travel in sitting position
- ✓ Advised to sitting in a correct posture
- ✓ Advised to do *Yogam* regularly
- ✓ Advised to follow the dietary regimen
- ✓ Advised to follow the *Theranpinianugavidhi*

3.KAAPPU (PREVENTION)

The prevention of diseases was well said in the Siddha system of Medicine as mentioned in the text, ***TheraiyarPinianugaaVithi***'

"பாலுண்போம் எண்ணெய்பெறின் வெந்நீர் குளிப்போம்

பகற்புணரோம்; பகற்றுயில்வோம்: பாயோதரமு மூத்த

ஏலஞ்சேர் குழலியரோ டிளவெயிலும்விரும்போம்;

ரண்டடக்கோம்; ஒன்ரைவிடோம்; இடதுகையிற்படுப்போம்"

MODERNASPECT

SCIATICA

Sciatica is a very common problem and has a universal distribution. The most important symptoms are radiating leg pain and related disabilities. Among the collection of causative factors, the common cause of low backache seems to be the lumbar disc disease. Many synonyms for sciatica appear in the literature, such as lumbosacral radicular syndrome, ischia, nerve root pain and nerve root entrapment.

EPIDEMIOLOGY:

Less than 1% to 40% of people have sciatica at some point in time. It is the most common in people's 40s and 50s, and men are more frequently affected than women. The condition has been since ancient times. The first known use of the word sciatica dates from 1451. Back symptoms is the most common cause of disability in those < 45 years. 70% of persons will have back ache at some point in their lives. Low back pain has been cited as the 2nd most frequent reason to visit a physician for a chronic condition, 5th most disease of hospitalization, 3rd most frequent reason for a surgical procedure.

5%-10% of patients with low back pain have sciatica, whereas the reported lifetime prevalence of low ack pain ranges from 49% to 70%. The annual prevalence of disc related sciatica in the general population is estimated at 2.2%. Approximately 84% of men and 74% of women have vertebral osteophytes. 30% of men and 28% of women aged 55-64 years have lumbar osteophytes.

- Harrison's principles of internal medicine
- https://www.ncbi.nim.nih.gov>pmc

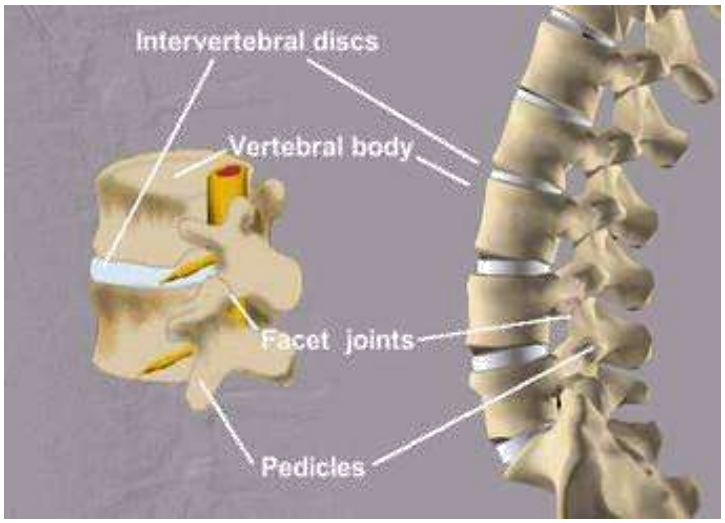
ANATOMY OF LUMBAR VERTEBRAE:

The lumbar vertebrae, numbered L1-L5, have a vertical height that is less than their horizontal diameter. They are composed of the following 3 functional parts:

- The vertebral body, designed to bear weight.
- The vertebral (neural) arch, designed to protect the neural element.
- The bony processes (spinous and transverse), which function to increase the efficiency of muscle action.

The first 4 are typical, and the 5th is atypical. A lumbar vertebra is identified by its

- ✓ Larger in size
- ✓ Absence of costal facets in the body
- ✓ Absence of foramen in transverse process



Vertebral Body:

The body is large, kidney shaped and is wider from side to side than from before backward, and a little thicker in front than behind. The height of the body is slightly greater anteriorly than posteriorly. This difference contributes the forward convexity of the lumbar spine. The lumbar vertebral bodies (vertebrae) are the heaviest components, connected together by the intervertebral discs.

Pedicles:

The pedicles are short and very strong, directed backward from the upper part of the body. They project backward from the upper part of the body, so the inferior vertebral notches are much deeper than the superior. Each vertebral arch is composed of 2 pedicles.

Vertebral foramen:

Triangular in shape. It is larger than in the thoracic region and smaller than in the cervical region.

Transvers process:

The length of the transverse processes increases from L1 to L3 and, thereafter, it decreases.

Ligamentum Flavum:

The ligamentum flavum is a strong ligament that connects the laminae of the vertebrae.

Lamina:

The laminae are broad, short, and strong; the vertebral foramen is triangular, larger than in the thoracic, but smaller than in the cervical region.

Spinous process:

The spinous process is thick, broad, quadrilateral, it projects backward and ends in a rough, uneven border.

Articular process:

The superior and inferior articular processes are well-defined, projecting respectively upward and downward from the junctions of pedicles and laminae.

Facet Joint:

The facets on the superior processes are concave, and look backward and medial ward, those on the inferior are convex, and are directed forward and lateral ward.

Intervertebral Discs

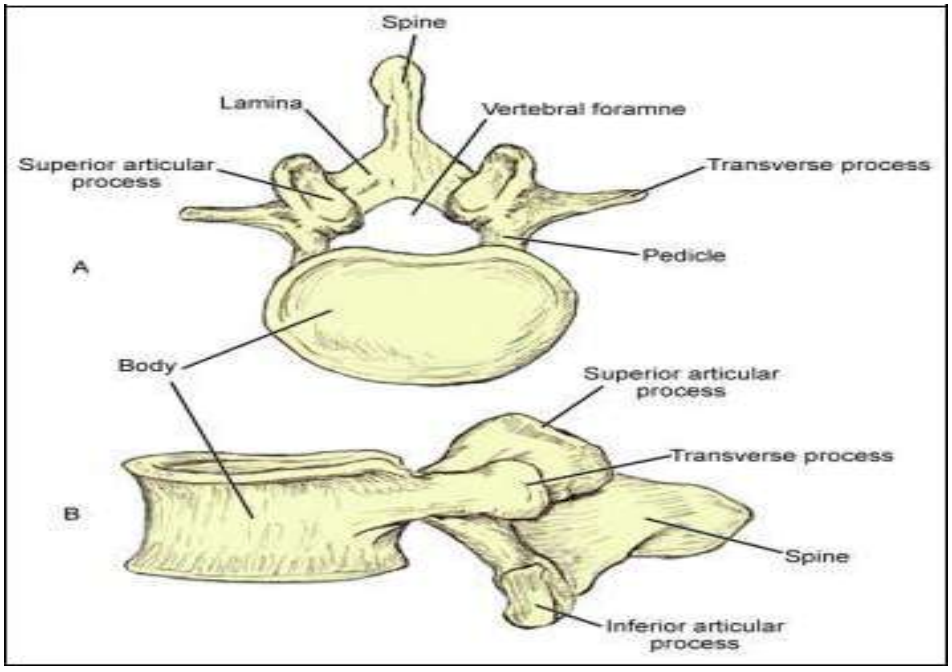
The disc is made up of, the nucleus pulposus and the annulus fibroses.

Annulus fibrosus:

The annulus fibrosus is much more fibrous than the nucleus. It also has a much higher collagen content and lower water content (lower in proteoglycan) when compared to the nucleus. The annulus is made of 15 to 25 concentric sheets of collagen (a tough cartilage-like substance) that are called Lamella.

Nucleus pulposus:

The nucleus pulposus is the water-rich (proteoglycan-rich), gelatinous centre of the disc, which is under very high pressure when the human is upright--especially in the seated or flexed position. It has two main functions to bear or carry the downward weight of the human body and to act as a 'pivot point' from which all movement of the lower trunk occurs. It's third function is to act as a ligament and bind the vertebrae together.



PATHOLOGICAL PHYSIOLOGY:

In the course of evolution from quadrated to ortho grade animal, the relatively straight spinedevelops forward and backward curves as it yields to the forces of gravity. when the spinebecomes displaced and unbalanced, greater number of muscle fibres are called into play an morefrequent intervals to keep the spine straight. The posture of the hip joint is the key to that of thewhole body because it determines the pelvic inclination, the pelvis being the foundation for thespine and rotation of the legs.

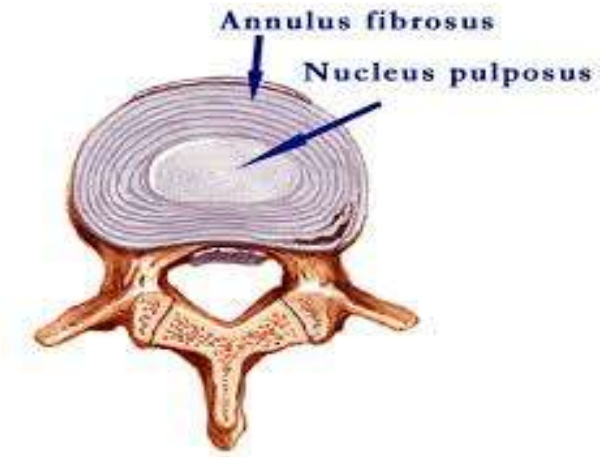
Lumbar vertebral joints

The mobility of the vertebral column is provided by the symphyseal joints between the vertebral bodies, formed by a layer of hyaline cartilage on each vertebral body and an intervertebral disc between the layers.

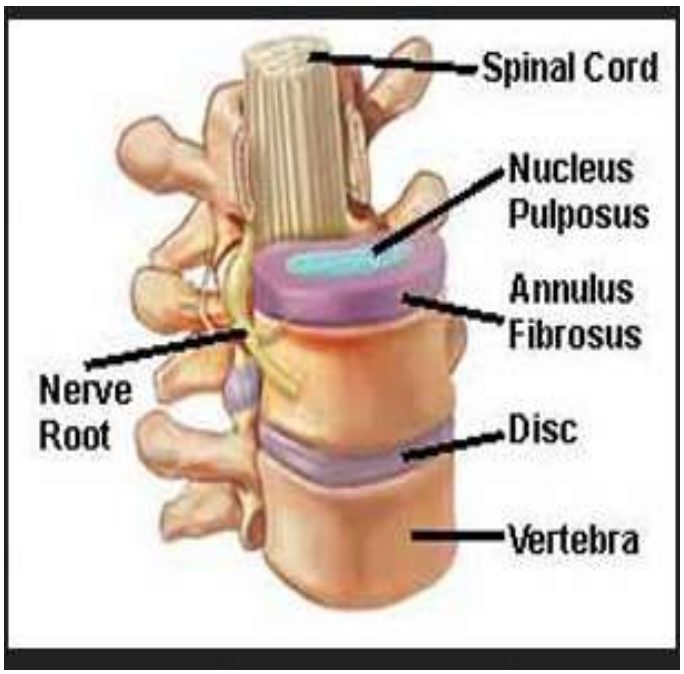
The synovial joints between the superior and inferior articular processes on adjacent vertebrae are termed the facet joints (also known as zygapophysial joints or Z-joints*)*. They permit simple gliding movements. The movement of the lumbar spine is largely confined to flexion and extension with a minor degree of rotation (see the image below). The region between the superior articular process and the lamina is the pars interarticularis. A spondylolysisoccurs if ossification of the pars interarticularis fails to occur.

LUMBAR DISC DISEASE AND DISC PROLAPSE

DISC ANATOMY

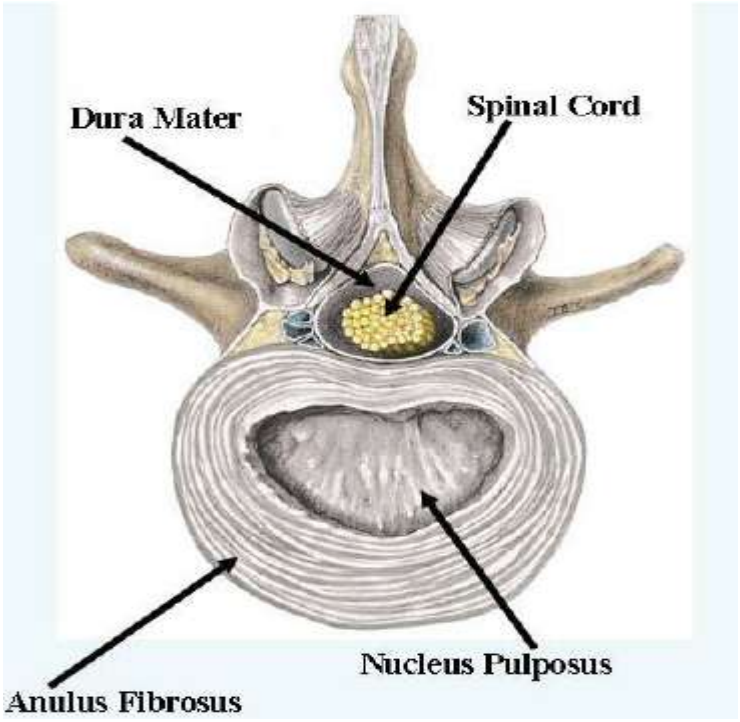


Development of spine starts from the third week of intrauterine life and continues until third decade of life. There are 23 discs throughout the spine, absent only in the atlanto-axial joint. It is thinnest in the thoracic region and thickest in the lumbar. Each disc is interposed between the bodies of a pair of vertebrae. Body of each vertebra is covered by a thin end plate of a bone, which is perforated by numerous tiny holes. This in turn is covered by a hyaline cartilage, which may be considered as the outermost portion of the disc.



Discs form the main connection between vertebrae and forms a fibrocartilaginous joint. They bear loading during axial compression and allow movement between the vertebrae. Their size varies depending on the adjacent vertebrae size and comprises approximately one quarter the length of the vertebral column.

The disc consists of two parts, an outer fibrous ring, the anulus fibrous disc intervertebralis, which surrounds an inner gel-like centre, the nucleus pulposus. Nucleus pulposus, which is made up of collagen fibrils, fibrocytes, chondrocytes, gelatinous matrix, water and salt. Peripherally, it has annulus fibrosus, which is fibrocartilaginous tissue. It is thick anteriorly and thin posteriorly more so in the posterolateral aspect. Hence, posterolateral disc prolapse is more common. The fibres of annulus are joined by diagonal fibres also known as Sharpe's fibres. With age, water content of the disc decreases, fibrous tissue and cartilage cells increase, and the nucleus becomes granular and friable.



ABOUT DISC

- It gives mobility to the spine.
- It acts as a shock absorber
- It increases the height of spine by 25%

SCIATIC NERVE:

It is the thickest nerve in the body and largest branch of the sacral plexus. In its upper part, it forms a band about 2cm wide. It begins in the pelvis and terminates at the superior angle of the popliteal fossa by dividing into the tibial and common peroneal nerves.

It is the main continuation of the sacral plexus. Its root value is **L4, L5, S1, S2, S3**. It is made up of 2 parts. The tibial part and common peroneal part, **the tibial part** is made up of ventral division of anterior primary rami of L4, L5, S1, S2, S3. **The common peroneal part** is made up of dorsal divisions of anterior primary rami of L4, L5, S1, S2.

Course:

In the pelvis,

The nerve lies Infront of the piriformis, under cover of its fascia.

In the gluteal region,

It enters the gluteal region via the greater sciatic foramen, below the piriformis muscle runs downwards between the greater trochanter and ischial tuberosity, and enters the back of the thigh. It does not give any branches in the gluteal region

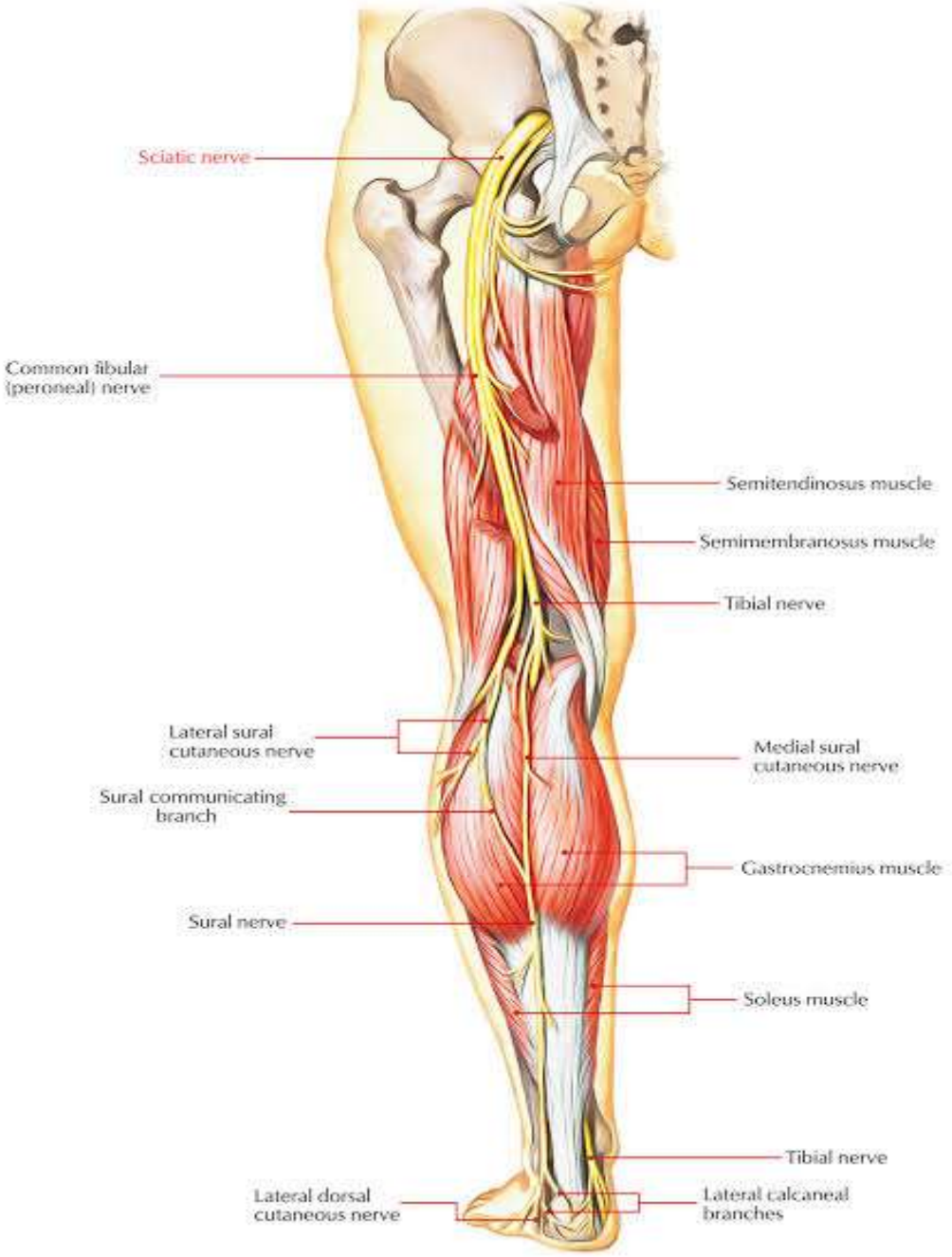
In the thighs,

It enters the back of the thigh at the lower border of the gluteus maximus. It runs vertically downwards up to the superior angle of the popliteal fossa, at the junction of the upper two-thirds and lower one third of the thigh, where it terminates by dividing int the tibial and the common peroneal nerves.

Branches:

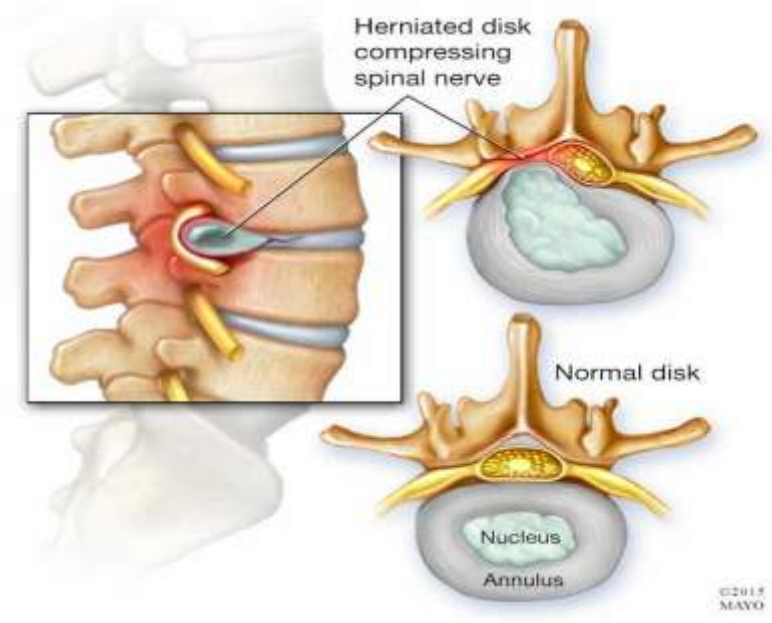
Articular branches to the hip joint arise in the gluteal region.

Muscular branches: The tibial part of sciatic nerve supplies the semitendinosus, the semimembranosus, the long head of the biceps femoris, and the ischial head of the adductor magnus from its medial side. The common peroneal part supplies only the short head of the biceps femoris.


Sciatic nerve
Common fibular (peroneal) nerve
Semitendinosus muscle
Semimembranosus muscle
Tibial nerve
Lateral sural cutaneous nerve
Medial sural cutaneous nerve
Sural communicating branch
Gastrocnemius muscle
Sural nerve
Soleus muscle
Tibial nerve
Lateral dorsal cutaneous nerve
Lateral calcaneal branches

NATURAL HISTORY OF LUMBAR DISC DISEASE

Degenerative process is divided into three stages



1. **Stage of dysfunction**
    - Seen between 15 and 45 years of age
    - Circumferential and radial tears are seen in the disc annulus
    - Localized synovitis of the facet joints is seen
2. **Stage of instability**
    - Seen between 35 and 75 years of age.
    - There is an internal disruption of the disc.
    - Progressive disc resorption takes place.
    - Degeneration of facet joints with lax capsules, subluxation and joints erosion are seen.
3. **Stage of stabilization**
    - Seen over 60 years of age
    - Progressive development of hypertrophic bone about the disc and facet joints leading to segmental stiffening or frank ankyloses is seen.
    - Disc herniation is considered as a complication of disc degeneration in stages II and I. Spinal stenosis is a complication in late instability and early stabilization stages. Disc can herniate either into the body as Schmorl's node or posteriorly towards the canal compressing the nerve roots.

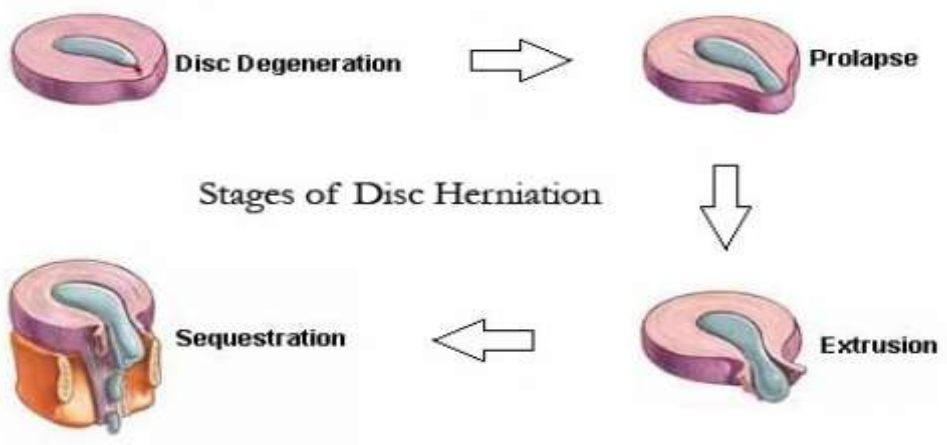
Herniation of disc:

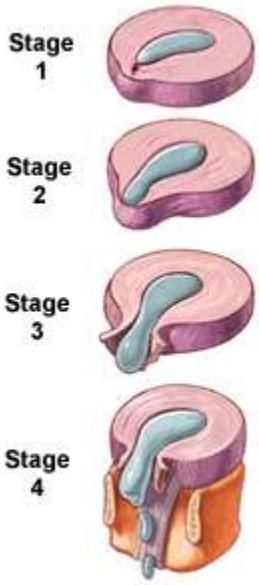
Herniation of nucleus pulposus occurs when the nucleus pulposus breaks through the anulus fibrosis of an intervertebral disc. A herniated disc occurs most often in the lumbar region of the spine especially at the L4-L5 and L5-S1 levels. This is because the lumbar spine carries most of body's weight. People between the ages of 30 -50 appears to be vulnerable because the elasticity and water content of the nucleus decreases with age.

There are 4 stages:

1. Disc protrusion
2. Prolapsed disc
3. Disc extrusion
4. Sequestration

Stage 1 and 2 are referred to as incomplete herniation, where 3 and 4 are complete herniations. Pain resulting from herniation may be combined a radiculopathy, which means neurological deficit. The deficit may include sensory changes (tingling and numbness) and motor changes (weakness, reflex loss). These changes are caused by nerve compression created by pressure from interior disc material.





Cauda equina syndrome:

It occurs from the central disc herniation and is serious requiring immediate surgical intervention. The symptoms include bilateral leg pain, loss of perianal sensation, paralysis of bladder, and weakness of the anal sphincter.

Spinal canal stenosis:

It is an abnormal narrowing of spinal cord or neural foramen that results in pressure on the spinal cord and nerve roots. Symptoms may include pain, numbness or weakness in the legs. Severe symptoms may include loss of bladder and bowel control, or sexual dysfunction.

SCIATICA:

Sciatica is caused by impingement of the L4, L5 or S1 nerve and, manifests as unilateral or bilateral neuropathic pain extending from the gluteal region down the posterolateral leg to the foot. The radicular pain is typically sharp in nature. Coughing, sneezing or voluntary contraction of abdominal muscles may elicit the radiating pain. The pain may increase in posture that stretch the nerve roots. And nerves. Sitting with the leg outstretched places traction on the sciatic nerve and L5, S1 roots. Burning sensation or electrical quality although favours radiculopathy.

Causes for Sciatica:

- ✓ Lumbar disc disease(most common)
- ✓ Degenerative spinal disease:
  - ➢ Lumbar spinal stenosis
  - ➢ Intervertebral foraminal or lateral recess narrowing
    1. Disc osteophytes
    2. Facet or uncovertebral hypertrophy
    3. Lateral disc protrusion
  - ➢ Spondylosis
  - ➢ Spondylolisthesis
- ✓ Spinal infection
  - ➢ Tuberculosis
  - ➢ Vertebral osteomyelitis
  - ➢ Septic disc
  - ➢ Meningitis
  - ➢ Lumbar arachnoiditis
  - ➢ Spinal epidural abscess
- ✓ Neoplasm
  - ➢ Metastatic, hematologic, primary bone tumour
- ✓ Fractures
  - ➢ Trauma/falls
- ✓ Atraumatic fractures
  - ➢ Osteoporosis
  - ➢ Neoplastic infiltrations
  - ➢ Osteomyelitis
- ✓ Metabolic bone disease:
  - ➢ Osteosclerosis (paget's disease)
- ✓ Congenital:
  - ➢ Spondylosis
  - ➢ Sacralization
  - ➢ Kyphoscoliosis
  - ➢ Tethered spinal cord
  - ➢ Spina bifida

- ✓ Autoimmune inflammatory arthritis
- ✓ Other causes
    - ➢ Piriformis syndrome
    - ➢ Psychiatric
    - ➢ postural

Risk factors:

- ➢ personal factors:

    age (30 – 50)

    increasing risk with height

    smoking

    mental stress

- ➢ occupational factors:

    strenuous physical activity- for example, frequent lifting, especially while bending and twisting

    driving including vibration of whole body

    IT sector (due to improper posture)

Indicators of sciatica:

- ✓ Unilateral / bilateral leg pain greater than low back pain
- ✓ Pain radiating to foot or toes posterolaterally.
- ✓ Numbness and paraesthesia in the same distribution
- ✓ Straight leg raising test induces more leg pain
- ✓ Localized neurology that is limited to one nerve root

EXAMINATIONS:

SCIATIC NERVE STRETCH TEST:

Patient is in supine position, one of the leg is raised with one hand, ipsilateral knee is pressed over by other hand. This test produce tension in the hamstring muscles which in turn compresses the sciatic nerve and produces pain.

BREGARD'S TEST or FAJERSZTAJN'S TEST:

After doing SLRT, dorsiflex the foot. It produces further tension on the sciaticnerve and the patient complains of pain.

LASEGUE'S TEST:

Here the hip is flexed, knee is right angle to hip and the leg is slowly straightened.

BIICKLING'S SIGN:

Perform as SLRT until the patient complaints of pain. Now ask thepatient to flex the knee.Pain decreases due to relief of tension on the nerve.

SICARD'S TEST:

After doing SLRT, dorsiflex the great toe. This puts further tension on thesciatic nerve and the patient complains of the pain.

WEEL LEG RAISIN TEST:

Here, the patient is asked to perform SLRT of the normal limb. Ifthe patient complains of pain on the affected side, then it is highly suggestive of disc prolapse and this is a pathognomonic test which has more relevance then the conventional SLRT.

BILATERAL STRAIGHT LEG RAISING TEST:

Here, patient is asked to raise both the legssimultaneously. This is a test for the sacroiliac joint rather than the spine. During the first 70-degree, stress is on the SI joint, over 70-degree stress is on the lumbar spine.

FEMORAL NERVE STRETCH TEST (REVERSE SLRT):

Here, the patient is in proneposition and is asked to lift the leg straight. This puts a stretch on the femoral nerve. If the patient complains of the pain it indicates high level disc prolapse(L1-L2-L3).

Examination for neurological features in lumbosacral spine:

Lumbosacral nerve root	**reflex**	**sensory**	**Motor**	**Pain distribution**
L4	Knee(quadriceps)	Medial calf	Knee extensor and thigh adductor	Knee, medial calf, anterolateral thigh
L5	-	Lateral calf Dorsal aspect of foot	Hip abductor, Foot: dorsiflexors, Eversion Toe: dorsiflexors	Buttocks, posterolateral thigh, lateral calf, dorsal foot
S1	Ankle (gastrocnemius/ soleus)	Plantar and lateral aspect of foot	Foot: plantar flexion Hip: extension Great Toe: flexion	Buttocks, posterior thigh, posterior calf, bottom foot

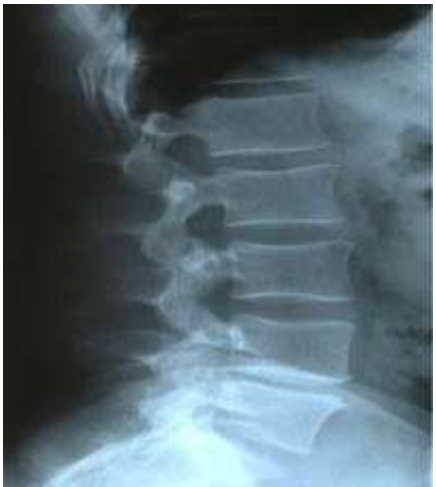
INVESTIGATIONS OF LOW BACK ACHE: DIAGNOSIS

Diagnosis is mainly based on X-rays and MRI – LS Spine

1. X- Ray Lumbar Spine

- AP view – look for vertebral column, any pedicular lesion.
- Lateral view – shape & size of vertebral body.

Oblique view– side to side collapse, Inter vertebral disc space

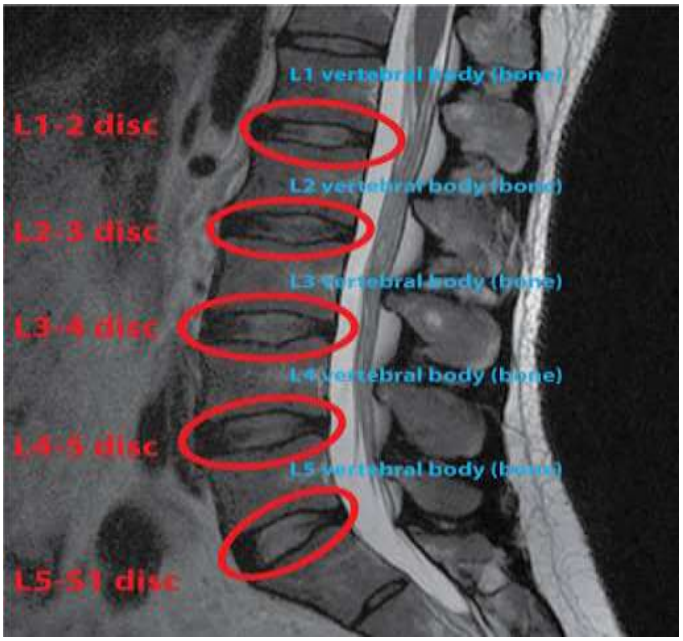


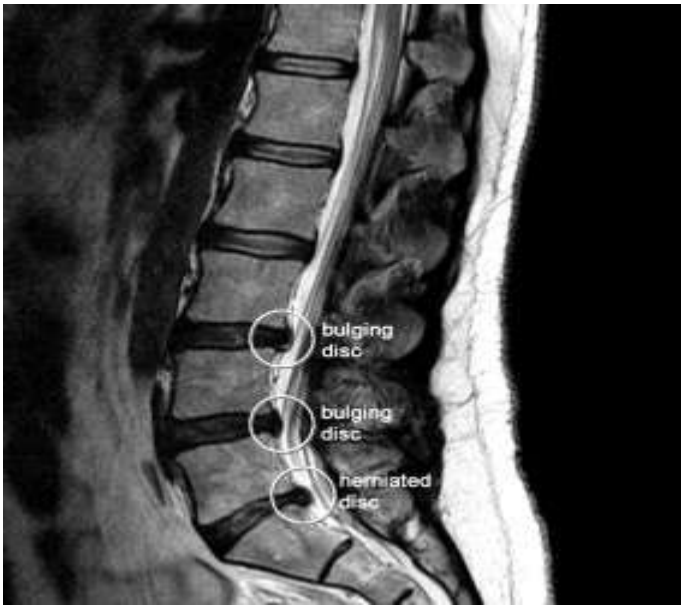
2. Computed Tomography (CT):

It is useful in non-invasive painless outpatient procedure. It gives a cross sectional study of the pathology. CT helps to detect the foraminal structures and lateral disc prolapse.

3. MRI

MRI helps to detect intra-spinal lesion, examine entire spine, identifies degenerative disc.





4. Myelograph

Consists of injecting radio opaque dye (myodil was used earlier now it is the water soluble iopamiro300, which is being used) into the spinal canal and taking radio graphs of the back.

RADIOGRAPHY:

Radiography of the back is not very reliable as normal findings are observed in 7-46% ofthe cases. Disc space is reduced in old cases.

Other Tests:

Discography, Bone scans, EMG

DIFFERENTIAL DIAGNOSIS

- Multiple myelomas
- Extra duraltumors.
- Peripheral neuropathy
- Herpes zoster
- Multiple sclerosis
- Ankylosing spondylitis
- Vascular insufficiency
- Osteoporosis with stress fractures

COMPLICATIONS

- Severe spinal stenosis
- Paraplegia
- Cauda equina syndrome
- Neurogenic claudication

VARMAM

வர்மம் என்பது உடலின் நிலையான ஆற்றலைக்குறிக்கும் சொல்லாகும். வர்மம் என்பது வாசி எனவும் பொருள்படும்.

"வாசி தட்டும் இடமெல்லாம் வர்மம்"

- Varma OdivuMurivu Sara Soothiram-1200

Varmam can be defined as the flow of life force in relationship with breathing.

“செப்புறு தசைகளென்பு சிறு பெரு நரம்புசந்து
தப்புறு நாடியாறும் தங்குமிடம் வன்மமாமே.”

- Varma Vidhi

The points where life force resides and flows in the human body are known as varmam. It alsomeans the points where breathing energy resides in the body.

- VaagadaNithaanam Verse- 31

வேறுபெயர்கள்:

காலம், புரவி, பிராணன், சுவாசம், கலை, யோகம், சிவம், சரம், வாசி

-VaagadaNithaanam

The vital points (varmam) are located in the junction of nerves, joints, bones, muscles, ligaments and internal organs.

History of Varmam:

"தேறவே சிவன் உமைக்குச் சொன்ன போதம்
ஆறாமல் நான் அறிந்துஇந்நூல் சொன்னேன்."

- Varma OdivuMurivu Sara Soothiram-1500, Song-833

Lord Siva taught *Varmam* to his wife Paarvathi; later Paarvathi taught Varmam to their son Lord Murugan. Lord Murugan then taught to the SiddharAgasthiyar. *Agasthiyar* later gave a written form that reached the people.

"பண்பாக அகத்தியனார் ராமதேவர்
பணிவாக போகமுனிவர் தானும்
பருவமாய் மனிதர்கள் பிழைக்கவென்று
பாங்காகச் சொன்னதொரு நூல்கள் கண்டு
பார்த்திடவே சுருக்கமாய்பிறித்துச் சொன்னேன்."

-Kai MaathiraiThiravukoll

Varmam has grown under three independent schools of thoughts, mainly governed by three ancient siddhar's namely *Akasthianyar, Bohar and Rama Devar*. The term *Varmam*appears in the Rigveda where Indran hits Vritran in a Varmam with his vajram. The word also presents in ancient tamil literatures named *tholkappiyam, thirumanthiram*.

Classification of Varmam:

"ஆகுமே வர்மத்தின் வகைக ளெல்லாம்
அடங்குமே பாவில் அடங்காது சொன்னேன்
தாகுமே வர்மமொரு நூற்றெட்டிற்கும்
தகைமைதனைப் பிரித்துரைக்கும் சார்வைக் கேளு"

There are 108 Varmam or Varma points in our body.

"படுவர்மம் பதினெட் டாகும் பாங்கன
தொடுவர்மம் தொண்ணூற் றாறாகும்"
-நறம்பரைநூல்(கும்பமுனி)

1.According to the text Varma OdivuMurivuSoothiram:

Paduvarmam – 12
Thoduvarmam – 96

Injury or any hit in the *Paduvarmam* points may lead to severe deformities or even death also. The *ThoduVarmam* points are mostly used in therapeutic purposes.

2. According to the text Varma Kannaadi

Human body is divided into five divisions, they are:

"வகுத்த எண்ஜான் உடம்பதிலே கண்டமைந்து
பகுத்துவிரித்துக் கருவி சொல்வோம்
தொகுத்த கழுத்தின் மேலேகண்டமது ஒன்றேயாகும்
தொடுத்த கழுத்தின்கீழ் நாபிக்குமேலே கண்டம் ரண்டாம்
தொகுத்த நாபியின்கீழ் மூலத்தின் மேலே
தோன்றுதற்கு கண்டமொன்றாய் விரித்துச் சொன்னோம்
தொகுத்த கரம்ரெண் டதுமே பாகம்
தொடர்ந்த கால்ரெண் டதுமே பாகம் தானே".

S.no	Area	Number of points
1	From top of the head to neck	25
2	From neck to naeval point	45
3	From naeval point to anus	9
4	Both hands	14
5	Both legs	15
	Total	108

3.According to the text Varma Soothiram,

VathaVarmam	-	64
PitththaVarmam	-	24
Kabavarmam	-	06
Ul Varmam	-	06
ThattuVarmam	-	08
Total	-	108

The main causes for impact to nerve centre (Varmam)

“கேளப்பா தடியடிகள் படுத லாலும்
கெடியான எறிவிசைகள் கொள்ளலாலும்
வாளப்பா கட்டைகுற்றி தட்ட லாலும்
மாற்றானின் கைப்பிடிகள் படுதலாலும்
வேளப்பா ஆகசா மதிலே நின்று
மெய்மறந்து கைமறந்து விழுத லாலும்
தாளப்பா பற்பலவாம் விதத்தி னாலே
சங்கையில்லாக் காலமது சாருந் தானே”.

-OdivuMurivu Saari-1200

- Hit sustained by a thick and rough stick.
- Stone thrown at a high speed from a sling.
- Fall from a tree or height.
- Fall while running.
- By leaping.
- By fainting

Varma Kalai is said to link up the material body with the spiritual life or Soul, through the medium of *panchapoothangal* or five elements activating the movement of "life" within the body carried through the ten vayu. This is the fundamental principle of *Yogam and Samadhi*.

A human body requires thasavaayus (10 vaayus) namely, Praanan, Abaanan, Udaanan,Viyaanan, Samaanan, Naagan, Koorman, Kirukaran, Devadatthan and Dananjayan,for its proper functioning each vayu has its own function to keep the body healthy and disease free.

Pranavayu controls the function of all other vayu. It flows across the six *aatharam*, the three *thasanaadi* (*Idakalai, Pingalai, Suzhimunai*) from vertex to sole. The entire pathway of the *praanavaayu*consists of junctions or places where it stays temporarily. These junctions are called *Varmam.*

When the body gets injured on a particular part due to some trauma leading to shock or fracture, the *praanan* changes its path and gets scattered from its original place to any other area. During this time the person may experience excruciating pain which may also refer to other area leading to syncope, and even coma. These sorts of injury if not treated within a specific period may lead to death or fatal conditions.

Varmam treatment

Varmam therapy is a systematic study of vital points (varmam) on human body and also on animal bodies.

"உள்ளபடிநூற்றெட்டு தலம் சாவாகும்
உணர்வாகி அத்தலங்கள் உயிரு மாகும்
கள்ளமுற்ற அத்தலங்கள் பிணியு மாகும்
களங்கமற்றால் அத்தலங்கள் சுகமே காணும்
உள்ளுணர்வாய் அத்தலங்கள் வாசி யேற்ற
உற்றதினால் அத்தலங்கள் உறுதி சேரும்
புள்ளடிபோல் அத்தலங்கள் கண்ட வர்கள்
புகலார்கள் எல்லோரும்புவியினுள் ளோர்க்கே."

-Varma OdivuMurivu Sara Soothiram-1200

It is a martial art which has been widely used during war as protection and defence purpose. Now a days it is used as therapeutic purpose for healing. Right or wrong vibration of the vital points will either promote or impair health. Its aim is to produce healthy and stable individuals.

Varma therapy can be used for Low back ache, Spinal problems, Head ache and Migraine, Arthritis, Frozen shoulder and Neuromuscular problems. It is a safe and effective system of healing and for rejuvenation. It provides a complete natural healing to rejuvenate the toxic imbalances.

In this present study, 40 cases of *Vathasthambam* were diagnosed clinically. Among them 20 patients were treated by *Varmam* treatment along with the trial drugs.

The following Varmam points manipulated for Sciatica**:**

- **Mudichu-5**
- **Nanganapoottu**
- **Komberi kalam**
- **Kudhikalvarmam**
- **Viruthi kalam**
- **Ullangalvellai**

1) MUDICHUGAL:

முடிச்சுகள் என்பது முதுகுதண்டெலும்பில் ஒன்றிற்கு மேற்பட்ட நரம்புகள் சந்திக்கும் இடமாகும். இவை 5 வகைப்படும்

1. கருணாமிர்த முடிச்சு
2. சர முடிச்சு
3. துன்னல்முடிச்சு
4. பாச முடிச்சு
5. கும்பக முடிச்சு

“அடைவான முடிச்சி ஐந்தும் சொல்லக்கேளு
அடைவான தேகமதில் முடிச்சுப்பாரு
நடைவான ஆளேற முடியாதப்பா
நளினமென்ற மேருகிரி மலையோரத்தில்

உறைவான தலை பிடரி நடுப்பொருத்தில் கொழுகி
உள் அறையொட்டி பொருத்தமாக
தடையில்லாதிருக்குமப்பா உள்ளே தானும்
தப்பாமல் கருணாதி முடிச்சி ஒன்று.

முடிச்சியப்பா கழுத்தடியில் புசம் நேராக
முன்னொளியாம் சரமுடிச்சி ஒன்று
கடச்சியப்பா முதுகுவரி நட்டெல்லு பூட்டு
கனமான துன்னலென்னும்முடிச்சி ஒன்று
படச்சியப்பா நாங்ன்ஙணத்தின் பொருத்துக்குள்ளே
பசு பதியாம் பாசமெனும்முடிச்சி ஒன்று
சடச்சியப்பா கோச பீசத்தடிக்குள்ளே தான்
சரமிசையும் கும்பகத்தின் முடிச்சியொன்றே”

-Varma noolthoguthi 2

SARAMUDICHU:

Location:

Junction point between C7 and T1,

Procedure:

Place a middle 3 finger over the saramudichu.

Clock wise 3 rotation and anticlock wise 3 rotation for saramudichu stimulation.

Then the pranan should be loaded in thunnalmudichu.

THUNNAL MUDICHU:

Location:

Junction between T8 and T9.

10 fingers below saramudichu.

Procedure:

Clock wise 3 rotation and anticlock wise 3 rotation over the varmam point, then the pranan should be loaded in pasamudichu.

PASAMUDICHU:

Location:

Junction point between the T12 and L1.

Starting point of the 12th rib.

Procedure:

Clock wise 3 rotation and anticlock wise 3 rotation over the varmam point, the pranan should be loaded in kumbagamudichu.

KUMBAGA MUDICHU:

Location:

On the sacram bone.

Procedure:

Clock wise 3 rotation and anticlock wise 3 rotation over the varmam point.

2) NANGANA POOTTU (NAAIRUPPU VARMAM)

Synonyms:–

SorutheendaVarmam, NattaluVarmam

NaairuppuVarmam- Varma Aani

Putti Varmam- Sathura Mani Soothiram

"மூலத்தில் நின்று புஷ்டம் என்ற
நாங்ஙன பொருத்தே சுற்றிடுமாம் நட்டெலும்பு
இருவசமும் கைபாகம் அரிந்து செய்யே
ஆர்அறிவார் அருமைதானே !

- Kumbamuninarambarai 10

“பூணவே நால்விரல் மேல் பத்தாயவர்மம்
பொருந்திய மூவிரல் மேலே புட்டிவர்மம்.”

-Sathura Mani Soothiram

Location:

Sacral groove or 3 fingers from the lumbosacral joint

Sacroiliac articulation situated in the region of sacrum on both sides of spinal column(or) A center point present 6 finger below from vayukalam. Nanganaaputtuvarmam present 3 finger right and left side from the centersacram bone.

Procedure:

Place the medial aspect of the palm and give lateral rotation over the varmam. Then the pranan should be loaded in poovadangal towards the lateral aspect of the gluteal region**.** Then the pranan should be loaded in the uppukuttrivarmam via the posterior compartment of lower limb.

Indication:

Lumbar spine related diseases.

-(Ref: varmapulligalinerupidam, Pg. no:334)

Strengthen the lower limbs

-(Practical guidance given by Thiru. Shanmugam Aasaan)

<u>3. KOMBERI VARMAM</u>

Synonyms:

ThumbikaalaVarmam - Varma NoolavuNool

KomberiVarmam- Varma Soothiram

"குதிரைமுக வர்மத்திலிருந்து (5 விரலுக்கு)
கீழ்நோக்கி அளக்க தும்பிக்கால வர்மம்
அறியலாம்."

-Varma NoolalavuNool

".....குதிரை முகவர்மம்
கண்டாயே அங்குலந்தான் நாலின் கீழே
கடந்திட்டால் கொம்பேறி வர்மமாகும்."

"ஏகும் முடவு றைரண்டில்தும்பிகாலம்."

-Adi Varma Sootcham-500

"காலிலே குதிரைமுகக் காலத்தின் கீழ் அங்குலம்
நாலிலே நவிலுவோம் கொம்பெறி வர்மத்தின் தானம்."

-Varma Laada Soothiram-300

Location:

Komberivarmam is located 5 fingers below from the KuthiraiMughaVarmam point (the middle of the both legs) in the anterior aspect of both legs. (or) 8 fingers above from the medial malleolus. (Inner aspect of the tibial bone).

Procedure:

Press and release the varmam by using middle 3 fingers of the hand.

4. ULLANKAAL VELLAI VARMAM

Synonyms

Adangalvarmam	-	varmasoothiram 1200
Kaalvellaivarmam	-	adivarmasootcham 500
Allankaalvarmam	-	varmaviralalavunool
Adikkuzhivarmam	-	varmavidhi
Vellaivarmam	-	varmaodivumurivusarasoothiram

"கீர்த்தியாம் பாதமதில் வெள்ளைவர்மம்."

- Varma OdivuMurivu Sara Soothiram -1200

"சூட்சமடா வெள்ளையதில் அடங்கல் வர்மம்."

- Varma Soothiram- 101

"படைமுறித்தான் வர்மத்துக்குரண்டுவிரலுக்குக்
கீழே உள்ளங்கால் வர்மம்.....

-Varma NoolalavuNool

"அவனிதனில் உள்ளங்கால் வெள்ளைவர்மம்."

- Varma Peerangi-100

"அகமான உள்ளம் கால் வெள்ளைவர்மம்."

-Adi Varma Sootcham-500

"நாளான காலில்வெள்ளைவர்மங் கொண்டால்
நரம்புவலி இடுப்புவலி மண்டைக் குத்து
பாழான தேகமது நிமிரவொட் டாது
பாதமது களைப்பிளகி பனிரும் தேகம்

Location:

Present in between the ball of the foot. (a point present in between the 1st and 2nd metatarsal bone of the plantar aspect of the ball of the foot.

Procedure:

Press and release the varmam 3 times by using thumb.

Uses:

It cures giddiness, vomiting, faint, hysteria, convulsions and delirium.

5. VIRUTHTHI KAALAM:

Synonyms:

VirdhiVarmam-Varma Kannaadi 500

VirtthiVarmam-Adi Varma Soothiram

ViruthiVarmam - Varma LaadaSoothiram 300

"நவிலுகின்ற பெருவிரலிறைக்கு மேலாம்
ஒன்றான விற்தி என்ற காலமாகும்
உரையதின் மேல்ரண்டிறைக்குள் சுண்டோதரி....."

-Varma Kannaadi-500

"போமென்ற பெருவிரல் மொழி மேல் விர்த்திகாலம்."

- Adi Varma Sootcham-500

"வெல்லுவார் பெருவிரலுக்கு மேலிறை ஒன்றில் விருத்தி."

- Varma Laada Soothiram-300

Location:

Meatimg point of 1st and 2nd toe.

VirutthiVarmam is located 2.5 cms, above the tip of the big toe.

Procedure:

Press and release the varmam 3 times by using the great finger that time the other 3 fingers should be placed over the ullankalvellaivarmam.

6. KUDHIKAAL VARMAM:

Location:

7 fingers above from the heel (on achilis tendon)

Procedure:

Press and release the varmam by using middle 3 fingers of the hand.

Uses:

Strengthen the legs, used in emergency treatment.

MATERIALS AND METHODS

The study on *Vathasthambam* was carried out in the Department OfSirappuMaruthuvam, National Institute of Siddha.

According to "*Pranarakshamirthasindhu* and *Kannusamyparambaraivaidhyam*, "*Raajamaarthandha*Ilagam (Internal) and *VaathakajakesariThylam*" (External) are the preparations Indicated for *Vathasthambam*".

STUDY DESIGN AND CONDUCT OF THE STUDY

ABOUT THE DISEASE

The disease "*Vathasthambam*" has been dealt in the Siddha Maruththuvam as one among the 80 types of *vatha* diseases. Patients were selected according to the clinical features as mentioned in *Yugivaithiyachindhamani*.

STUDY PERIOD: 18 months

STUDY DESIGN: An Open Clinical Trial

STUDY PLACE:

Department of SirappuMaruthuvam, AyothidossPandithar Hospital, National Institute of Siddha, Chennai-47.

SAMPLE SIZE: 40 patients

Patients are divided into 2 groups.

GROUP A : Trail drugs without varmam

GROUP B : Trail drugs with varmam

TRIAL DRUGS:

INTERNAL MEDICINE:

RAAJAMAARTHANDA ILAGAM:

Dosage : 6gms (*paakalavu*)

Duration : 45 days.

Ref : *Prana Rakshamirthasindhu*

EXTERNAL MEDICINE:

VAATHAKAJA KESARI THYLAM:

Dosage **:** Q. S (for External application)

Ref **:** Kannusamyparambaraivaidhyam

VARMAM:

Mudichu-4

Nanganapoottu

Komberi kalam

Kudhikalvarmam

Viruthi kalam

Ullangalvellai

STANDARD OPERATIVE PROCEDURE

Source of trial medicine:

The required raw drugs for the preparation of *Raajamaarthandhailagam* (Internal) and *Vaathakajakesarithylam* (External) was purchased from a well reputed country shop and the raw drugs was authenticated by the competent authority (Medicinal Botany). After that the raw drugs was purified separately and the medicine is prepared in *Gunapadam* laboratory - National Institute of Siddha.

Preparation of Trial Drugs

Internal Drug:

RAAJAMAARTHANDHA ILAGAM:

Ingredients:

Table-1:

s.no	Tamil name	Botanical name	Parts used	Quantity
1.	Elam	Elatteriacardamomum	fruit	8gm
2.	Kirambu	Syzygiumaromaticum	Flower	8gm
3.	Perungaayam	Ferula asafetida	Gum	8gm
4.	Thippili	Piper longum	Fruit	8gm
5.	Thippilimoolam	Piper longum	Root	8gm
6.	Jathikkai	Myristicafragrans	Fruit	8gm
7.	Siruthekku	Clerodendrumserratum	Root	8gm
8.	Muthakasu	Cyperusrotandus	Bulbous root	8gm
9.	Seeragam	Cuminumcyminum	Seed	13gm

10.	Karunjeeragam	Nigella sativa	Seed	13gm
11.	Sirunaagappu	Mesuanagasserium	Flower	13gm
12.	Kugaineeru	Marantaarundinacea.Linn	Root powder	17gm
13.	Chukku	Zingiberofficinale	Rhizome	70gm
14.	Milagu	Piper nigrum	Fruit	70gm

Table-2:

S.No	Tamil name	Botanical name	Parts used	Quantity
15.	Sangam ver	Clerodendruminerme	Root	350gm
16.	Kandankathiriver	Solanum surattense	Root	175gm
17.	Seviyam	Piper nigrum	Root	175gm
18.	chittramuttiver	Pavoniazeylanica	Root	88gm
19.	Iruveliver	Veteveriazizonoids	Root	88gm
20.	Kodiveliver	Plumbago zeylanica	Root	88gm
21.	Nilapanaikizhangu	Curculigoorchioides	Rhizome	88gm
22.	Seenthilver	Tinosporacardifolia	Root	88gm
23.	Vilvaver	Aegle marmelos	Root	88gm
24.	Thippilimoolam	Piper longum	Root	88gm

Table-3:

S.No	Tamil name	Botanical/chemical name	Parts used	Quantity
25.	Naatucharkarai	Jaggery	-	420gm
26.	Nei	Ghee	-	140gm
27.	Then	Honey	-	140gm

Purification of raw drugs:

Elam: (*Elettariacardamomum Linn*)

Dried under sunlight without any dust particle.

Kraambu: (*Syzygiumaromaticum Linn*)

The nab of the raw drug was removed.

Perungayam: (*Ferula asafoetida Linn*)

It isroasted in light flame then powder it.

Thippili: (*Piper longum Linn*)

The drug should be soaked into lemon juice for 24 min (1 nazhigai) then dry it under sunlight.

Thippilimoolam: (root of*Piperlongum Linn*)

It is dried under sunlight without any dust particle

Jadhikkai: (*Myristicafragranshoutt*)

After scraping the outer layer, the drug was dried under sunlight.

Siruthekku: (*Clerodendrumserratum Linn*)

After scraping the outer layer, the drug was dried under sunlight.

Muthakkaasu: (*Cyperusrotundus Linn*)

It is dried under sunlight without any dust particle.

Seeragam: (*Cuminumcyminum Linn*)

It is dried under sunlight without any dust particle.

Karunseeragam: (*Nigella sativa Linn*)

The drug to be dried under sunlight and roast it.

Sirunaagappu: *(Mesuanagassarium Linn*)

It is dried under sunlight without any dust particle

Koogaineeru: (*Marantaarundinacea Linn*)

The powdered drug was washed with pure water. filter the drug and dry under sunlight.

Sangam ver: (*Azimatetracantha Linn*)

It is washed with water & dry it.

Kandangkathriver: (*Solanum surattense Linn*)

It is washed with water & dry it.

Seviyam: (Root of*Piper nigrum Linn*)

After scraping the outer layer, the drug was dried under sunlight.

Chitramuttiiruveliver: (*Pavoniazeylanica Linn*)

Wash the raw root with water,dry it.

Kodiveli: (*vettiveriazyzonoides Linn*)

Kodiveli root bark was powdered.

Par boiling machine poured with milk and closed by a clean cloth.

Keep the kodiveli powdered root bark over the cloth for the purification process.

Steam it in under low flame.

After finishing the procedure make fine powder by using pestle(kalvam)

Seendhilver: (*TinosporacordifoliaThunb*)

To remove the outer layer of the root.

Vilvamver :(*Aegle marmelos Linn*)

The root was washed and dried under sunlight.

Nilapanaikizhangu: (*CurculigoorchioidesGaerth*)

The raw drug was powdered.

Par boiling machine poured with milk and closed by a clean cloth.

Keep the nilapanaiver powdered root bark over the cloth for the purification process.

Steam it in under low flame up to 3 hours (1 samam)

Later it was dried under sunlight and then grain that into a fine powder.

Chukku: (*Zingiberofficinale Roscoe*)

It is soaked with lime stone water for 3 hours (1samam). After that the drug should be washed and dried.

The outer layer was scrapped.

Milagu: (*Piper nigrum L*)

Keep the drug in butter milk for 3 hours (1 samam) and dry it.

Neer: **(Water)**

To filter the water into folded cloth directly.

Seeni: **(Jaggery)**

To remove the dust particles.

Nei: **(Ghee)**

Melt the butter in slow flame. Filter it.

Then: **(Honey)**

To allow the honey through the heated rod.

Method of preparation:

The drugs under table 1 are finely powdered after purification process.

The drug which is mentioned under table 2 should be made as decoction. (water quandity 1 marakal=5.37ltr) properly.

Add a sugar into the decoction (fluid medium) and a syrup is prepared by gently heating it.

At the suitable syrup stage, the dry powder (under table 1) are added and stirred.

When quite warm, ghee is mixed into the mass.

When cool, honey is added and mixed.

B. External Medicine:

Ingredients:

Pachaichithramoolaverpattai	
(Root bark of *Plumbago indica Linn*)	-5 palam (175gm)
Omam(*Trachyspermumroxburghianum*)	-2 ½ palam(87.5gm)
Oomathaiilaichaaru(*Datura metel Linn*)	-1 padi(1.34ltr)
Nallennai(Gingelly oil)	-1 padi(1.34ltr)
Karpooram(Camphor)	-1 palam(35 gm)

Purification of drug:

Pachaichithramoolaverpattai:(Root bark of*Plumbagoindica Linn*)

Kodiveli root bark was powdered. Par boiling machine poured with milk and closed by a clean cloth, then keep the kodiveli root bark powder over the cloth for the purification process. The entire setup was heated under low flame. After finishing the procedure make into fine powder by using pestle(kalvam).

Omam: (*Trachyspermumroxburghianum*)

The drug was soaked into lime stone water and dried it properly.

Omathaiilaichaaru:*(juice of Datura metal Linn)*

Clean the leaf with dry cloth. The central and peripheral stalk was removed and juice it.

Karpooram:

Dust particle was removed.

Method of preparation:

Chithramoola root bark was grained with Aloe vera juice and omamwas grained with oomathai leaf juice. Take a vessel and pour the umathai leaf juice and nallennai. The vessel was kept under low flame. After preparing the thylam, powdered karpooramwas added in to it. Then it was stored in dry container.

Drug storage:

The trial drug *Raajamaarthandailagam* is stored in clean and dry container and *Vaathakajakesarithylam* is stored in clean and dry glass bottles.

Dispensing:

The Ilagam is given in packets and *Thylam* is given in dry container.

Ilagam:

OPD pt : 84gm (6gm,bid x 7 days)

IPD pt : 12gm (6gm,bid)

Thailam:

OPD pt : QS (50 ml bottle)

IPD pt : QS (daily)

SUBJECT SELECTION:

Patients reporting with symptoms of *VATHASTHAMBAM* will be included in the study using screening Proforma.

INCLUSION CRITERIA:

- Age: 20 - 60 Yrs.
- Sex: male, female and transgender.
- Non-Insulin dependent diabetes mellitus
- Low back pain radiating to lower limb posterolaterally
- Numbness and paresthesia
- Low back ache aggravates after prolonged standing and walking
- Difficulty in bending and lifting
- Coughing exacerbate the low back pain
- Patients willing to undergo radiological investigation and Laboratory investigations.

EXCLUSION CRITERIA:

- Insulin dependent Diabetes mellitus
- H/o uncontrolled hypercholesterolemia
- Spondylolisthesis
- Tuberculous arthritis
- Pyogenic bone infection
- Vertebral fracture
- Tumour in vertebral body
- Osteochondritis
- Metabolic bone disease
- Limb weakness and foot drop

- Ankylosing spondylitis
- Spinal deformity
- Sexually transmitted disease
- Bowel and bladder incontinence

WITHDRAWAL CRITERIA:

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

8.TESTS AND ASSESSMENTS:

A. Clinical assessment

B. Laboratory investigations

C. Radiological investigations

D. Siddha system assessment

A. **CLINICAL ASSESSMENT:**

- Tenderness (lumbosacral region)
- Stiffness
- Difficulty to walking prolonged standing, forward bending and lifting
- Exacerbation the pain while coughing
- Indicators of sciatica
    - Unilateral leg pain greater than low back pain.
    - Pain radiating to foot or toes
    - Numbness and paraesthesia in same distribution
    - Straight leg raising test induces more leg pain
    - Localized neurology _that is limited to one nerve root

CLINICAL TEST:

- SLR: straight leg raising test.
- Flip test
- Braggards test
- Zigards test
- Lasseque test
- Femoral nerve stretch test
- EHL weakness

B. Routine investigation:

Blood:

- Hb
- Total WBC Count
- DC
  - Polymorphs
  - Lymphocytes
  - Eosinophil
  - Monocytes
  - Basophils
- Total RBC count
- ESR

  ½ Hr: 1 Hr:
- Blood sugar

  Fasting:

  Post prandial:

Urine:

- Albumin
- Sugar Fasting:
- Post prandial:
- Deposits

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

C.SPECIFIC INVESTIGATIONS:

- CRP
- ASO TITRE
- RA FACTOR
- VDRL

SIDDHA PARAMETERS:

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram
    a. Neikkuri
    b. NeerKuri

DATA COLLECTION FORMS:

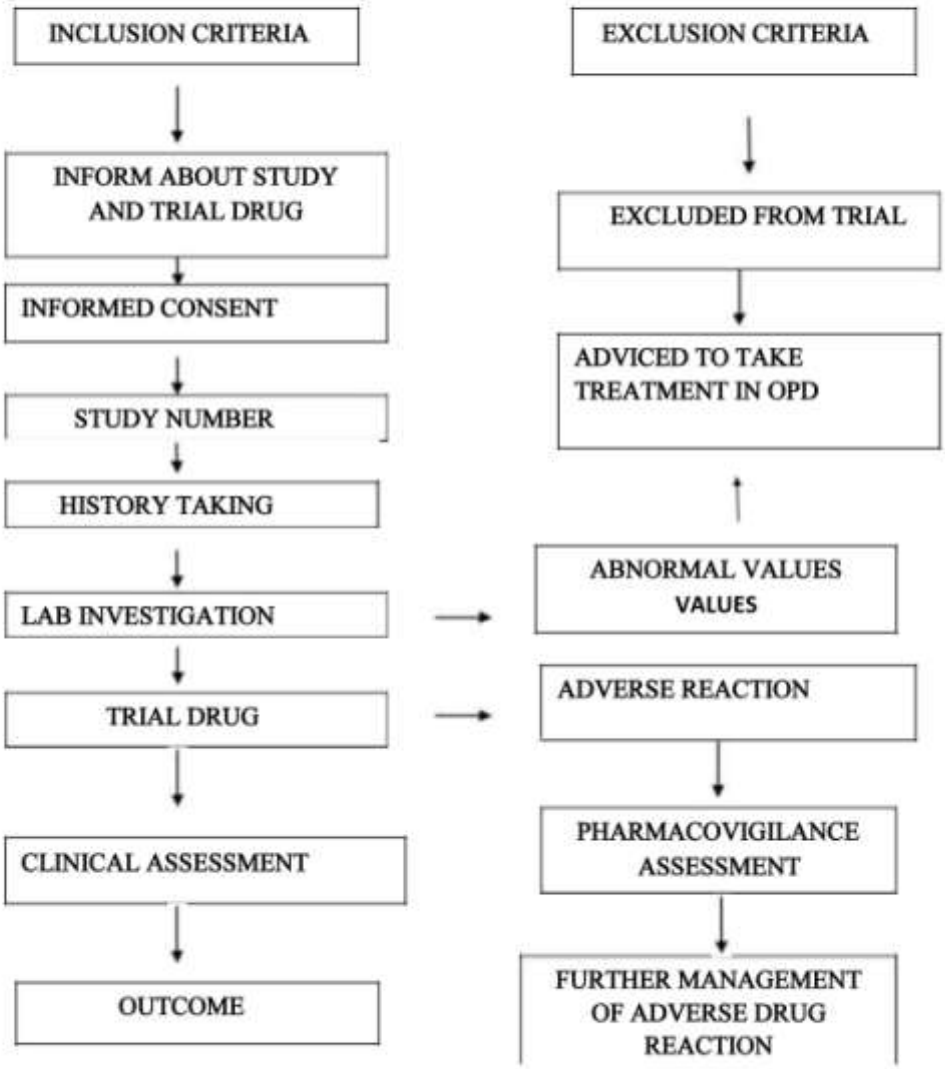
Required information was collected from each patient by using the following forms:

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 — Adverse reaction form
- Form XI — Dietary Advice form

METHODOLOGY
PATIENT SCREENING

Inclusion/Exclusion



STUDY ENROLLMENT:

Patients reporting at the OPD with the clinical symptoms of *Vathasthambam* (Sciatica) were examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled would be informed (Form VI) about the study, trial drugs, possible outcomes and the objectives of the study in the language and terms understandable to them and informed consent would be obtained in writing from them in the consent form (Form VI). All these patients will be given unique registration card in which patients Registration number of the study, Address, Phone number and Doctors phone number etc. was given, so as to report easily, it any complications arises.

Complete clinical history, complaints and duration, examination findings and laboratory investigations -- would be recorded in the prescribed Proforma. Patients will be advised to take the trial drug and to follow the appropriate dietary advice.

CONDUCT OF THE STUDY:

The trial drugs *Raajamaarthandhailagam (internal) 6gm (BID along withwater)* (Internal) and*vaathakajakesarithylam*(External) are givencontinuously for 45 days for all the 40 patients. Out of these 40 patients, 20 patients will be treated with varmam therapy. Patients are requested to visit the hospital OPD once in seven days for this study. IPD patients (who are willing to admitted) progress was assessed daily. In every visit, the clinical assessment is done and prognosis is noted in the prescribed proforma in the presence of faculty members of Dept.ofSirappuMaruthuvam. Laboratory and radiological investigation were done on before and the after (48^{th} day) the trial. Defaulters were be allowed to continue the trail and to be withdrawn from the study.

DATA ANALYSIS:

After enrolling the patient for the study, a separate file for each patient were opened and all forms were kept in the file. Study No. and Patient No. were 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 were made at the assessment form or other suitable form. The screening forms were filed separately. The data recordings were monitored for completion and adverse event by guide (concerned faculty).

All forms were statistically analysed by the senior research officer for logical errors and incompleteness of data to avoid any bias. No modification in the results was permitted for unbiased report.

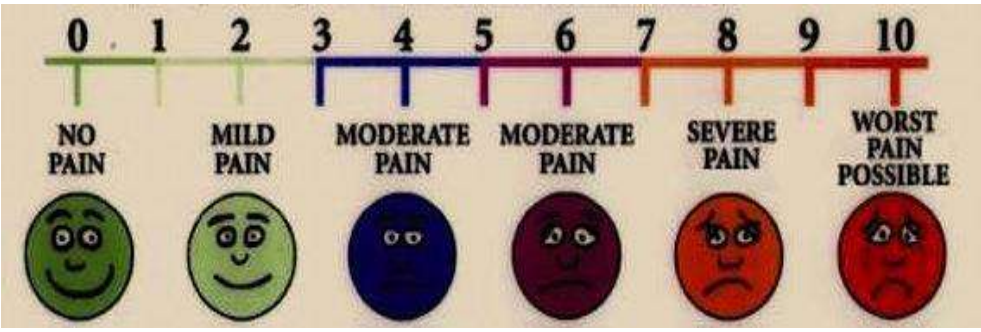
OUTCOME:

Primary outcome:

Primary outcome of the study was pain relieving and it was assessed by using the **Universal Pain assessment scale** (before and after treatment)

Restricted movement assessment 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)

PHARMACOVIGILANCE:

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT

If the trial patients develop any adverse reaction, he/she was immediately withdrawn from the trial and proper management will be given in OPD of National Institute of Siddha and the same was informed to the Pharmaco-vigilance committee of NIS.

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 were used.
2. No other external or internal medicines will be used, other than the trial drug for *VATHASTAMBAM*. There were no infringement on the rights of the patient.
3. The data collected from the patient were kept confidential.
4. After getting the consent of the patient only (through consent form in their own vernacular language) they were enrolled in the study.
5. Treatment would be provided free of cost.
6. In any adverse reaction observed during the trial the patients were withdrawn from the study and alternative treatment was given at National Institute of Siddha for further management.

DRUG REVIEW

Properties of drugs:

1.Elam: (Elettariacardamomum Linn)

Family name : Saterminaceae

Useful parts : fruits,driedripe,seeds

Organoleptic Character:

Taste : kaarpu

Potency : veppam

Division: kaarpu

Actions : stimulant, carminative, stomachic, diuretic, aromatic

Elam is indicated for cough, diarrhoea and disease in throat, mouth.

தொண்டை வாய்கவுள் தாலுகு தங்களில்
தோன்றும் நோயதி சாரம்பன் மேகத்தால்
உண்டை போல்எழுங் கட்டி கிரிச்சரம்
உழலை வாந்தி சிலந்தி விஷஞ்சுரம்
பண்டை வெக்கை விதாகநோய் காசமும்
பாழுஞ் சோமப் பிணிவிந்து நட்டமும்
அண்டை யீளைவன் பித்தம் இவைக்கெல்லாம்
ஆல மாங்கமழ் ஏலமருந்ததே

(தேரையர் குணவாகடம்)

Chemical constituents:

Volatile oil of the seeds contains terpinyl acetate, cineole, free terpinol etc, potassium salts, starch nitrogenous mucilage, Mn.

Pharmacological activity:

A comparable **anti-inflammatory effect** of the oil takes out from commercial *Elatteriacardamomum* seeds and indomethacin was performed, which proved to be obviously marked[5].

Cardamom oil produced the maximum in vitro permeation development for ion-paired diclofenac sodium (DS)

Antispasmodic activity of the oil take out from cardamom seeds was determined. The outcomes proving that cardamom oil employs its antispasmodic action through muscarinic receptor blockage[7].

2. Kraambu: (Syzygiumaromaticum Linn)

Family name :Myrtaceae

Useful parts : flower bud

Organoleptic Character:

Taste : karppu

Potency : veppam

Division: karppu

Actions : anti spasmodic, carminative, stomachic, anti oxidant

Kraambuis indicated for giddiness, vomiting, diarrhoea, ear disease, cataract, skin diseases.

பித்த மயக்கம் பேதியொடு வாந்தியும்போம்
சுத்தவிரத் தக்கடுப்புந் தோன்றுமோ–மெத்த
இலவங்கங் கொண்டவருக் கேற் சுகமாகும்
மலமங்கே கட்டுமெனவாழ்த்து

சுக்கிலநட் டங்கர்ண சூர்வியங்க லாஞ்சனந்தாட்
சிக்கல்விடாச் சர்வா சியப்பிணியு– மக்கிக்குட்
டங்கப் பூவோடு தரிபடருந் தோன்றிலில்
வங்கப்பூ வோடுரைத்து வா.....

(தேரையர் குணவாகடம்)

Chemical constituents:

16 volatile oil like eugenol, beta caryophyllene, vanillin, crategolic acid, tannins such as bicornin, gallotannic acid, methyl salicylate, campesterol, stigmasterol, sequesterpenes etc

Pharmacological activity:

Eugenol is routine **analgesic agent**. The effect has been attributed to its capability to suppress prostaglandins and other inflammatory mediators such as leukotriene. It is also depressing the sensory receptor involved in pain perception[8,9].

It **inhibits the conduction of action potential** in sciatic nerve and N-methyl D-aspartate (NMDA) receptors.

Clove oil contains significant **anti-inflammatory effect** and is due to cox-2 inhibition[12].

3. Perungayam:(Ferula asafoetida Linn)

Family name :Umbelliferae

Useful parts : Resin

Organoleptic Character:

Taste : kaippu, karakarappu

Potency : veppam

Division: kaarpu

Actions : stimulant, carminative, anti-spasmodic, expectorant, laxative, anthelmintic, diuretic, aphrodisiac, emmenagogue, nervine and pulmonary stimulant

Perungayamis indicated for teeth disorders, indigestion, ulcer, ascites, dysmenorrhoea, pain

தந்தவே தந்த மூலத்தெழும்பிணி
சருவகாளம்விருச்சிகங்கீடம்மா
மந்தம்வாதம் உதாவர்த்தம் அல்குல்நோய்
மார்பணங்கட்ட குன்மம்மகோதரம்
உந்துகெர்ப்பத்தின் வித்திரஞ்சூலைச்சூர்
உதிரப்பூச்சி சிலேத்துமத்துறும்வலி
வந்தமெய்க்கடுப் போடிவைமுற்றுமே
மாயுநாறுநற் காயங்கிடைக்கினே.

(தேரையர் குணவாகடம்)

Chemical constituents:

Organic sulphur compounds, volatile oil, essential oil of garlic allylpersulphide and 2 terpenes, ferulic acid, ester of asaresino- famol.

4. Thippili: (Piper longum Linn)

Family name : Piperaceae

Useful parts : Immature berries

Organoleptic Character:

Taste : Inippu

Potency : Veppam

Division: Inippu

Actions : stimulant, carminative, alternative, tonic, aphrodisiac.

Thippiliis indicated for cough, ulcer, anaemia, giddiness, tastelessness, headache, disorders in ear-eye-throat-nose.

ஆசனநோய் தொண்டைநோய் ஆவரண பித்தமுதல்
நாசிவிழி காதிவைநோய் நாட்புழுநோய்–வீசிடுவி
யங்கலாஞ்ச னஞ்சிதையும் அம்பாய் அழிவிந்தும்
பொங்கலாஞ்ச நங்கையர்கோட்போல்

(தேரையர் குணவாகடம்)

Chemical constituents:

Volatile oil, fatty oil, starch, alkaloid (piperine), inorganic compounds

Pharmacological activity:

Gum extract have some **good relaxant compounds** which interfere with a range of histamine, muscarinic receptor and adrenergic activities, or the movements of calcium ions across membrane required for smooth muscle contraction non-specifically

anti-nociceptive effect of asafoetida on neurogenic and chronic pain in mice.

***5. Thippilimoolam:* (root of *Piper longum Linn*)**

Family name : Piperacae

Useful parts : root

Organoleptic Character:

Taste : karppu

Potency : veppam

Division : karppu

Actions : stomachic, stimulant, carminative, alternative, tonic, vermifuge, aphrodisiac

Thippilimoolamis indicated for fever, cough, horsiness of voice, body pain, thirst, diarrhoea, loss of appetite etc

தாகபித்தஞ் சோகந் தணியாச் சுரமிருமல்
மேகங்குரற்கம்மல் மெய்க்கடுப்பும் – ஏகுங்காண்
திப்பிலிமூ லங்கண்டத் திப்பிலிய தாம்நறுக்குத்
திப்பிலியென் றேயொருக்காற் செப்பு.

–அகத்தியர் குணவாகடம்

Chemical constituents:

Alkaloid (piperine), organic matter, starch, volatile oil, fatty oil, gum, resin

Pharmacological activity:

The aqueous extract of *Piper longum* root powder given orally to mice and rats to study its **analgesic effects** similar to that of NSAID drugs (P<0.0001)

The extract of *Piper longum* were reported to possess **anti-inflammatory activities** on prostaglandin and leukotriene cox-1 effect and this exhibit anti-inflammatory activity

***6. Jadhikkai:* (*Myristicafragranshoutt*)**

Family name : Myristicaceae

Useful parts : dried seeds

Organoleptic Character:

Taste : thuvarppu, karppu

Potency : veppam

Division: karppu

Actions : stimulant, carminative, narcotic, aromatic, aphrodisiac, tonic

Jathikkaiis indicated for head ache, bronchial asthma, cough, chronic diarrhoea, disease initiated by pitham, stomach pain, indigestion etc

தாது நட்டம் பேதி சருவாசி யஞ்சிர நோய்
ஓதுசுவா சங்காசம் உட்கிரணி – வேதோ
டிலக்காய் வரும்பிணிபோம் ஏற்றமயல் பித்தங்
குலககா யருந்துவர்க்குக் கூறு.

(தேரையர் குணவாகடம்)

Chemical constituents:

Volatile oil 2.8pc, a fixed oil (myristin, myristic acid), proteins, fat, starch, mucilage.

Pharmacological activity:

The **anti-inflammatory effect** of *M.fragrans* is due to the myristin that it contain the same effect as that of indomethacin.

The **anti-inflammatory action** of myristin might be due to inhibition of chemokines, cytokines, nitrous oxide and growth factors in double stranded RNA stimulated macrophages via the calcium pathway

***7. Siruthekku:* (*Clerodendrumserratum Linn*)**

Family name : Verbenaceae

Useful parts : Root

Organoleptic Character:

Taste : kaippu, thuvarppu

Potency : veppam

Division: kaarpu

Actions : stimulant, sedative

Siruthekkuis indicated for mental disorder, bronchial asthma, fever, sinusitis, chronic vaatha disease, body pain, depression etc

கண்டுபா ரங்கியெனுஞ் சிறுதேக குண்டேல்,
காலெங்கே பித்தமெங்கே கபந்தா னெங்கே
தொண்டுதொட்டுத் தொடர்சுவாச காச மெங்கே
சுரமெங்கே வெறியெங்கே தொனிநோ யெங்கே
மிண்டுபுரி பீநசநீர்க் கோவை யெங்கே
வெளிநீருண் ணீரெங்கே விறற்கா லெங்கே
அண்டுபடாச் சீதசுரங் கடுப்பு மெங்கே
யழலையக நோயெங்கே யறைகு வீரே

(தேரையர் குணவாகடம்)

Chemical constituents:

Alkaloid, starch.

Pharmacological activity:

Clerodendrumserratum roots showed significant **anti-inflammatory activity** in comparison with Dexamethasone.

8. Muthakkaasu: (Cyperusrotundus Linn)

Family name : Cyperacae

Useful parts : tuber or bulbous root

Organoleptic Character:

Taste : kaippu

Potency : veppam

Division: kaarpu

Actions : stimulant, tonic, carminative, diaphoretic, demulcent, astringent, diuretic, anthelmintic, stomachic, vermifuge, emmenagogue

Muthakkaasuis indicated for plantar fasciitis, fever, thirst, diarrhoea, vomiting etc

சீத சுரந்தீர்க்குஞ் செம்புனல்பித் தம்போகும்
வாத சுரந்தணிக்கும் வையகத்தில் – வேதைசெய்ய
வந்த பிணியையெல்லாம்வாட்முத் தக்காசு
கொந்துலவும் வார்குழலே கூறு.
அதிசாரம் பித்தம் அனற்றாகம் ஐயங்
குதிவாதஞ் சோபங் கொடிய – முதிர்வாந்தி
யாரைத் தொடர்ந்தாலும் அவ்வவர்க்கெ லாங்குளத்துக்
கோரைக் கிழங்கைக் கொடு.

–அகத்தியர் குணவாகடம்

Chemical constituents:

Trace of alkaloid, fibre, starch, essential oil, albuminous matter, carbohydrates, fat.

Pharmacological activity:

Alcoholic extract of *C.rotandus* showed highly significant ($P<0.001$) **anti-inflammatory activity** against the exudative and proliferative phase of inflammation in 2 animal model.

Hydro-alcoholic extract of *Cyperusrotandus* shown **analgesic activity** have investigated for the anti-nociceptive activity of in mice

9. Seeragam: (*Cuminumcyminum Linn*)

Family name : Umbelliferacae

Useful parts : fruits

Organoleptic Character:

Taste : karppu, inippu

Potency : thatpam

Division: inippu

Actions : carminative, aromatic, stomachic, stimulant, astringent

Seeragamis indicated for stomach pain, liver disorders, renal calculi, bronchial asthma, horsiness of voice, sinusitis.

வாந்தி யருசிகுன்மம்வாய்நோய்பீ லிகமிரைப்
பேற்றிருமல் கல்லடைப்பி லாஞசனமுட் – சேர்ந்தகம்மல்
ஆசனகு டாரியெனும் அந்தக் கிரகணியும்
போசனகு டாரியுண்ணப் போம்.

(தேரையர் குணவாகடம்)

Chemical constituents:

Essential oils, thymine rich in carvone seeds contain cuminol 56 pc, hydrocarbon, cymene, terpene, protein compound, fatty oil, resin, mucilage.

Pharmacological activity:

The analgesic and anti-inflammatory effects of *Cuminumcyminum*extracts showed highly significant activity in acidic acid induced writhing, while ethanolic extract were effective in hot plate method[41].

10. ***Karunseeragam:* (*Nigella sativa Linn*)**

Family name : Ranunculaceae

Useful parts : Dried fruits and seeds

Organoleptic Character:

Taste : kaippu

Potency : veppam

Division : karppu

Actions : carminative, diuretic, emmenagogue, galactagogue, anthelmintic, stomachic, parasiticide, emollient, aromatic, diaphoretic, digestive.

Karunseeragamis indicated for eczema, head ache, ulcer, cough, nausea, inflammation, jaundice, eye disorders etc

கருஞ்சீ ரகத்தான் கரப்பனொடுபுண்ணும்
வருஞ்சிராய்ப் பீநசமு மாற்றும் – அருந்தினால்
காய்ச்சல் தலைவலியுங் கண்வலியும் போமுலகில்
வாய்ச்ச மருந்தெனவே வை.

– அகத்தியர் குணவாகடம்

Chemical constituents:

Volatile oil, fixed oil 37.5 pc, essential oil, mucilage, organic acid, toxic glucoside, melanthin, Arabic acid.

Pharmacological activity:

Nigella sativa seeds revealed promising **narcotic analgesic activity** mediated possibly through opioid receptors.

The oral administration of oil dose dependently suppressed the nociceptive response in the hot plate, tail pinch test, acetic acid induced writhing test and in the early phase of formalin test.

The **anti-inflammatory effect** of *Nigella sativa* was demonstrated by its inhibitory effect on carrageenan induced paw edema in mice. It inhibits the eicosanoid generation and membrane lipid peroxidation, through the inhibition of cyclooxygenase and 5-lipoxygenase pathways of arachidonate metabolism, thus responsible for the anti-inflammatory activity.

11. ***Sirunaagappu: (Mesuanagassarium Linn*)**

Family name : Guttiferae

Useful parts : flower bud, fruit, flower, seed, bark oil

Organoleptic Character:

Taste : kaippu, thuvarppu

Potency : thatpam

Division: karppu

Actions : astringent, carminative, aromatic, purgative, sudorific, stomachic

Sirunaagappuis indicated for leucorrhoea, cough, diarrhoea, ulcer, abscess, burning sensation in legs, oliguria

சிறுநாகப் பூவினது செய்கைதனைச் சொல்வோம்
குறியாகும் மேகத்தைக் கொல்லும் – நெறிவிட்டுத்
தீதாய்ச் செல்வாயுவையுந் தீர்க்குமிருமற்போக்கும்
கோதாய் இதையறிந்து கொள்.

Chemical constituents:

Oleoresin, fixed and essential oil

Pharmacological activity:

Non-polar fraction of **anti-nociceptive activity** in terms of reduction in writhing response

It revealed to have promising **anti-inflammatory activities** in carrageenan induced paw edema, cotton pellet granuloma and granuloma pouch inflammatory models

***12. Koogaineeru:* (*Marantaarundinacea Linn*)**

Family name : scitaminaceae

Useful parts : tuber powder

Organoleptic Character:

Taste : inippu

Potency : thatpam

Division: inippu

Actions : refrigerant, demulcent, nutrient, tonic

Koogaineeruis indicated for cough, fever, thirst.

மேனியிடும்வாய்க்குமிருதுவாம் ஆக்கியுண்ணத்
தானிருமல் வெப்பதிக தாகமிவை – ஏனிருக்கும்
அம்பேறினங்கிழங்கு தியாவர்க்கு மாமணப்பூங்
கொம்பே கூகைக்கிழங்கைக் கூறு.

Chemical constituents:

The arrow root powder contains sodium, potassium, magnesium, iron, zinc, calcium, phosphorus, carbohydrates, fat, protein and B-complex vitamins and starch.

13. Chukku: (Zingiberofficinale Roscoe)

Family name : Zingiberaceae

Useful parts : rhizome

Organoleptic Character:

Taste : kaarpu

Potency : veppam

Division: kaarpu

Actions : stimulant, stomachic, carminative

Chukkuis indicated for

சூலைமந்தம் நெஞ்செரிப்பு தோடமேகப் பம்மழலை
மூலம்இரைப்பிருமல்மூக்குநீர் – வாலகப
தோடமதி சாரந் தொடர்வாத குன்மநீர்த்
தோடமா மம்போக்குஞ்சுக்கு.
– அகத்தியர் குணவாகடம்

வாதப் பிணிவயி றூதற் செவியாய்
வலிதலை வலிகுலை வலியிரு விழிநீர்
சீதத் தொடுவரி பேதிப் பலரோ
சிகமலி முகமக முகமிடி கபமார்
சீதச் சுரம்விரி பேதச் சுரநோய்
தெறிபடுமெனமொழி குவர்புவி தனிலே
ஈதுக் குதவுமி தீதுக் குதவா
தெனும்விதி யிலைநவ சுறுகுண முனவே.
– தேரன் குணவாகடம்

Chemical constituents:

Zingiberene, beta-bisabolene, monoterpene hydrocarbons, sabinene, geraniol, sesquiterpene, terpinol,

Pharmacological activity:

The **anti-inflammatory** properties have been found to inhibit prostaglandin biosynthesis and interfere with inflammation cascade and the vanilloid nociceptor.

Ginger can be distinguished from NSAID based on its ability to suppress leukotriene biosynthesis by inhibiting 5-lipoxygenase and also it inhibits the cyclooxygenase to have a better therapeutic profile[49,50].

Zingiberene was clinically effective **hypo analgesic agent** than NSAID in arthritis pain. Mechanism of action include modulation of leukotriene and prostaglandin synthesis and inhibition of NF-κ B[51].

It inhibits the release of substance P in rats via the receptors to which capsicin binds and it also have the **anti-nociception**[52].

14. *Milagu:* (*Piper nigrum L*)

Family name : **Piperaceae**

Useful parts : fruit

Organoleptic Character:

Taste : kaippu, kaarpu

Potency : veppam

Division: kaarpu

Actions : acrid, carminative, antiperiodic, rubefacient, stimulant, resolvent, antivatha, antidote

Milaguis indicated for

தியாகி யெங்கும் திரியுமதை யாவத்து
மேயாம லெப்படியு முண்டாக்காற் – பாயாது
போந்திமிர்வா தங்கிரந்தி புண்ணீரும் மண்ணவெர்க்கும்
காந்திமெய்வா தச்சலுப்பைக் காய்.

Chemical constituents:

Volatile alkaloid (piperine) 5 to 9 pc, Piperidine 5 pc, balsamic essential oil, fat.

Pharmacological activity:

It significantly reduced acute inflammation induced by carrageenan and dextran and formalin induced chronic models of inflammation. It also exhibited antinociceptive property in acetic acid induced writhing test. These studies revealed that black pepper possesses antioxidant, **anti-inflammatory and antinociceptive property.**

15. Sangam ver: (Azimatetracantha Linn)

Family name :Verbinaceae

Useful parts : root

Organoleptic Character:

Taste : kaippu

Potency : veppam

Division: karppu

Actions :alternative, febrifuge, tonic

Sangam veris indicated for eczema, scabies, pain, vatha and kaba diseases, snake bite etc

கரப்பான் கிரந்தி கருங்குட்ட ரோகம்
உரப்பான மேகம் ஒழியுங் கருவாம்
கருங்கிரந்தி செவ்வாப்புக் கட்டிகளு மேகம்
அருஞ்சங்கங்குப்பிக் கறி

வெட்டை சொறி சிரங்கு வீறி வருஞ்சூலை
துட்டவா தங்கபந்து ணுக்கிருமல் – கெட்டவிடம்
அங்கங்கொள் பூச்சிவை யாவும் போம் பித்தமுறுஞ்
சங்கங்குப்பிக்கெனவே சாற்று.

Chemical constituents:

Stearoptin, resin, ash contain NaCl

Pharmacological activity:

The **analgesic and anti-inflammatory activities** of the ethanol extract of whole plant of *C.inerme* were evaluated in acetic acid induced writhing and hot plate method for analgesic activity.

16. Kandangkathriver: (Solanum surattense Linn)

Family name : solanaceae

Useful parts : root, flower, fruit, seed, leaf

Organoleptic Character:

Taste : karppu

Potency : veppam

Division: karppu

Actions :expectorant, diuretic, carminative

Kandangkathiriveris indicated for cough, indigestion, fever, vatha disorders etc

காச சுவாசங் கதித்தஷய மந்தமனல்
வீச்சுரஞ் சன்னி விளைதோடம் – ஆசுறுங்கால்
இத்தரையு ணிற்கா, எரிகாரஞ் சேர்க்கண்டங்
கத்திரியுண் டாமாகிற் காண்.

Chemical constituents:

Alkaloids, sterols, saponin, flavonoids, glycosides and also carbohydrates, fatty acids, amino acids etc.

Pharmacological activity:

Chronic administration, it reduced the proliferative phase of inflammation

17. Seviyam: **(Root of *Piper nigrum Linn*)**

Family name : Piperaceae

Useful parts : seeds

Organoleptic Character:

Taste :kaippu, kaarpu

Potency : veppam

Division: kaarpu

Actions :acrid, carminative, anti-periodic, rubefacient, stimulant, resolvent

Seviyamis indicated for fever, anaemia, diarrhoea, anorectal disorders, ulcer, jaundice, pain etc

சூலை அருகிசன்னி தொல்லிருமல் ஈளைபித்தம்
மேலைக்குரற்கம்மல் வெங்களநோய் – மூலசுரம்
கவ்வியங்கத் தேறு கனதா வரவிடமுஞ்
செவ்வியங் கொள்ளவிடுந் தேர்.

Chemical constituents:

Volatile alkaloid (piperine) 5 to 9 pc, Piperidine 5 pc, balsamic essential oil, fat.

Pharmacological activity:

Studies revealed that black pepper possesses antioxidant, **anti-inflammatory and antinociceptive property.**

18.Chitramutti ver: (Pavoniazeylanica Linn)

Family name : Malvaceae

Useful parts : Root

Organoleptic Character:

Taste : thuvarpu

Potency : thatpam

Division: inippu

Actions :emolient

Chitramuttiis indicated for

அத்தி சுரமுதல் அளந்தசுரம் பித்தமும் போம்
மெத்த விழிக்கொளியாம் வீறுதயி – லத்திற்போம்
நற்றா மரைத்திருவு நாடு மெழிற்றிருவே
சிற்றாமுட்டித்துரைச் செப்பு.

Chemical constituents:

Alkaloids, glucosides etc.

Pharmacological activity:

To study the **anti-inflammatory and analgesic activities** of methanolic extract of *Pavoniazeylanica* in rats and mice. It reveals, good anti-inflammatory and analgesic effects in animal model.

19. *Iruveliver: (Vettiveriazizonoides)*

Family name : Poaceae

Useful parts : root

Organoleptic Character:

Taste : inippu

Potency : thatpam

Division: inippu

Actions :tonic, stimulant, antispasmodic, diaphoretic, diuretic, emmenagogue, febrifuge

Kuruveris indicated for

பித்தவி தாகம் சகிகா மிலங்கறைப் பித்தமனற்
றத்திடு குட்டஞ் சிரநோய் களமடி தாதுநட்ட
மத்திம நற்புண் டனப்புண்வன் மூர்ச்சை வரிவிழிநோய்
வித்திர மேகத்தின் கட்டியும் போம் வெட்டி வேரினுக்கே.

–அகத்தியர் குணவாகடம்

Chemical constituents:

Sesquiterpenes, essential oils

20. Kodiveli :*(Plumbago zeylanicaLinn*)

Family name : Plumbaginaceae

Useful parts : Root

Organoleptic Character:

Taste :kaarpu, viruviruppu

Potency : veppam

Division: kaarpu

Actions :anti-periodic, diaphoretic

Kodiveliis indicated for

கட்டிவிர ணங்கிரந்தி கால்கள் அரையாப்புக்
கட்டிச்சூ லைவீக்கங் காழ்மூலம் – முட்டிரத்தக்
கட்டுநீ ரேற்றங் கனத்த பெருவயிறும்
அட்டுங் கொடிவேலி யாம்.

கட்டியேசூலைக்கட்டு கருதிடு குறிப்புண் கிரந்தி
ஒட்டுமே கரணத்தோடு முறுமரை யாப்புமன்றி
விட்டிடா நெறிச்சுரம்பின் வியன்விட மச்சு ரந்தான்
பொட்டெனப் பறந்து போகும்புகழ்கொடி வேலி கண்டால்.

–(ஏடு)

Chemical constituents:

Plumbagin, isoshinanolone, plumbagic acid, betasito sterol, 4-hydroxybenzaldehyde, trans-cinaamic acid, vanilic acid, 2,5-dimethyl-7-hydroxychromone, indole-3-carboaldehyde

Pharmacological activity:

The root of *Plumbago zeylanica* extracted with methanol was used for determining the **anti-inflammatory effects**. The methanolic extract at 300/500 mg/kg produced 31.03 and 60.3% inhibition of acute inflammation.

The callus extract (PCE) and root extract (PRE) were evaluated for peripheral and **central analgesic activity** by glacial acetic acid induced writhing and tail immersion model respectively. PRE-significantly ($P<0.01$) reduced the writhing count whereas PCE alters the pain threshold significantly.

21. Nilapanaikizhangu: (*CurculigoorchioidesGaerth*)

Family name : Amaryllidaceae

Useful parts : root

Organoleptic Character:

Taste : inippu

Potency : thatpam

Division: inippu

Actions :tonic, diuretic, astringent, carminative, emolient

Nilapanaikizhanguis indicated for

மேக வனல்தணியும் வெண்குட்டந் தான்விலகும்
போக மிகமுறும் பொர்கொடியே – போகாத
சூலைமே கங்களோடு துன்னுகரும்புள்ளியும்போஞ்
சால நிலப்பனைக்குத் தான்.

– அகத்தியர் குணவாகடம்

Chemical constituents:

Orcinol glucosides,3-hydroxy-5-methylphenol, beta D- glucopyranoside, daucosterol etc.

22. Seenthilver: (TinosporacordifoliaThunb)

Family name : Menispermaceae

Useful parts : Root

Organoleptic Character:

Taste : kaippu

Potency : veppam

Division: kaarpu

Actions :alterative, antiperiodic, aphrodisiac, demulcent, stimulant, stomachic, tonic, mild diuretic

Seenthilis indicated for

அமுதவல் லிக்கொடி யக்கார முண்டிடத்
திமிருறு மேகநோய்த் தீயெலா மாறுமே

– தேரன் வெண்பா

Chemical constituents:

Alkaloids, diterpenoid lactones, glycosides, steroids, phenolics, aliphatic compound, polysaccharides.

Pharmacological activity:

The dried stem of *T.cordifolia* produced significant **anti-inflammatory effect** in both acute and sub-acute models of inflammation. *T.cordifolia*has been found to be more effective than acetylsalicylic acid in acute inflammation

23. Vilvamver :(Aegle marmelos Linn)

Family name : Rutaceae

Useful parts : root

Organoleptic Character:

Taste : inippu

Potency : thatpam

Division: kaarpu

Actions : aphrodisiac, astringent, laxative, stomachic

Vilvamis indicated for

சொல்வொணா பித்தந் தொடர்சோபை – வலகப
தாகசுரம் நீரேற்றஞ் சந்நியொடு மெய்வலியும்
வேகமொடு நீங்குமே.
அக்கினி மந்தம் அரோசிந்தி சாரம்விக்கல்
நிற்கரிய பித்தசுரம் நீள்வாந்தி – கட்க்னோய்
ஆதிய நோய் ஏகும் அழகோடு புஷ்டியுண்டாம்
கோதில்வில்வ வேரதனைக் கொள்.

Chemical constituents:

Skimmianine, lupeol, citrol, eugenol, tannin, citral, aegelin etc

INGREDIENTS OF *RAAJAMAARTHANDHA ILAGAM:*

INTERNAL MEDICINE

ELAM- Elatteriacardamomum ***KIRAMBU- Syzygiumaromaticum***

PERUNGAAYAM- Ferula asafoetida ***THIPPLI- Piper longum***

THIPPILI MOOLAM- Piper longum

JATHIKKAI- Myristicafragrans

MUTHAKASU- CyperusrotandusSEERAGAM- Cuminumcyminum

***KUGAINEERU- Marantaaruntiana*IRUVELI VER- Veteveriazizonoids**

MILAGU- Piper nigrum*CHUKKU- Zingiberofficinale*

SIRUTHEKKU- ClerodendrumserratumNILAPANAI KIZHANGU- Curculigoorchioides

SANGAM VER- ClerodendruminermeVILVA VER- Aegle marmelos

SEENDHIL VER- TinosporacardifoliaSIRUNAAGAPPU- Mesuanagasserium

KANDANKATHIRI VER- Solanum surattenseKODIVELI VER- Plumbago zeylanica

CHITTRAMUTTI VER- PavoniazeylanicaSEVIYAM- Piper nigrum

KARUNJEERAGAM-Nigella sativa

RAAJAMAARTHANDHA ILAGAM

INGREDIENTS OF SADAMAANJIL THYLAM EXTERNAL MEDICINE

NALLENNAI- Sesamum IndicumOOMATHAI- Datura metal

KODIVELI VERPATTAI- OMAM-
Plumbago zeylanicaTrachyspermumRoxburgianu

CAMPHOUR –*Cinnamomumcamphora*

VAATHAKAJAKESARI THYLAM

TOXICITYSTUDIES OF RAAJAMAARTHANDHA ILAGAM

The following in vivo toxicity studies were carried out on ***RAAJAMAARTHANDHA ILAGAM (RMI)*** by using Organization for Economic Co-operation and Development (OECD) guidelines.

1. **The Acute Oral Toxicity study (OECD guidelines -423)**
2. **Repeated Dose 28 days oral toxicity study (OECD guidelines -407)**

The toxicity study were 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/24042018/08)

DESCRIPTION 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, female in sex used in Acute oral toxicity study. Healthy adult animals of Wistar Albino Rats, both sexes 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 pallet 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

RAAJAMAARTHANDHA ILAGAM (RMI)

ROUTE OF ADMINISTRATION

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

ACUTE ORAL TOXICITY EXPERIMENTAL PROCEDURE

All animals were fasted prior to dosing. Following the period of fasting, the animals were weighted and then test substances was administrated. The control group received distilled water .After the substance has been administrated ,food was withheld for further 3-4 hours .The principle of laboratory animal care was followed. Observations were made and recorded systematically and continuously observed as per the guidelines after substance administration. An oral dose (5,50,300,2000 mg/kg body weight) were administrated step by step according to the guidelines.

The general behaviour of the rats were continuously monitored for ½ hour,1 hour,2 hour and 4 hour after dosing, periodically during the first 24 hours with special attention given during the first 4 hours and then daily thereafter, for a total of 14 days. Change in the normal psychomotor activity and external morphology and their body weights were monitored periodically before and the time at which signs of toxicity or mortality were recorded. At the end of the experiment, all animals were sacrificed and subjected to necropsy.

EXPERIMENTAL ANIMALS

Species and strain	: Wistar Albino Rats
Sex	: Female
Age/Weight	: 8-12 weeks,150-200 gm
Test guidelines	: OECD guidelines -423
Groups /Treatment	: Grouped by randomization
Drug the exposure to the RMI	: Single dose –one day
Study duration	: 14 days observation
Number of animals	: 3 Females/ Group (6 Females)

NUMBER OF ANIMALS AND DOSE LEVELS

Animals were divided into 2 groups, each group containing 3 female rats. One group is control group and another one group is test group, it was treated with test drug "RAAJAMAARTHANDHA ILAGAM (RMI)" at different doses 5,50,300,2000 mg/kg bodyweight respectively.

TABLE 1: GROUPING OF ANIMALS IN ACUTE ORAL TOXICITY STUDY

GROUP	NO OF RATS
Group I: Control -Vehicle	3Female
GroupII: Test drug RMI (2000 mg/kg b.wt)	3Female

Total :6 (6Female)

REPEATED 28 DAYS ORAL TOXICITY STUDY

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	: 5 (Female/ Male) / Group
	40 animals
Control group	: Vehicle (Water)
Route of administration	: Oral

JUSTIFICATION OF DOSE SELECTION

As started results of acute toxicity study in Wistar albino rats indicated that RMI was not toxic up to the dose of 2000 mg/kg body weight LD 50. The oral route was selected for use, because of oral route is considered to be a proposed therapeutic route. The low dose was calculated from the therapeutic dose (6 g) and body surface area of the rat (0.018).

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 2: GROUPING OF ANIMALS IN 28 DAYS ORAL TOXICITY STUDY

GROUPS	**NO. OF RATS**
Group I: Control - Vehicle (***Water***)	10(5M+ 5F)
GroupII:Test drug *(RMI)* - Low dose 540 mg/kg b.wt	10(5M + 5F)
GroupIII:Test drug *(RMI)* - Mid dose 1080 mg/kg b.wt	10(5M + 5F)
GroupIV:Test drug *(RMI)*- High dose 2160 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.

1. **Body weight changes:**

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

2. **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 investigations.

- 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, uterus/testis) 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, Haematology and biochemical parameters were subjected to one way ANOVA followed by Dunnet ‘t’ test using computer software programed graph Pad Instat-3.

ACUTE ORAL TOXICITY STUDY

In Acute toxicity study carried out as per OECD guidelines, there were no treatment related death or signs of toxicity developed in Wistar albino rats at dosage of 10 times of therapeutic dose throughout the study period.

Further, no gross pathological changes have been seen in the internal organs of both control and treated groups.

Table 3: Behavioral Signs of Acute Toxicity Study of RAAJAMAARTHANDHA ILAGAM (RMI)

No	**Dose mg/kg**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
1	Control	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-
3	2000	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-

1. Alertness 2. Aggressiveness 3. Pilo erection 4. Grooming 5. Gripping 6. Touch Response

7. Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia

12. Muscle relaxant 13. Hypnosis 14. Analgesia 15. Lacrimation 16. Exophthalmos

17. Diarrhoea 18. Writhing 19. Respiration 20. Mortality

+ Presence of Activity

- Absence of Activity

There was no mortality observed after dosing of RAAJAMAARTHANDHA ILAGAM (RMI) up to 2000mg/kg body weight during the study period of 14 days. This indicates that the LD50 of RMI is more than 2000mg/kg b.wt.

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

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

CROSS PATHOLOGY OBSERVATIONS OF CONTROL AND RMI TREATED EXPERIMENTAL ANIMALS

Table :4

ORGANS	**OBSERVATIONS**
Brain	No abnormal lesion observed
Eyes	No abnormal lesion observed
Lymph nodes	No abnormal lesion observed
Trachea	No abnormal lesion observed
Oesophagus	No abnormal lesion observed
Lungs	No abnormal lesion observed
Heart	No abnormal lesion observed
Liver	No abnormal lesion observed
Spleen	No abnormal lesion observed
Stomach	No abnormal lesion observed
Duodenum	No abnormal lesion observed
Pancreas	No abnormal lesion observed
Small and large intestine	No abnormal lesion observed
Kidney	No abnormal lesion observed
Sex organs	No abnormal lesion observed

Table : 6

OBSERVATIONS		SIGNS	OBSERVATIONS	SIGNS
Lethality		X	Stereotypies (chewing)	X
Convulsion		X	Stereotypies (head movement)	X
Tremor		X	Head twitches	X
Straub tail		X	Scratching	X
Sedation	#1	X	Respiration	X
	#2	X	Aggressiveness	X
	#3	X	Fear	X
Excitation	#1	X	Reactivity to touch	X
	#2	X	Muscle tone	X
	#3	X	Loss of righting reflex	X
Abnormal gait (rolling)		X	Ptosis	X
Abnormal gait(tip toe)		X	Exophthalmos	X
Jumps		X	Loss of grasping	X
Motor coordination		X	Akinesia	X
Loss of balance		X	Catalepsy	X
Fore paw treading		X	Loss of traction	X
Writhes		X	Loss of corneal reflex	X
Piloerection		X	Analgesia	X
Salivation		X	Defaecation	X
Lacrimation		X	Others	X

X – No signs/ present; values are expressed as Mean ± SD.

CROSS PATHOLOGY OBSERVATIONS OF CONTROL AND RMI TREATED EXPERIMENTAL ANIMALS.

Table: 7

ORGANS	**OBSERVATIONS**
Brain	No abnormal lesion observed
Eyes	No abnormal lesion observed
Lymph nodes	No abnormal lesion observed
Trachea	No abnormal lesion observed
Oesophagus	No abnormal lesion observed
Lungs	No abnormal lesion observed
Heart	No abnormal lesion observed
Liver	No abnormal lesion observed
Spleen	No abnormal lesion observed
Stomach	No abnormal lesion observed
Duodenum	No abnormal lesion observed
Pancreas	No abnormal lesion observed
Small and large intestine	No abnormal lesion observed
Kidney	No abnormal lesion observed
Sex organs	No abnormal lesion observed

28 DAYS REPEATED ORAL TOXICITY STUDY

FOOD (G/DAY) INTAKE OF ALBINO RATS EXPOSED TO RMI

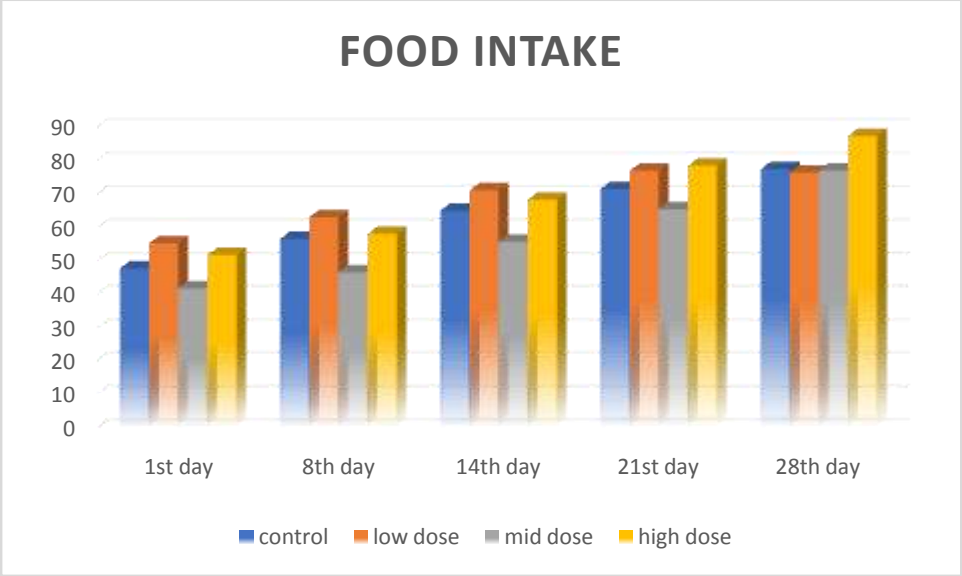
Food consumption of the animals significant difference in Food intake the test group animals were observed when compared with control group during the study period. but they are within physiological limit.

TABLE 8 : Food (g/day) intake of albino rats exposed to RMI

Dose (mg/kg/ day)	1st day	7th day	14th day	21st day	28th day
Control	47.5±3.53	56.83±7.17	64.78±5.64	71.28±3.24	77.21±3.94
Low dose	55±7.07	62.83±5.16	70.85±3.23	76.71±6.23	76.64±7.43
Mid dose	41.5±2.12	46.25±4.30**	55.42 ±4.12**	65.21±4.83*	76.78±6.12
High dose	51.5±12.02	57.08±9.69	68.09 ±9.98	78.21 ±8.94*	87.21 ±8.55**

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 :2



WATER (ml/day) INTAKE OF WISTAR ALBINO RATS EXPOSED TO VAYU KEELAGA ILAKAM (VK ILAKAM)

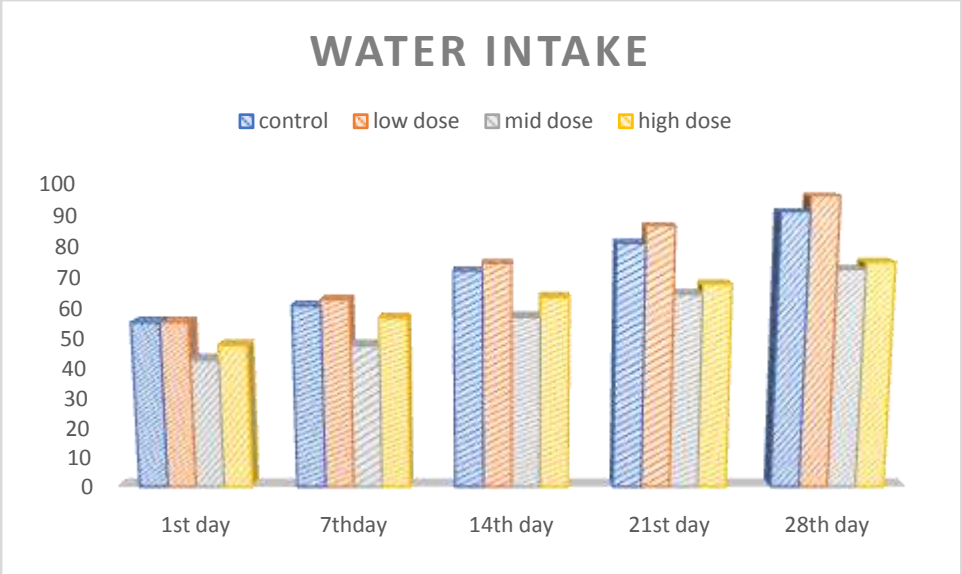
Water consumption the difference in Water intake of control and test group of animals observed during the study period. (Table 8), There was significant difference occurs in the group low and mid at 28 days compared with control group

Table 9 : Water (ml/day) intake of albino rats exposed to RMI

Dose (mg/kg/day)	1st day	7th day	14th day	21st day	28th day
Control	55±7.07	60.42±6.23	71.71±6.01	80.71±6.40	90.71±6.40
Low dose	55±7.07	62.35±6.68	74.14±6.26	86.16±6.42	95.71±7.4
Mid dose	42.5±3.53**	47.28 ±2.23**	56.71 ±3.47**	64.23 ±3.56**	72.21 ±4.1**
High dose	47.5±3.53*	56.28±5.50	63.21±5.43**	67.43±5.23**	74.53±4.48**

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



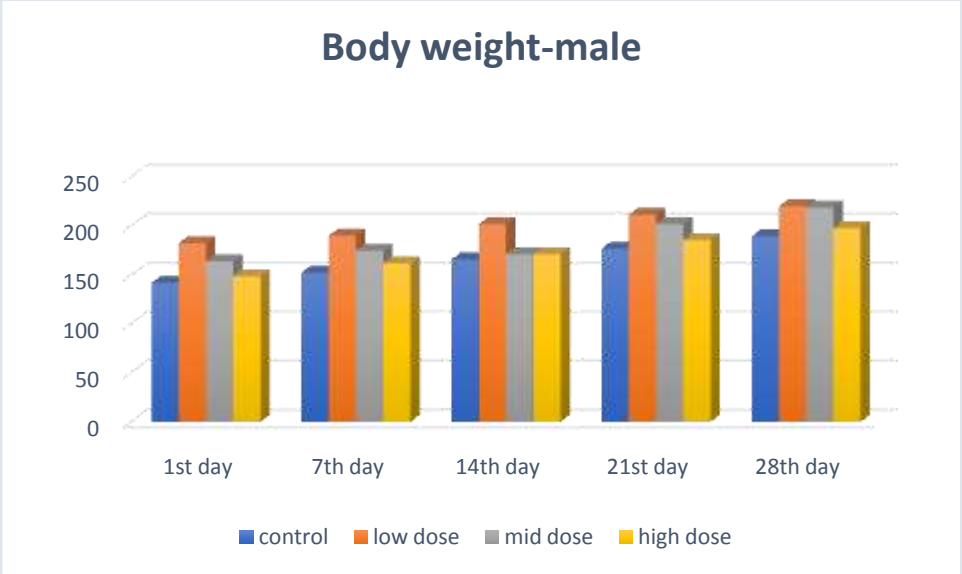
BODY WEIGHT (g) CHANGES OF ALBINO RATS (MALE) EXPOSED TO RMI

Table : 10

Dose (mg/kg/day)	1st day	7th day	14th day	21st day	28th day
Control	141.6 ± 7.23	152.2 ± 10.40	165.6 ± 10.54	176.8 ± 15.05	189.27 ±16.7
Low dose	182.2 ± 6.30	190 ± 6.24	201.8 ±8.75	211.4 ± 8.75	220± 9.61
Mid dose	163.6 ± 9.44**	174.6± 9.76**	171.2 ±3.76**	201.8 ± 15.69*	218.8 ±17.5**
High dose	148.4 ±6.26**	161.6± 4.56**	171.2 ±3.76**	185.4±2.19**	197.6± 4.92**

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



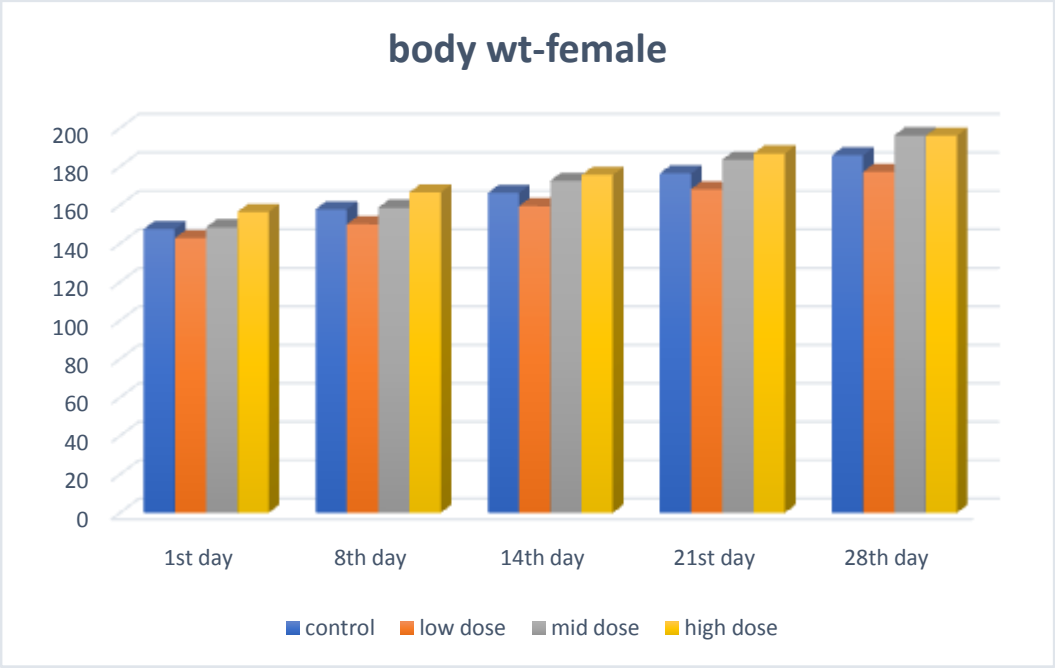
BODY WEIGHT (g) CHANGES OF ALBINO RATS (FEMALE) EXPOSED TO RMI

Table : 11

Dose (mg/kg/day)	1st day	7th day	14th day	21st day	28th day
Control	147.4± 8.41	157.8± 8.04	166.2± 8.70	176.4 ±8.26	185.8 ± 8.16
Low dose	142.8 ± 8.40	150± 7.68	159.4 ± 6.87	168.2 ± 4.32	177.2± 5.01
Mid dose	148.4 ±7.23	158.6±7.237	172.6 ± 5.12	183.6± 4.75	196.2± 1.78*
High dose	156.4 ±4.97	166.6 ± 5.89	175.6± 4.61	186.8 ±5.76*	196 ±6.04*

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 : 5



EFFECT OF RMI ON HAEMATOLOGICAL PARAMETERS

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

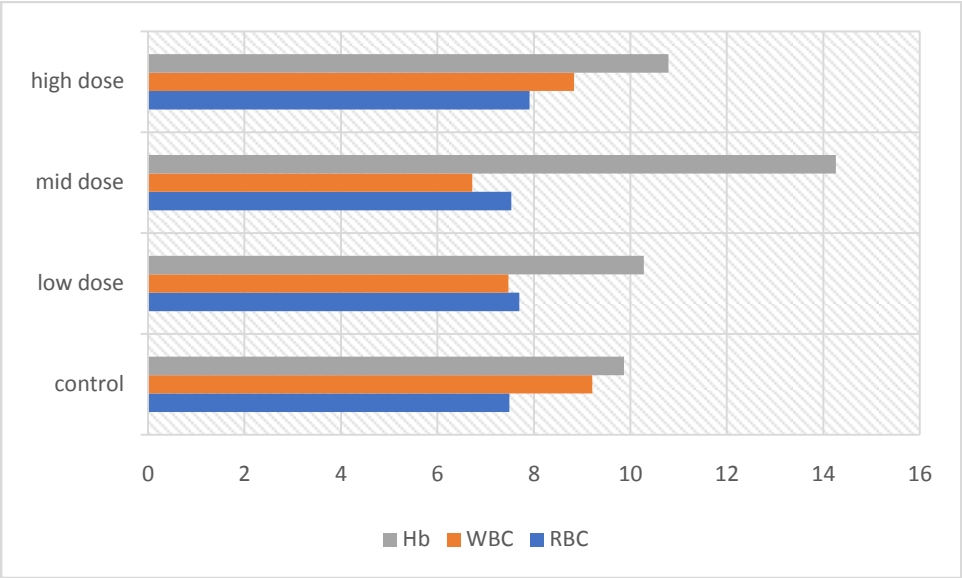
Table: 12

Parameter	control	LD	MD	HD
RBC ($x10^6$µl)	7.49±0.1640	77.08± 0.6749	7.53 ±0.1724	7.91 ± 0.6040
WBC($x10^3$µl)	9.21 ± 1.450	7.47 ± 1.8439*	6.72 ± 0.8942**	8.83± 0.7694
Platelets ($x10^3$µl)	619±4.23	511.6± 29.117	619.1± 4.235	714.1± 72.064
HGB(g/dl)	9.87± 0.4517	10.28 ±0.2959	14.26± 1.0660**	10.79±0.7408
Neutrophil (10^3mm^3)	4.33± 1.3342	2.87 ± 0.7798**	2.23 ± 0.7335**	2.23± 0.7335**
Lymphocyte (%)	86.95± 4.0486	86.98 ± 4.2282	88.22 ± 2.4453	82.29 ± 2.9500*
Monocyte (%)	1.79 ± 0.6331	1.91 ± 0.9873	1.78±0.8541	2.12± 0.5249
Eosinophil (%)	1.79± 0.6949	1.71 ± 0.6171	0.81± 0.7258*	1.89 ±0.8949
Basophil (%)	1.02 ± 0.4142	0.6 ± 0.4898	0.5 ± 0.5	0.6 ± 0.4898
MCH (pg)	19.6 ± 2.8818	17.58 ± 1.2278	19.98± 2.868	17.89 ± 0.6822
MCV (fl)	63.89 ± 2.3321	66.3± 0.2366	58.95 ±2.5753	56.07 ± 1.1619

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.

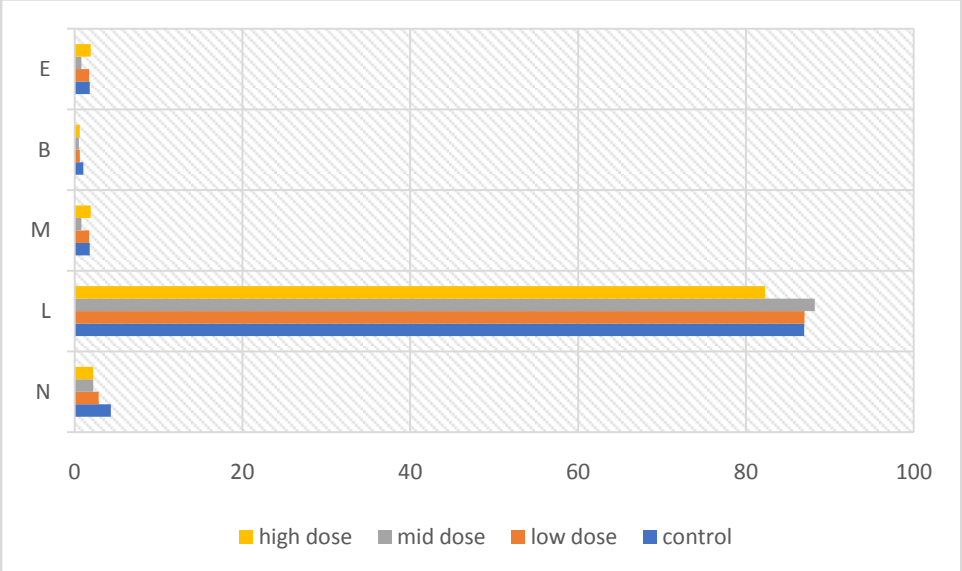
EFFECT OF RMI ON RBC, WBC & HGB

Fig : 6



EFFECT OF RMI ON NEUTROPHIL, LYMPHOCYTE, MONOCYTE, EOSINOPHIL AND BASOPHIL

Fig :7



EFFECT OF RMI ON BIOCHEMICAL PARAMETERS

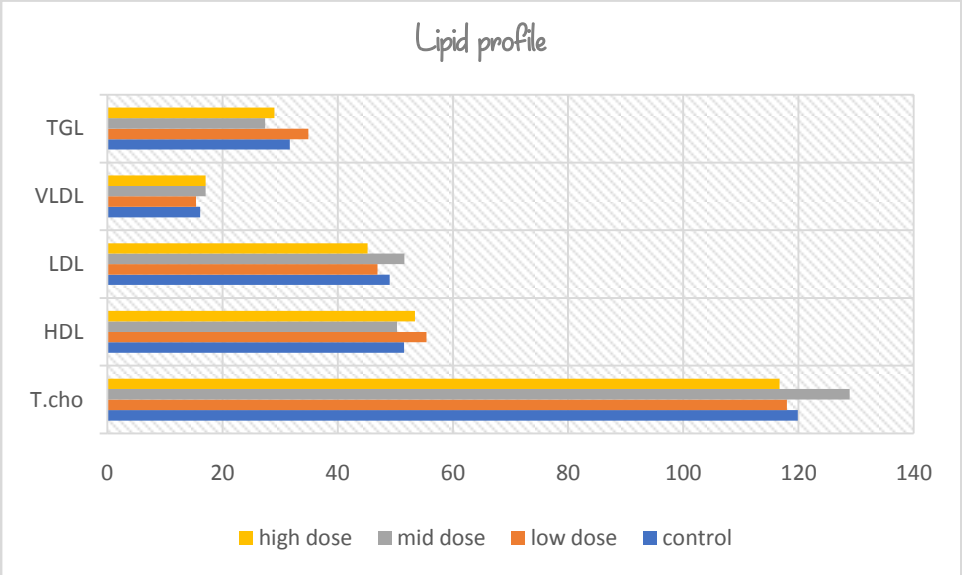
Biochemical investigations were conducted at the end of the study and the results were recorded. In test groups there was significant changes present in biochemical parameters, when compared with the control group. At the values were normal biological limits.

Table: 13

Dose (mg/kg)	control	LD	MD	HD
Total cholesterol (mg/dl)	119.99 ± 4.6631	118± 2.0537	128.91 ± 7.86**	116.74 ± 4.8050
HDL (mg/dl)	51.5± 2.0615	55.4 ± 2.4449*	50.315± 5.8660**	53.4 ± 2.01071
LDL (mg/dl)	49± 4	46.9 ±4.3	51.6 ± 7.2138	45.2 ± 3.6
VLDL (mg/dl)	16.11 ± 0.7673	15.45 ± 2.4536	17.07 ± 1.2961	17.06± 1.5252
Triglycerides (mg/dl)	31.7± 3.3166	34.9± 1.920	27.4± 5.2763**	29 ± 2.9342**

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 RMI ON RENAL PARAMETERS

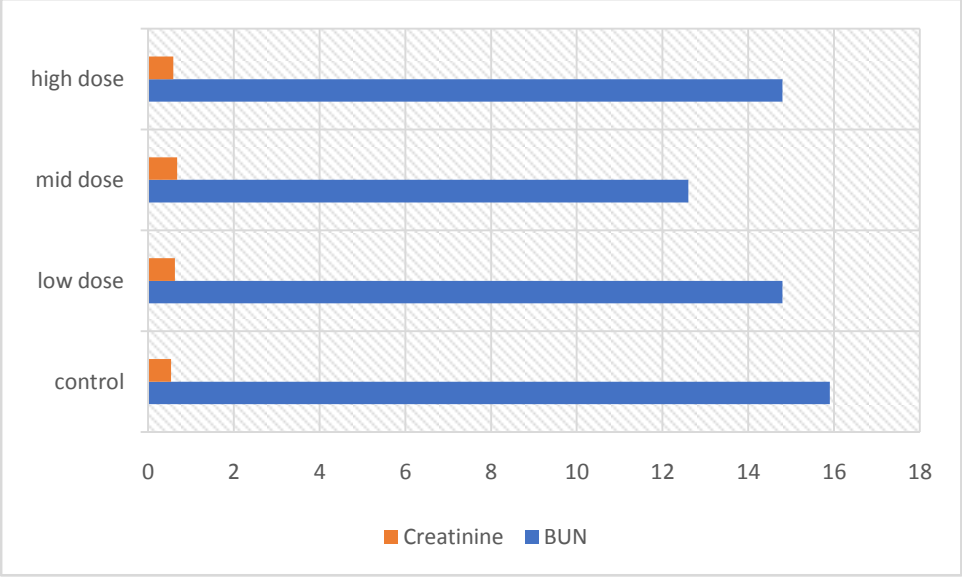
The results of the renal functions test conducted at the end of study, test groups revealed significant changes in levels of renal parameters, when compared with control group, and post retrieval group Renal function parameters towards normal, when compared with control group.

Table: 14

DOSE (mg/kg)	control	LD	MD	HD
BUN (mg/dl)	15.9± 1.5779	14.8± 1.536	12.6 ± 1.3564**	14.8 ± 1.8330
Creatinine (mg/dl)	0.54 ±0.2374	0.63 ± 0.3634	0.68 ± 0.0748	0.59 ± 0.13

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



EFFECT OF RMI ON LIVER PARAMETER

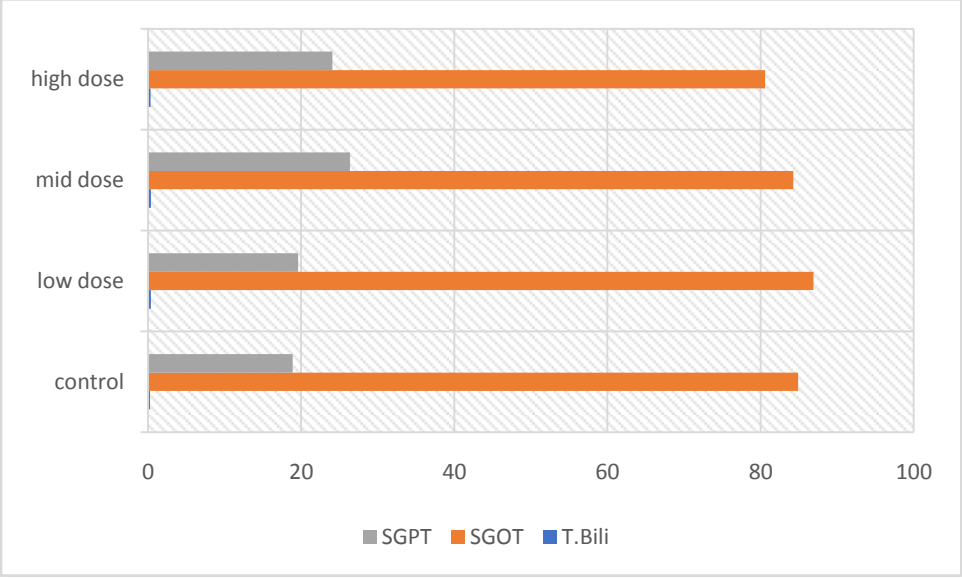
The results of the liver function test conducted at the end of the study, test groups revealed significant changes in levels of liver parameters, when compared with control group, and post retrieval group Liver function parameters towards normal, when compared with control group.

Table : 15

Dose (mg/kg)	Control	LD	MD	HD
Total bilirubin(mg/dl)	0.26± 0.663	0.36± 0.14	0.39± 0.07	0.32± 0.0979
SGOT(U/L)	84.9 ±3.2078	86.9 ±5.1855	84.3 ± 4.7759	80.6± 3.8781**
SGPT(U/L)	18.9 ± 1.2806	19.6± 1.2806	26.4 ± 5.3516**	24.1± 2.4677**

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.

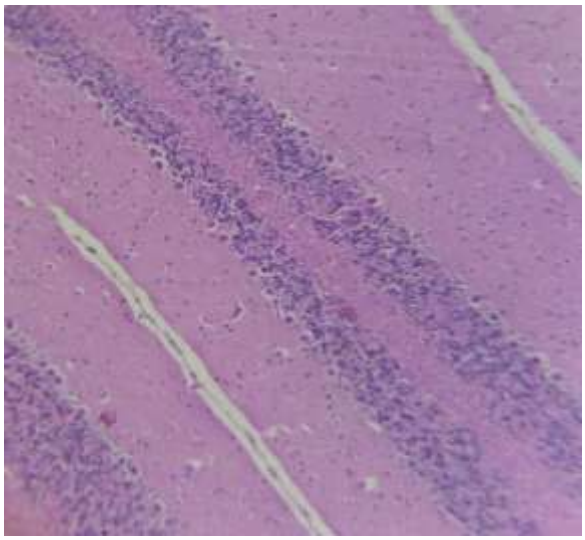
Fig : 10

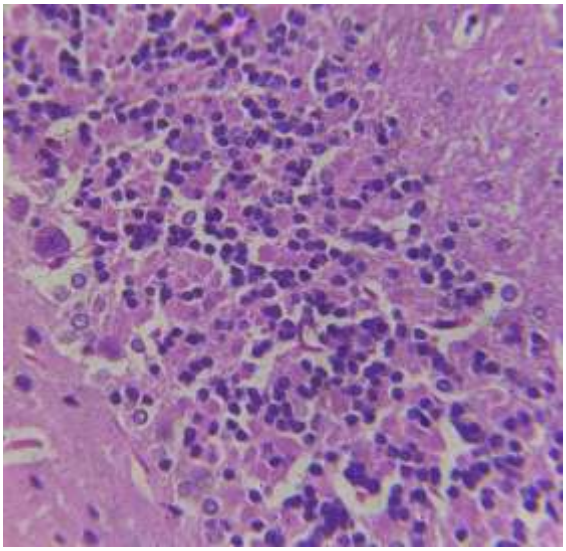


Sample Id: CMH

Histopathology of Brain

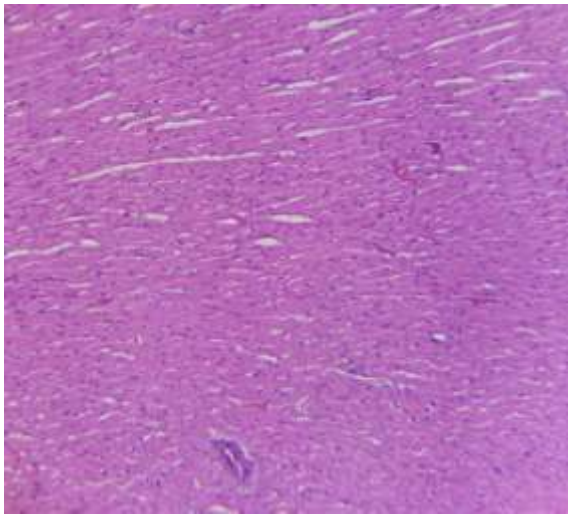
Low Power Magnification 10X **High Power Magnification 40X**

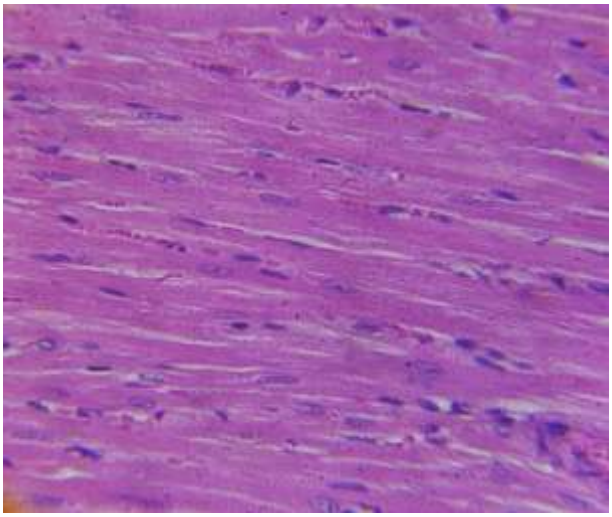




Histopathology of Heart

Low Power Magnification 10X **High Power Magnification 40X**





Histopathology of Lung

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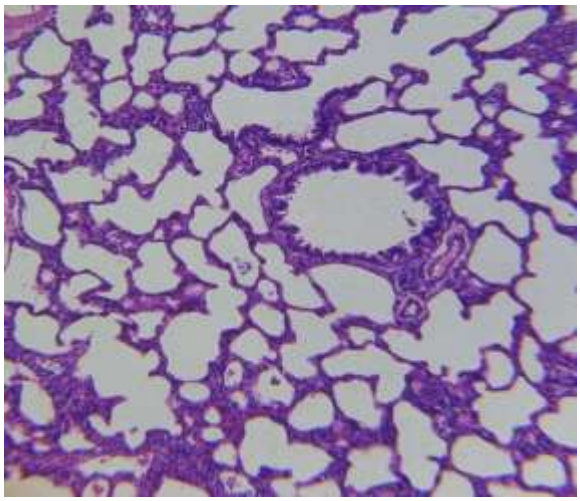

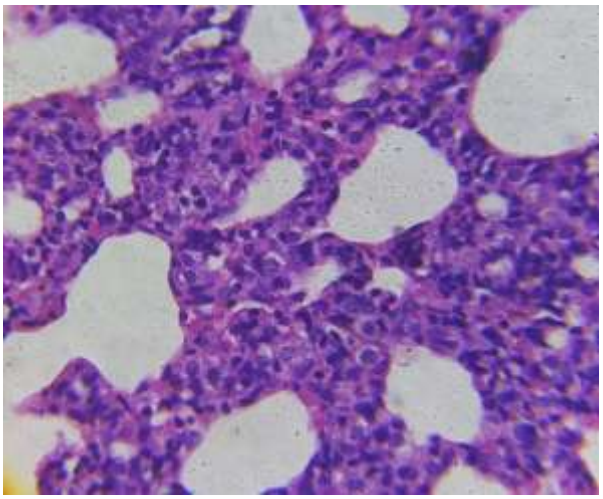

Histopathology of Stomach

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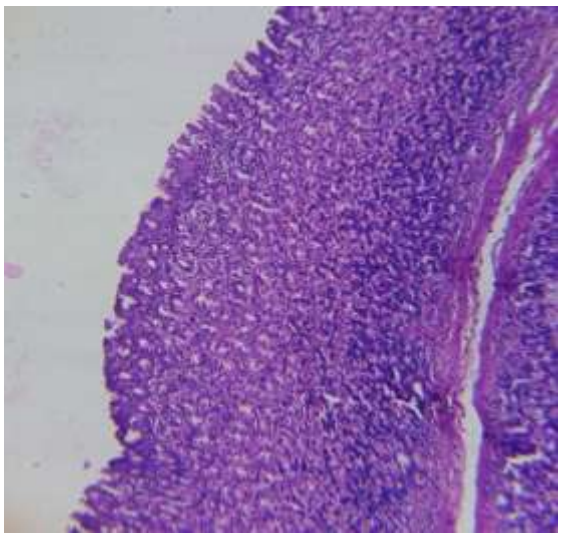
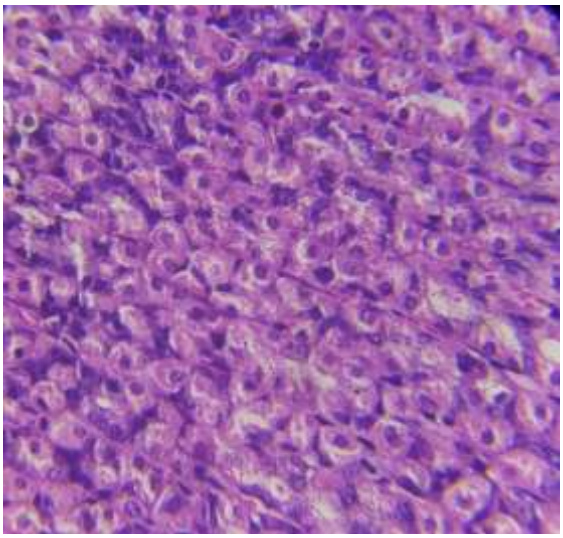
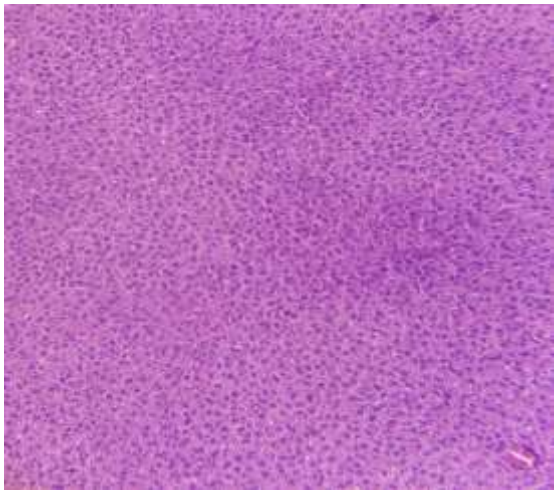


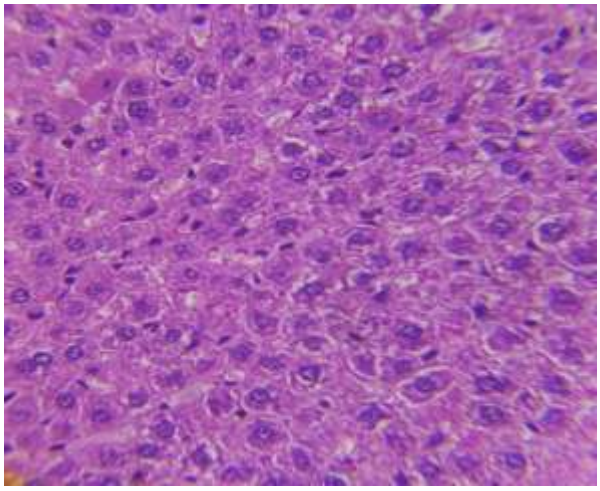


Histopathology of Liver

Low Power Magnification 10X

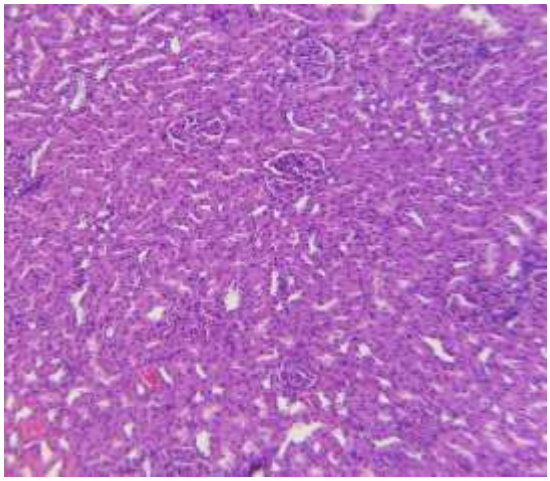


High Power Magnification 40X



Histopathology of Kidney

Low Power Magnification 10X



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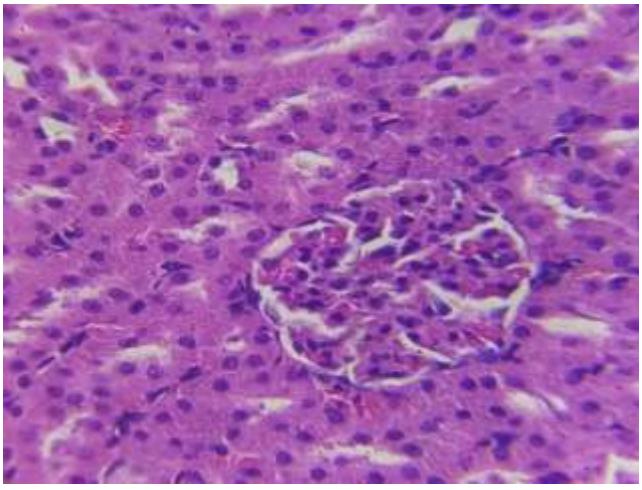
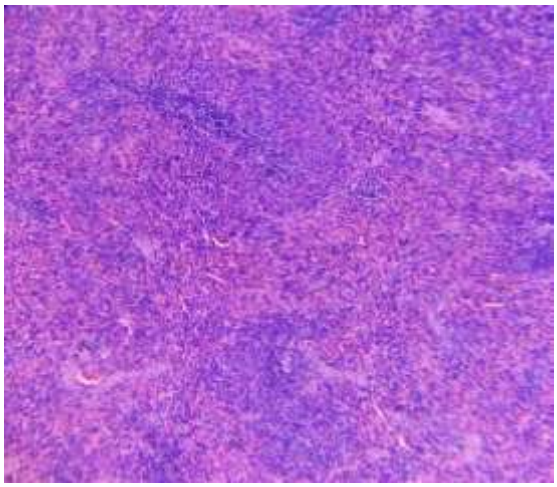
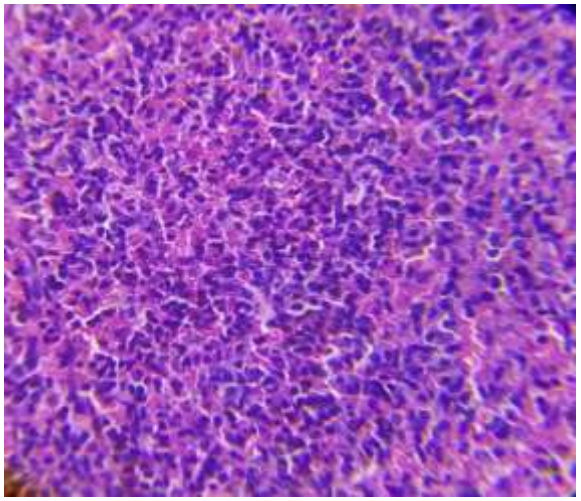


Histopathology of Spleen

Low Power Magnification 10X **High Power Magnification 40X**





Histopathology of Testes

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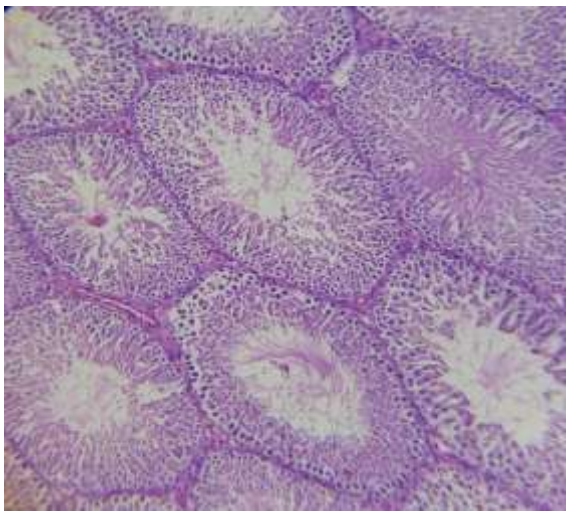
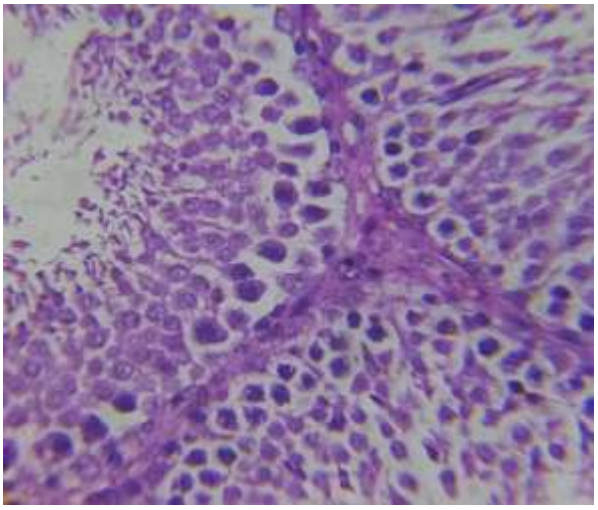




Pathology Report

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

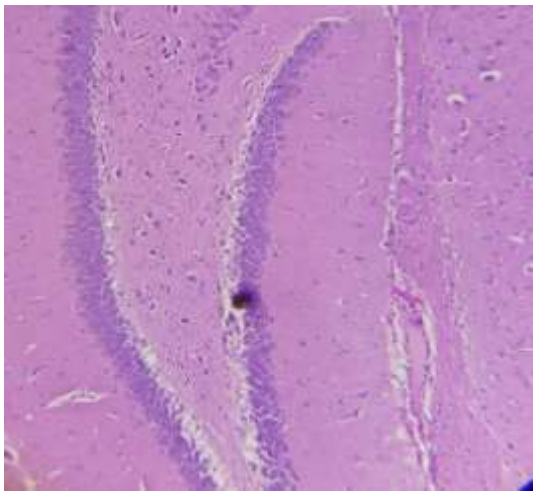
Spleen Regular appearance of red pulp is composed of a three dimensional meshwork of splenic cords and venous sinuses were observed

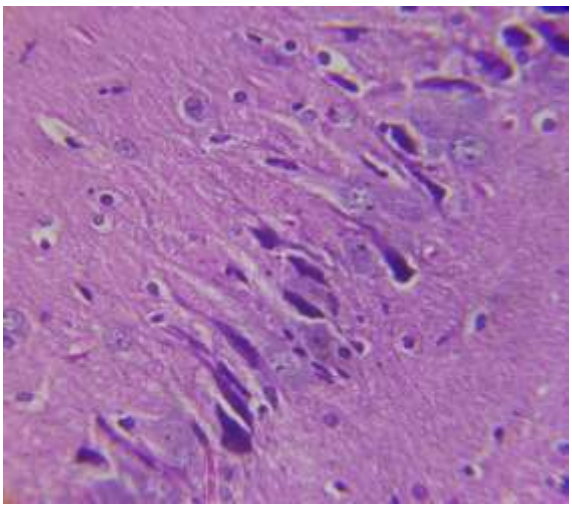
Testes Histo cytology of testicular tissue shows well differentiated germ cells with respect of spermatogonia includes spermatid and sperm were observed

Sample Id: CFH

Histopathology of Brain

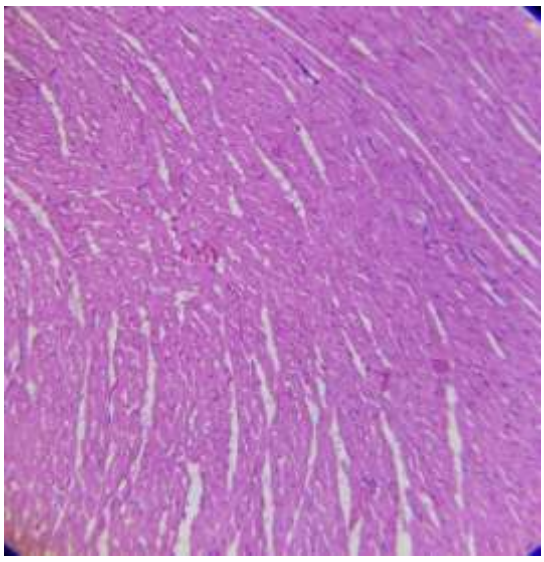
Low Power Magnification 10X **High Power Magnification 40X**

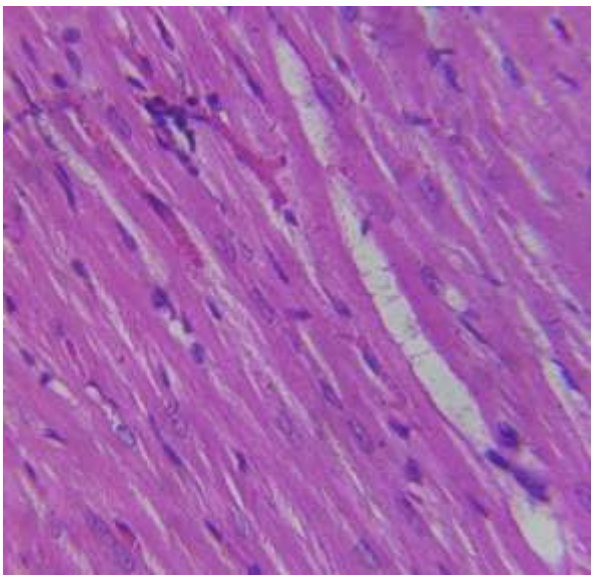




Histopathology of Heart

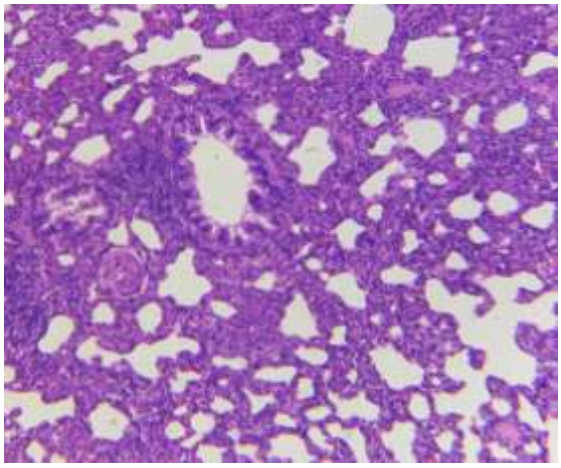
Low Power Magnification 10X **High Power Magnification 40X**

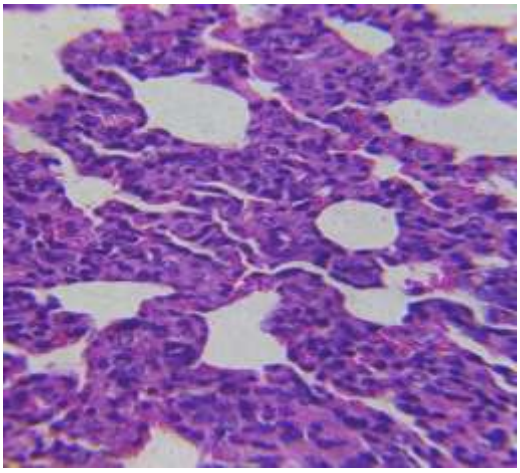




Histopathology of Lung

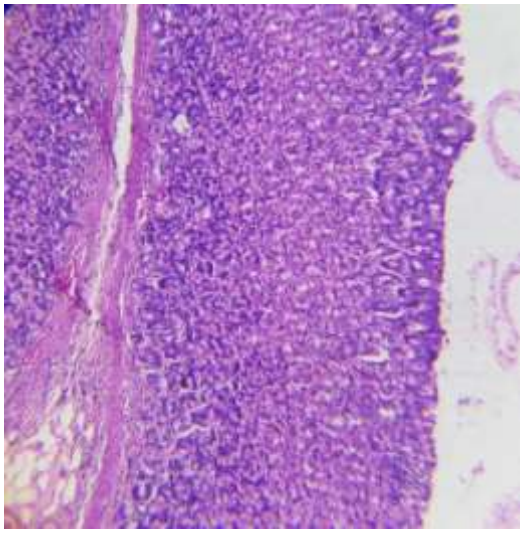
Low Power Magnification 10X **High Power Magnification 40X**

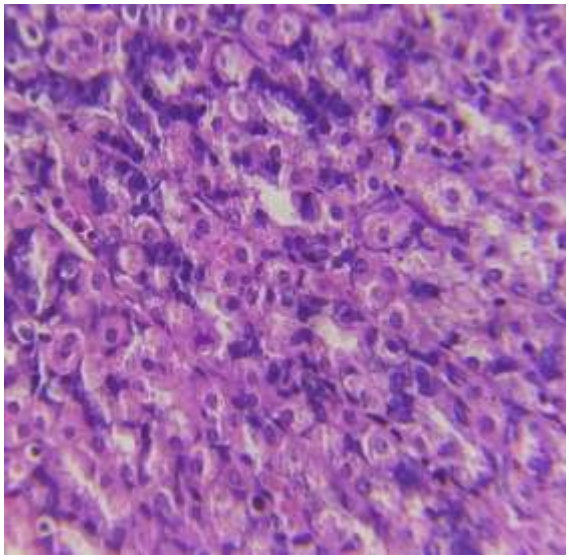




Histopathology of Stomach

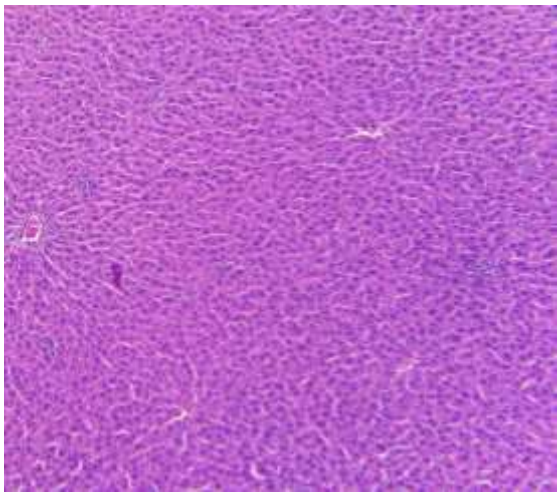
Low Power Magnification 10X **High Power Magnification 40X**



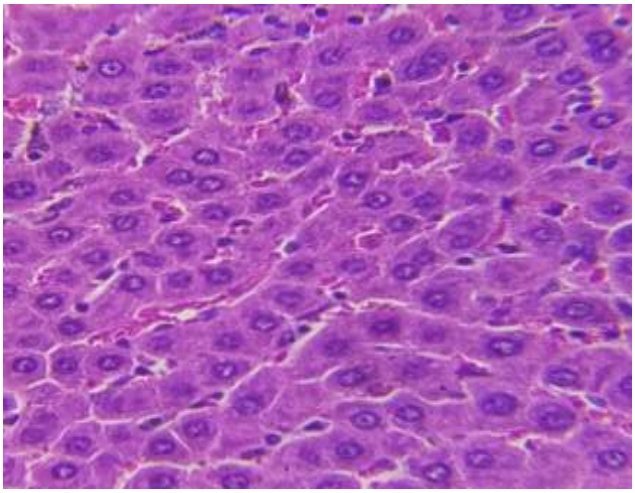


Histopathology of Liver

Low Power Magnification 10X

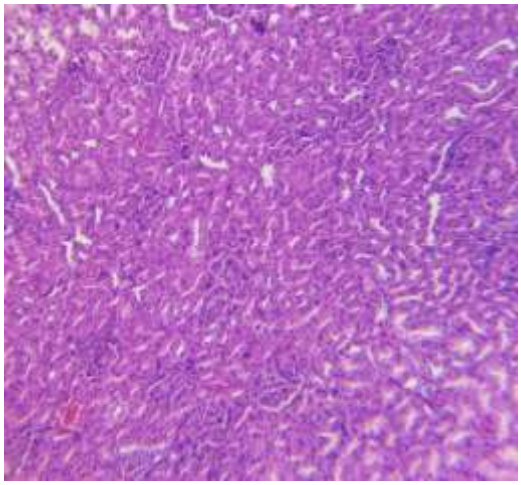


High Power Magnification 40X

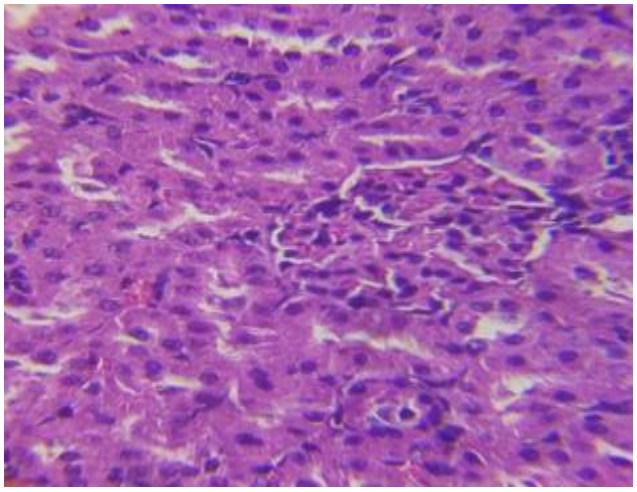


Histopathology of Kidney

Low Power Magnification 10X

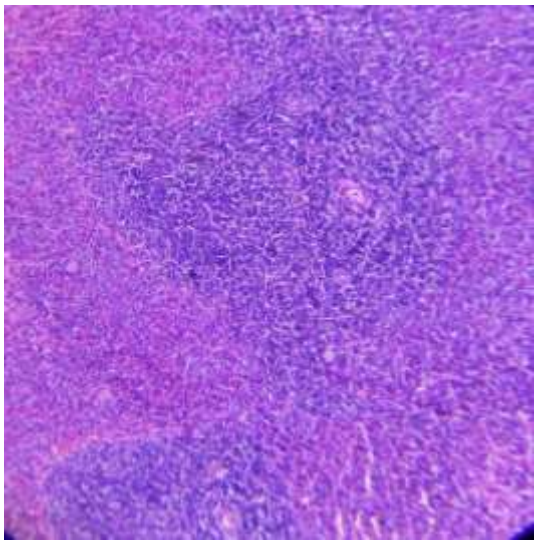


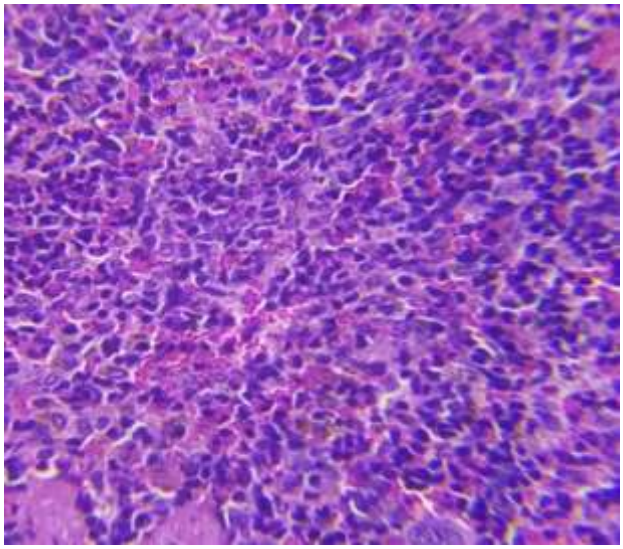
High Power Magnification 40X



Histopathology of Spleen

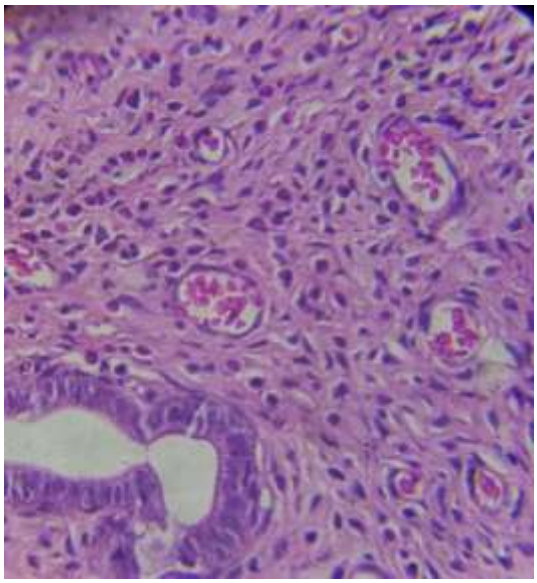
Low Power Magnification 10X **High Power Magnification 40X**

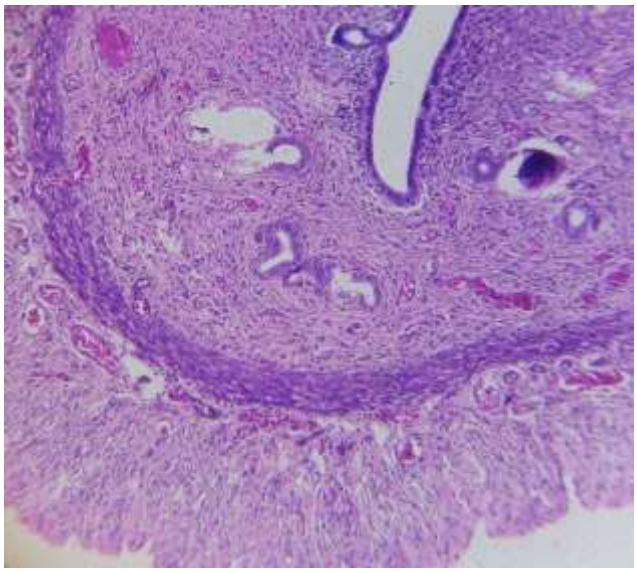




Histopathology of Uterus

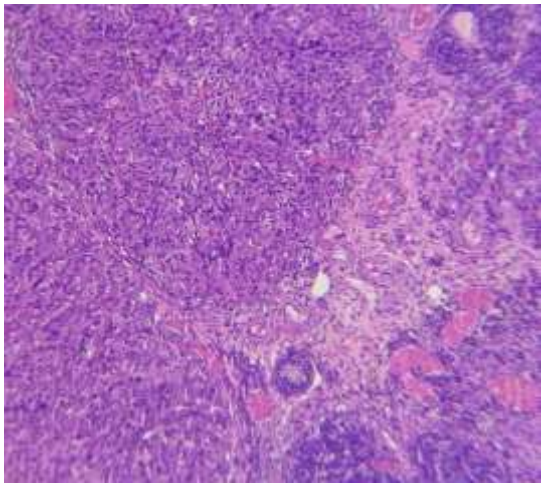
Low Power Magnification 10X **High Power Magnification 40X**

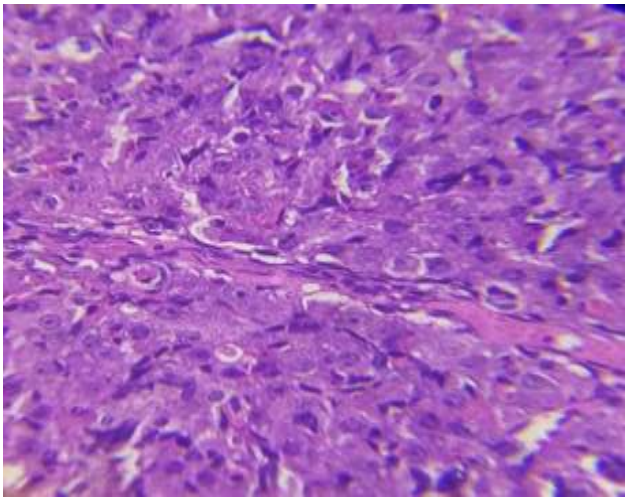




Histopathology of Ovary

Low Power Magnification 10X **High Power Magnification 40X**





Pathology Report

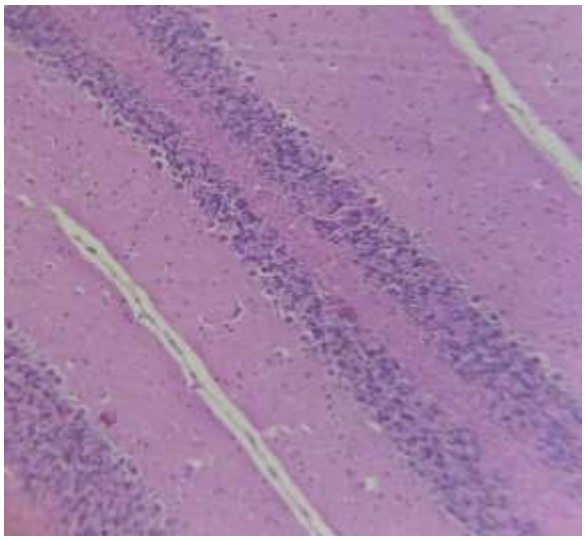
Sample Id : CFH

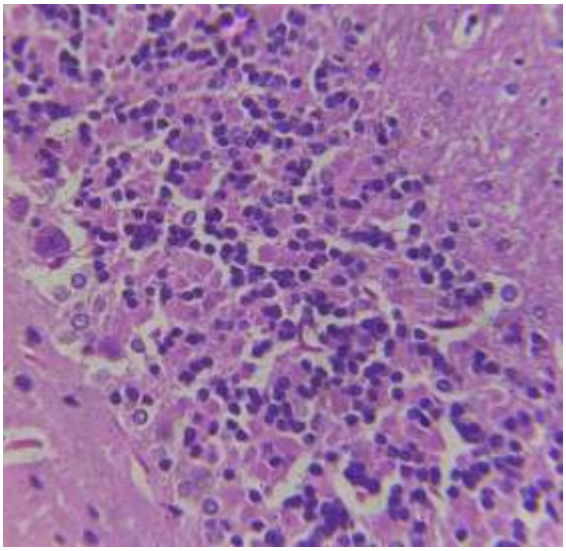
Brain	The CA zones of brain are fields with densely packed Pyramidal cells
Heart	Showing the normal histological structure of myocardium
Lung	Pulmonary alveoli and blood lumen appear normal
Stomach	Gastric epithelium and mucosa appear normal
Liver	Hepatic cords appears normal with radiating morphology
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: HMB

Histopathology of Brain

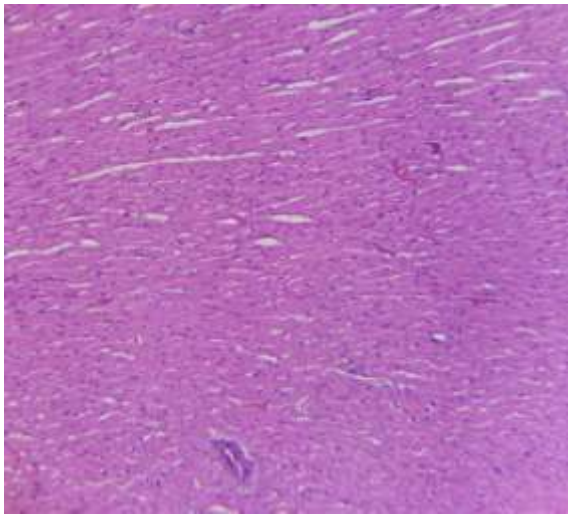
Low Power Magnification 10X **High Power Magnification 40X**

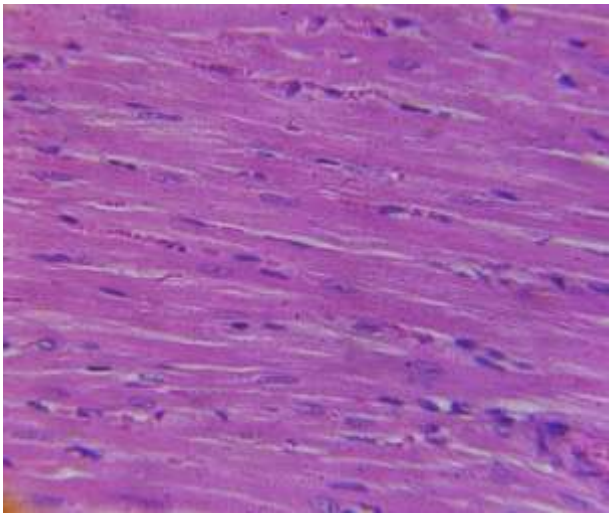




Histopathology of Heart

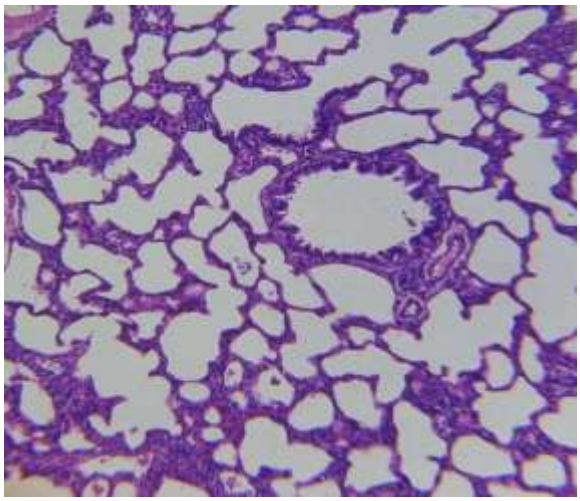
Low Power Magnification 10X **High Power Magnification 40X**

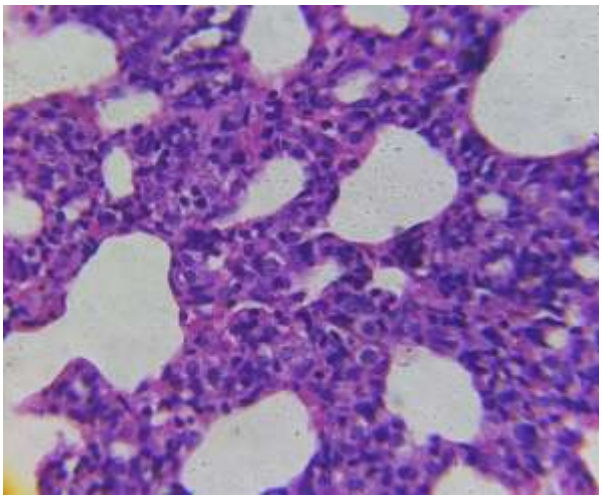




Histopathology of Lung

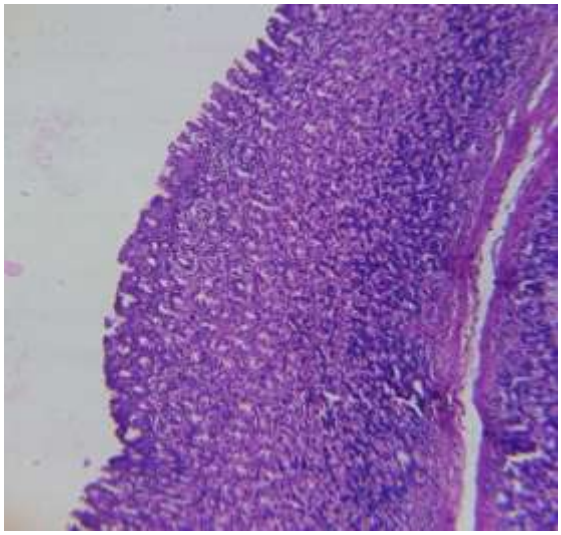
Low Power Magnification 10X **High Power Magnification 40X**

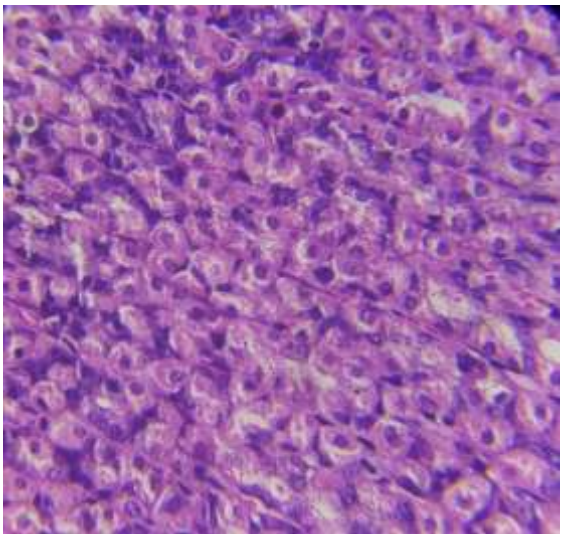




Histopathology of Stomach

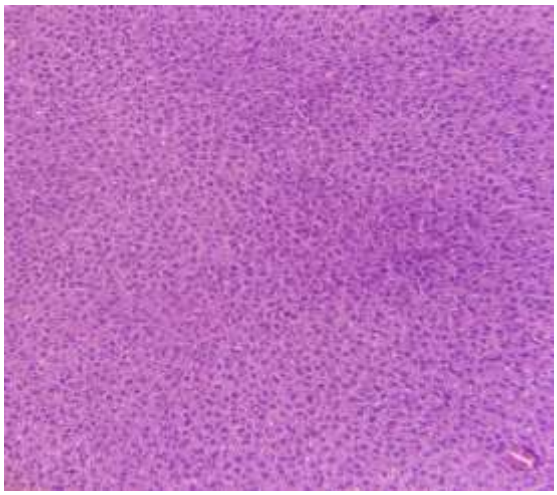
Low Power Magnification 10X **High Power Magnification 40X**

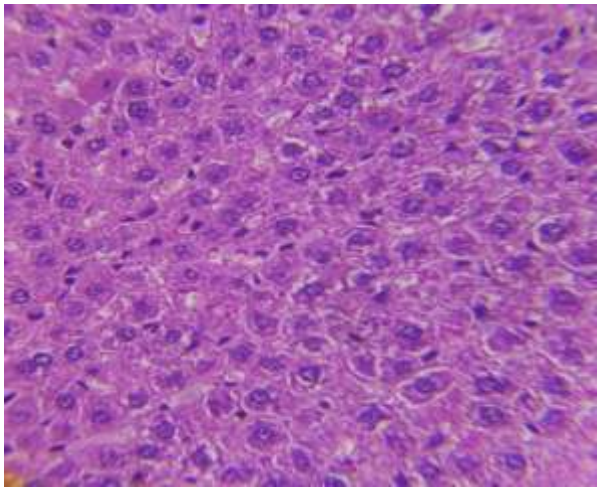




Histopathology of Liver

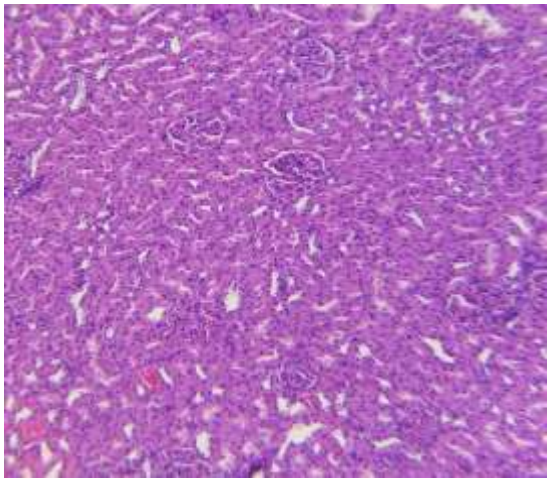
Low Power Magnification 10X **High Power Magnification 40X**

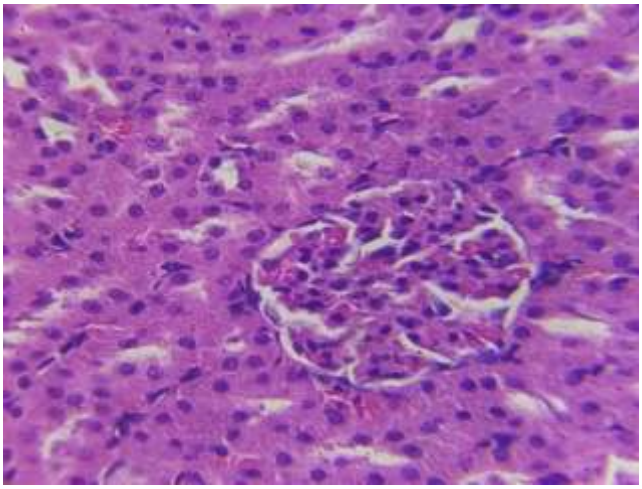




Histopathology of Kidney

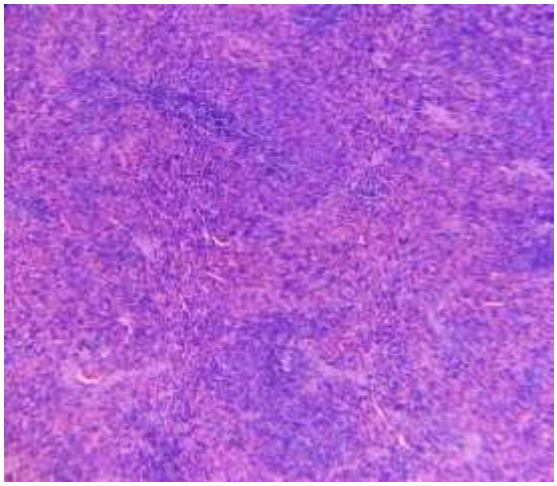
Low Power Magnification 10X **High Power Magnification 40X**

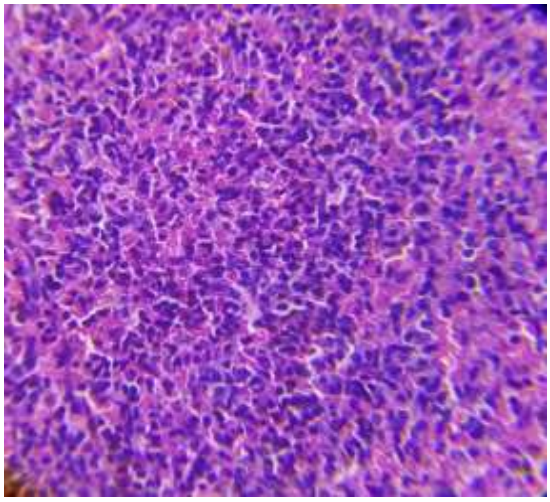




Histopathology of Spleen

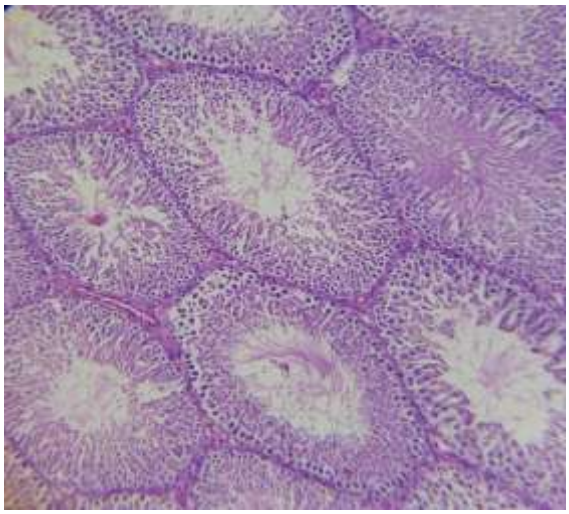
Low Power Magnification 10X **High Power Magnification 40X**

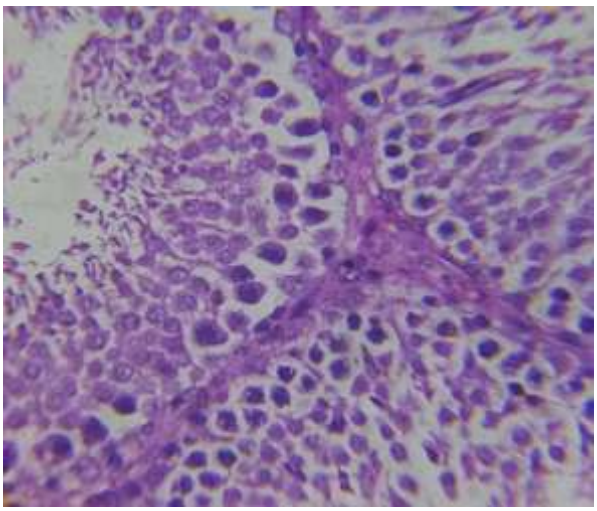




Histopathology of Testes

Low Power Magnification 10X **High Power Magnification 40X**





Pathology Report

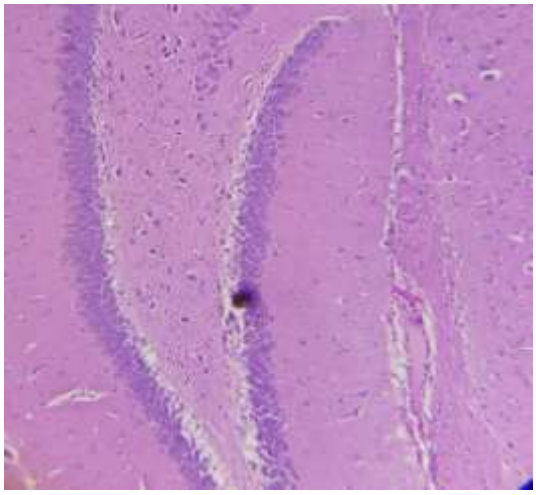
Sample Id: HMH

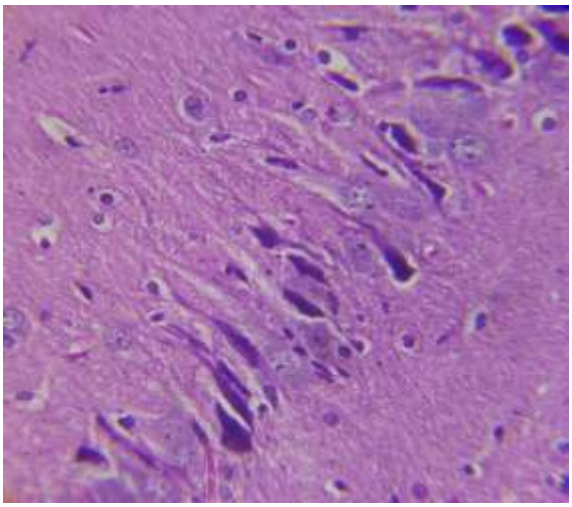
Brain	Morphology of neurons in CA1, CA2 and CA3 zones are normal
Heart	Normal appearance of myocytes; myofibers with no evidence of edema
Lung	Normal alveoli with equidistant arrangement and prominent histology
Stomach	Normal circular muscle and muscularis mucosa zone
Liver	Rare appearance of Kupffer cells with no evidence of phagocytosis in intra cytoplasmic region
Kidney	Arrangement of glomerular loop was normal with regular interstitium
Spleen	Morphology of capsule, nodes, red and white pulp appears normal
Uterus	Appearance of endometrium, myometrium and uterine glands was normal
Ovary	Appearance of antral follicle, primary oocyte and secondary follicles are normal

Sample Id: HFH

Histopathology of Brain

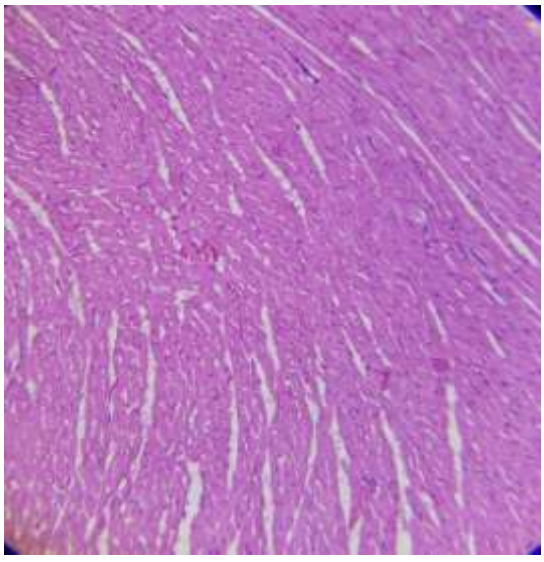
Low Power Magnification 10X **High Power Magnification 40X**

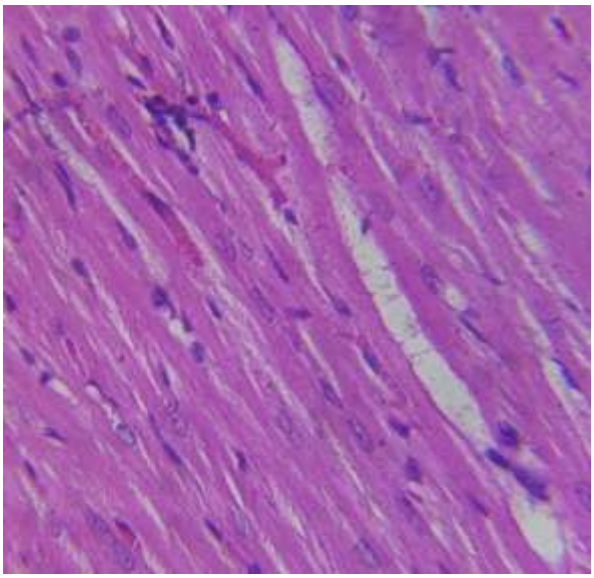




Histopathology of Heart

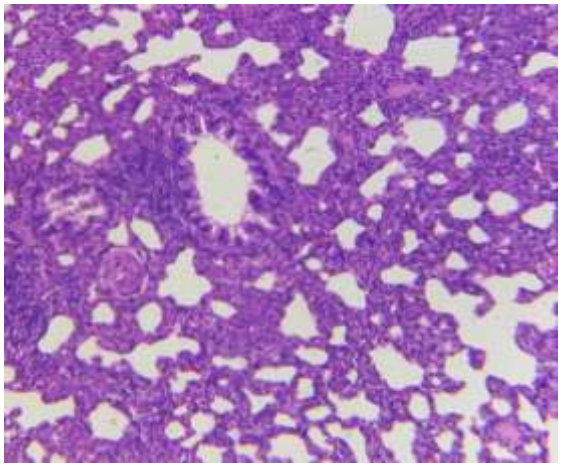
Low Power Magnification 10X **High Power Magnification 40X**

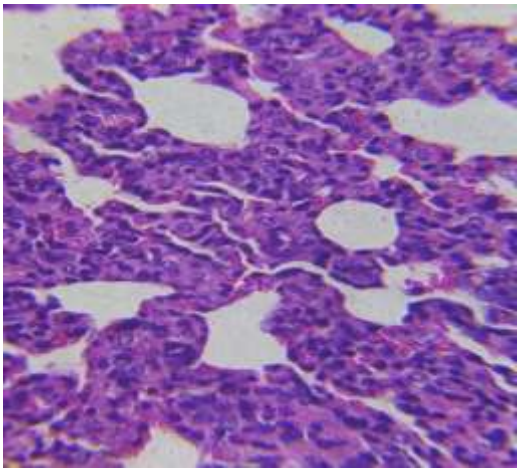




Histopathology of Lung

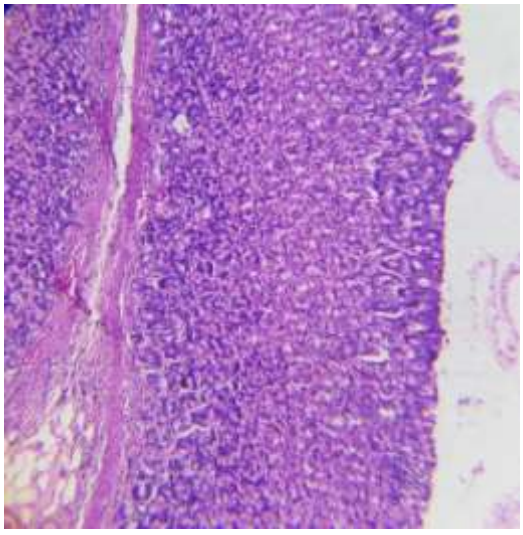
Low Power Magnification 10X **High Power Magnification 40X**

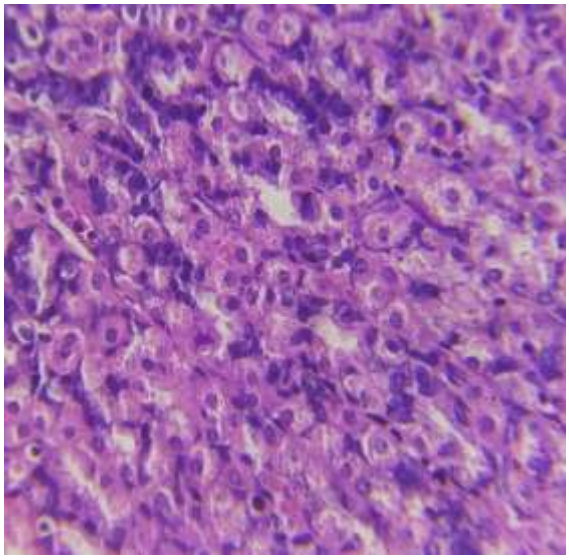




Histopathology of Stomach

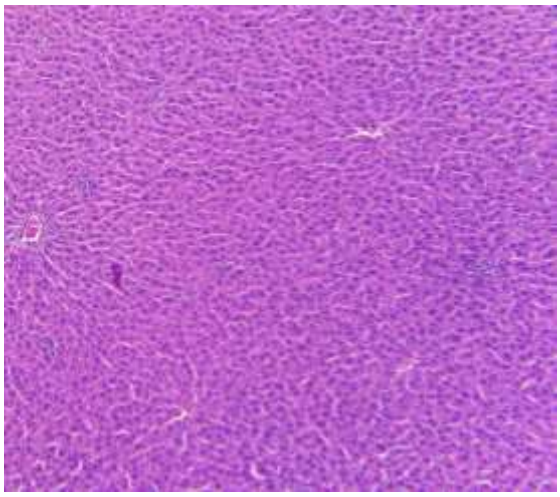
Low Power Magnification 10X **High Power Magnification 40X**

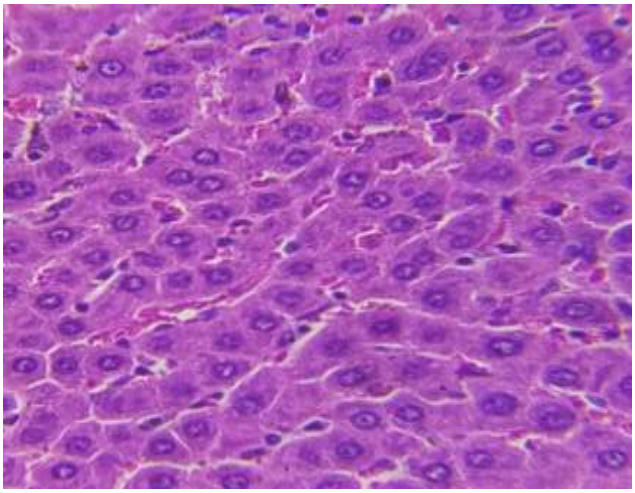




Histopathology of Liver

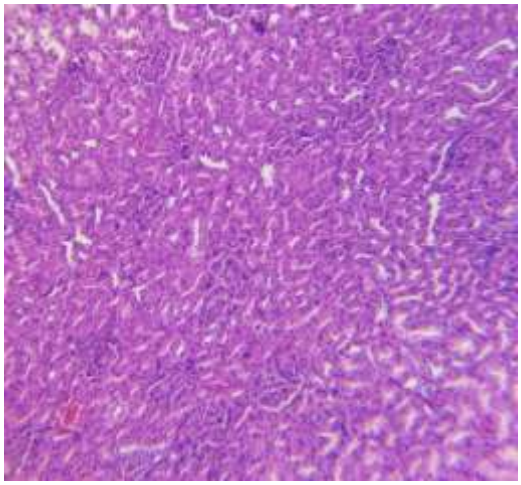
Low Power Magnification 10X **High Power Magnification 40X**

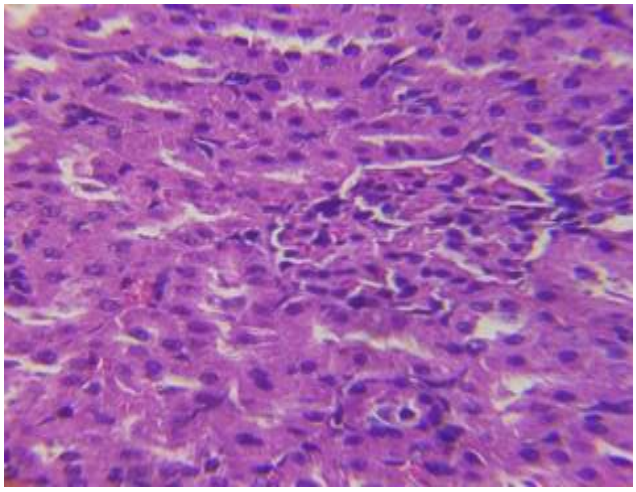




Histopathology of Kidney

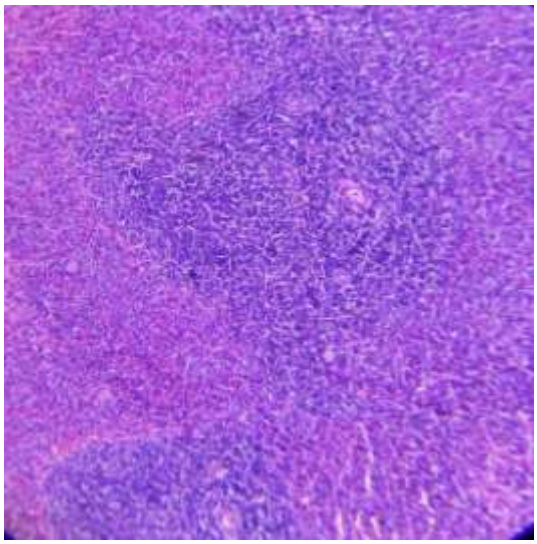
Low Power Magnification 10X **High Power Magnification 40X**

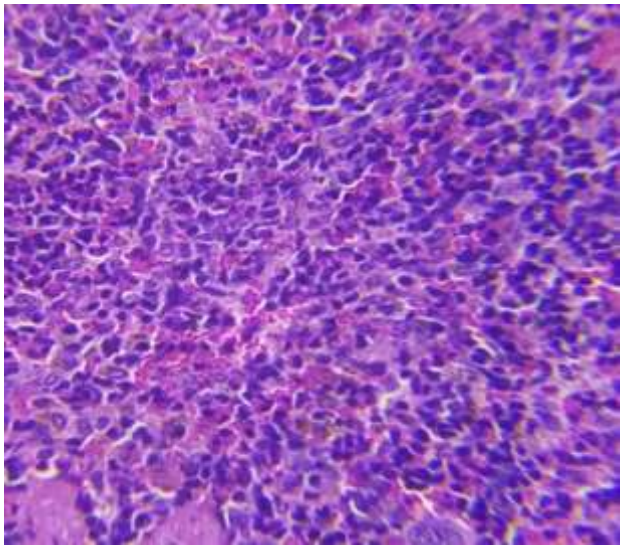




Histopathology of Spleen

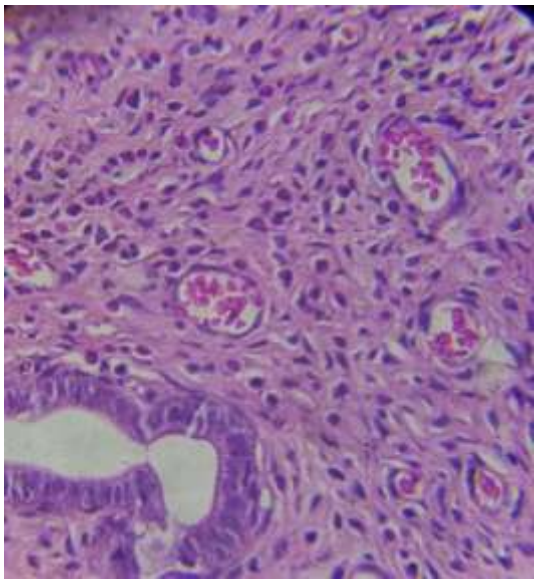
Low Power Magnification 10X **High Power Magnification 40X**

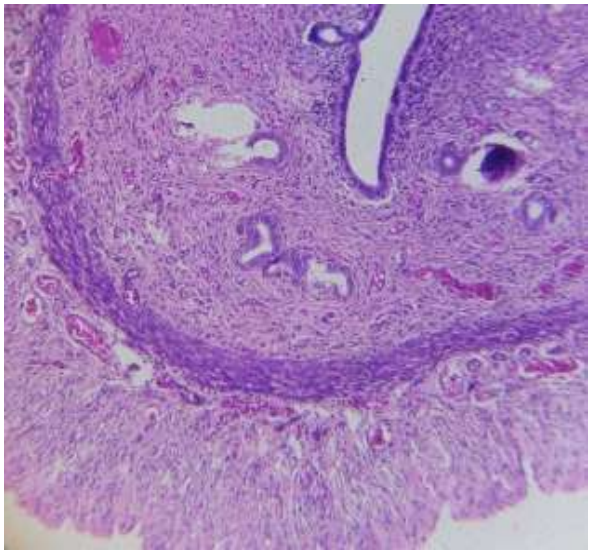




Histopathology of Uterus

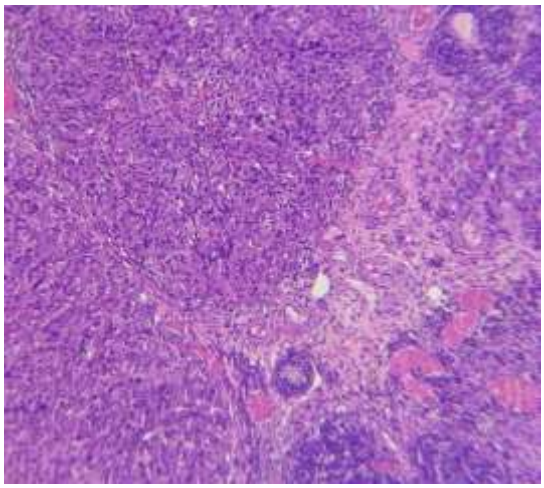
Low Power Magnification 10X **High Power Magnification 40X**

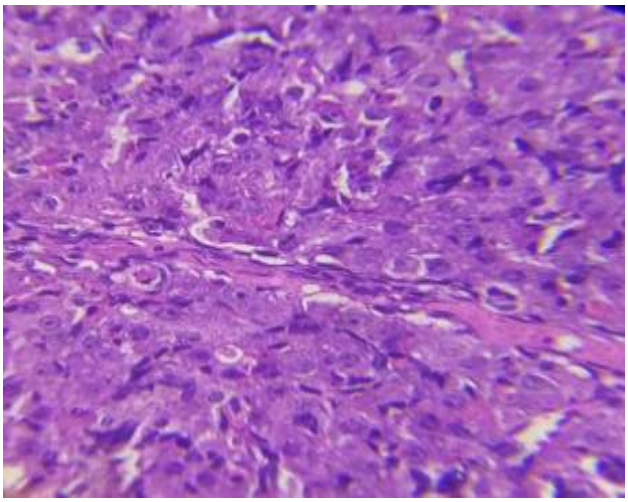




Histopathology of Ovary

Low Power Magnification 10X **High Power Magnification 40X**





Pathology Report

Sample Id : HFH

Brain	Morphology of neurons in CA1, CA2 and CA3 zones are normal
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Ovary	Appearance of antral follicle, primary oocyte and secondary follicles are normal

OBSERVATIONS AND RESULTS

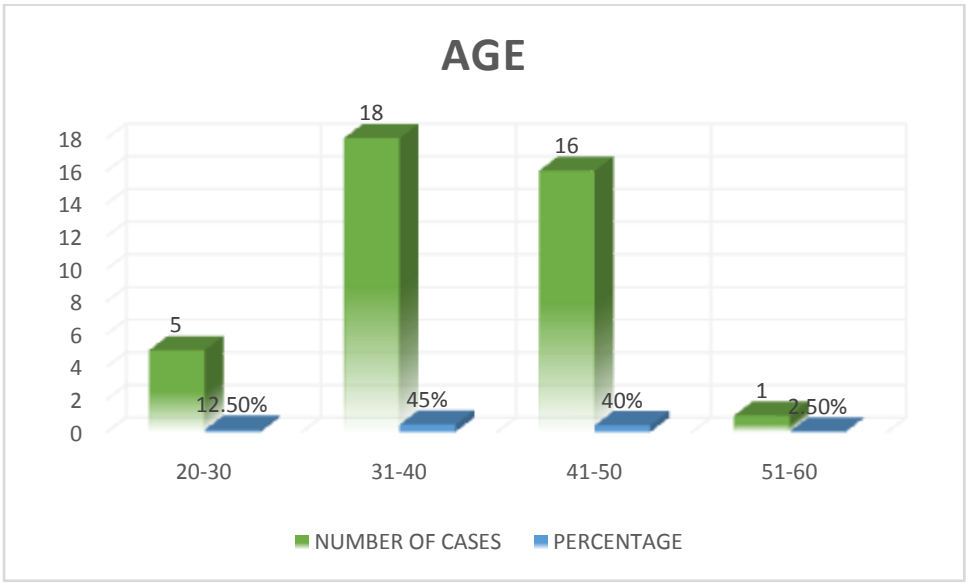
Results and observations were respect to the following criteria,

1. Age distribution
2. Gender distribution
3. Character
4. Body constitution
5. Age distribution
6. Gender distribution
7. Character
8. Body constitution
9. Seasonal changes
10. Socio economic status
11. Diet
12. Occupation
13. Duration of illness
14. Onset of illness
15. Distributions of Vatham
16. Distributions of Pitham
17. Distributions of Kabam
18. Neikuri analysis
19. Examination of Udalthathukkal
20. Examination of Kanmenthriyam
21. ExaminationEnvagaithervu
22. Clinical features
23. Precipitating factors
24. Outcome measurement
25. Result of Treatment

1.Age Incidence:

Table:1

AGE(YEARS)	NUMBER OF CASES	PERCENTAGE
20-30	05	12.5%
31-40	18	45%
41-50	16	40%
51-60	01	2.5%



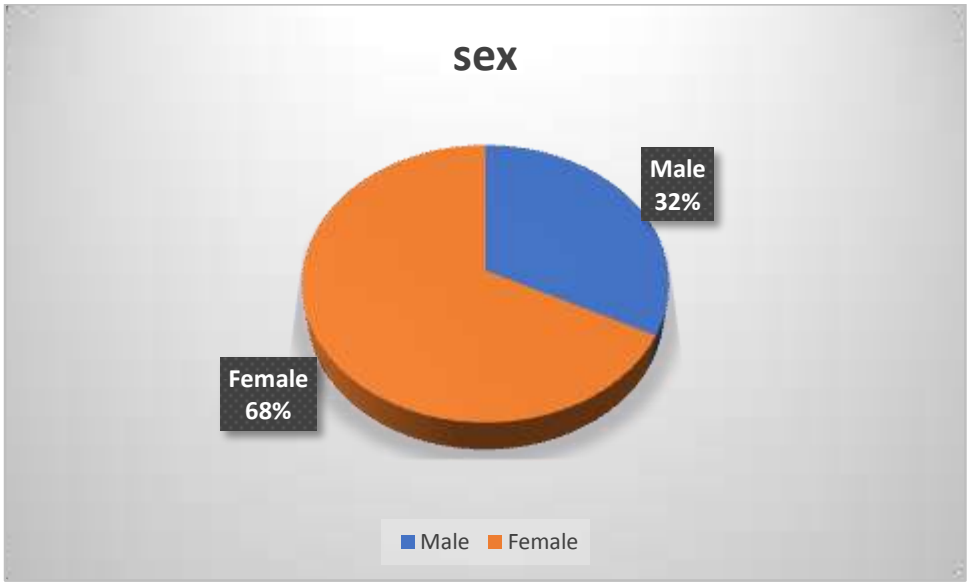
Observation:

In the study, the disease was found to be higher in the age group of 31 – 50 years

2.Sex Distribution:

Table 2:

Gender	Number Of Cases	Percentage
Male	13	32.5%
Female	27	67.5%
Total	40	100%



Observation:

Among the 40 patients selected, the disease was found to be female 27(67.5%) and male13 (32.5%)

4.Gunam:

Table 4:

Gunam	Number of cases	Percentage
Sathuvagunam	0	0%
Rasathagunam	40	100%
Thamogunam	0	0%
Total	40	100%

Observation:

Among the 40 patients recruited, all cases are having Rasathagunam.

5.Body Constitution:

Table 5:

Constitution of the body	Number of cases	Percentage
Vathathegi	0	0%
Pithathegi	0	0%
Kabathegi	0	0%
Thondhathegi		
Vathapitham	12	30%
KabaPitham	8	20%
Pithavatham	18	45%
Pithakabam	2	5%
Total	40	100%

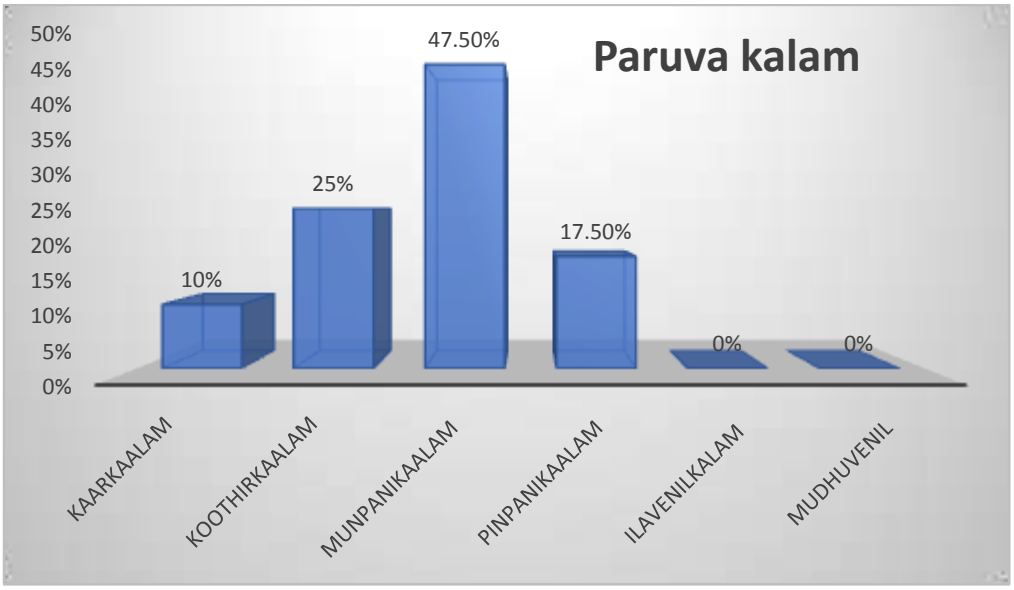
Observation:

Among the 40(100%) patients recruited, all of them were belongs to ThonthaUdal.

6.Paruva Kaalam(season):

Table 6:

Paruva kalam	Number of cases	Percentage
Kaarkaalam (Aug16th–Oct 15th)	04	10%
Koothirkaalam (Oct 16th – Dec 15th)	10	25%
Munpanikaalam (Dec16th – Feb15th)	19	47.5%
Pinpanikaalam (Feb 16th – Apr 15th)	17	17.5%
Total	40	100%



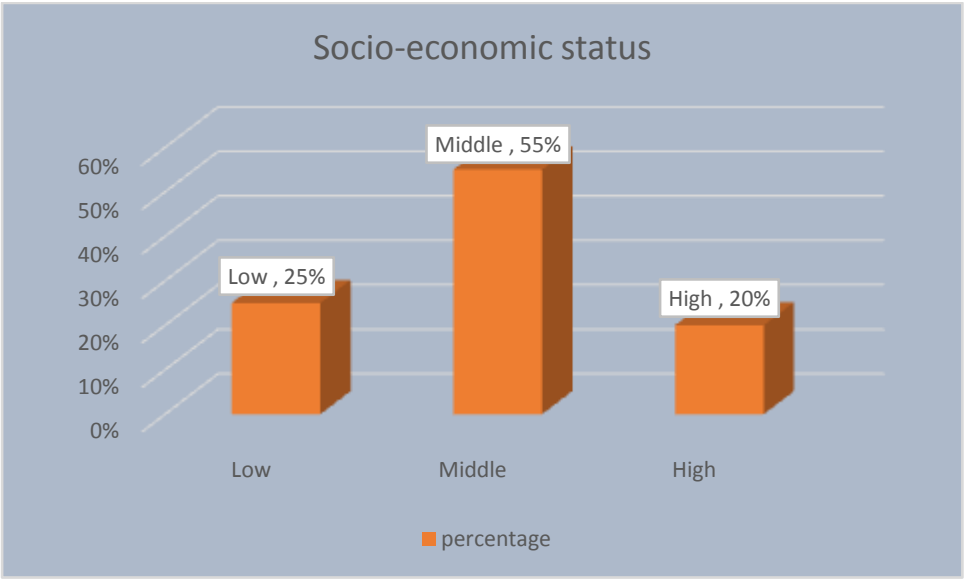
Observation:

Among the 40 patients recruited, most of the cases 19(47.5%) were recruited in munpanikalam, 10 cases (25%) in koothir kalam, 07 cases (17.5%) in Pinpanikalam, in karkalam 04 cases (10%).

8.Socio-Economic Status:

Table 8:

Socio-economic status	Number of cases	Percentage
Low economic status	10	25%
Middle economic status	22	55%
High economic status	08	20%
Total	40	100%



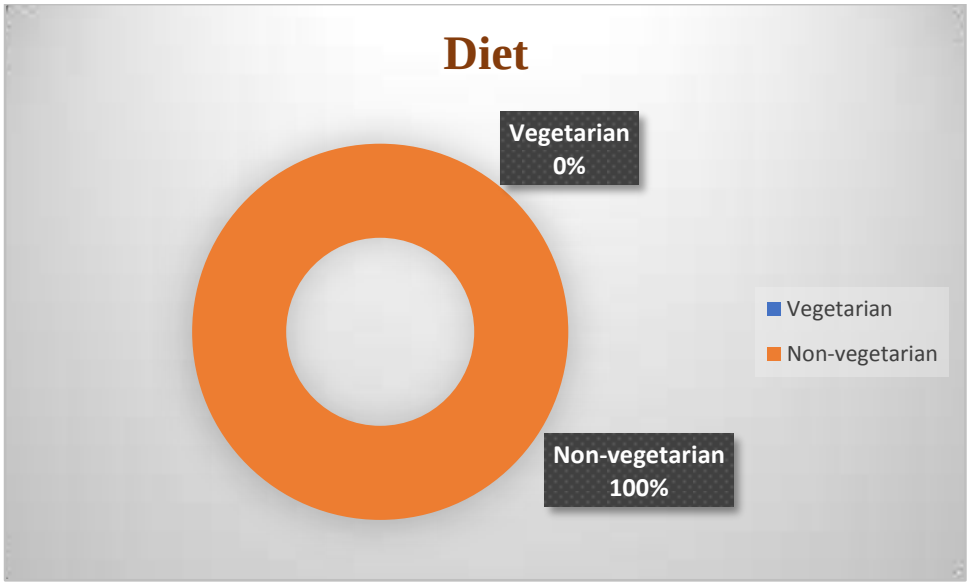
Observation:

Among the 40 patients recruited, 22(55%) cases belongs to Middle economic status, 10 cases (25%) belongs to Low economic status, 8 (20%) cases belongs to High economic status.

9. Diet

Table9

Diet	Number of cases	Percentage
Vegetarian	0	0%
Non-vegetarian	40	100%
Total	40	100%



Observation:

Among the 40 cases recruited, the prevalence of the disease seems to higher in Non vegetarian 40 (100%) cases.

10. OCCUPATIONAL DISTRIBUTION:

Table 10:

Occupation	No. of cases	Percentage
Home maker	10	25%
Tailor	2	5%
Construction work	6	15%
Driver	1	2.5%
Student	2	5%
Cooking	2	5%
Farmer	4	10%
IT sector	1	2.5%
Accountant	1	2.5%
Sales man	4	10%
Security	1	2.5%
Nurse	1	2.5%
Civil engineer	1	2.5%
Painter	1	2.5%
Business man	2	5%
House keeping	1	2.5%

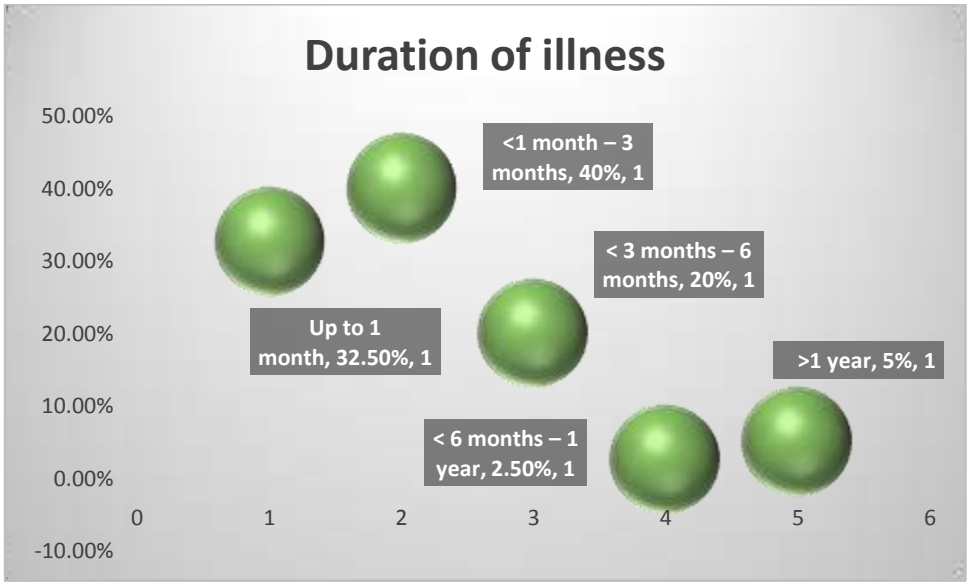
Observation:

Among the 40 patients recruited, the prevalence were more in Housewives 10 (25%), 6 (15%) were in construction work, 4 (10%) were in farmers and company, sales department, 2 (10%) were in tailor, students, cooking job and business man and 1 (5%) were in driver, accountant, IT sector, security, civil engineer, nurse and painter.

11.Duration of Illness:

Table:11

Duration of illness	No of cases	Percentage
Up to 1 month	13	32.5%
<1 month – 3 months	16	40%
< 3 months – 6 months	08	20%
< 6 months – 1 year	01	2.5%
>1 year	02	5%



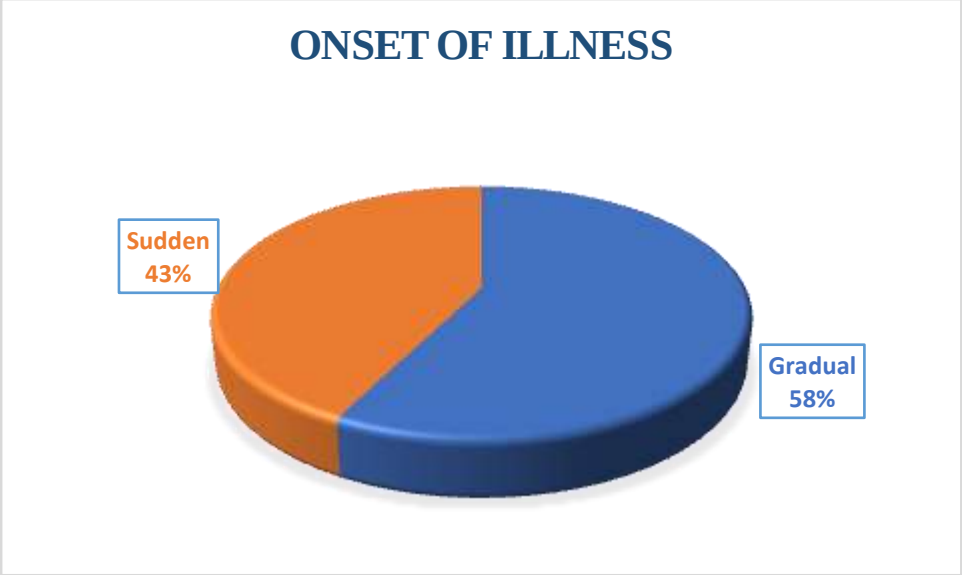
Observation:

The chronicity of illness before recruitment for the study was more in 16 (40%) cases who were between the time interval of more than one month to 3 months, 13(32.5%) cases had chronicity of within a month, 8 (20%) had chronicity of more than 3 months to 6 months, 1 (2.5%) had chronicity of 6 months - 1 year and 2(05%) cases had chronicity of more than 1 year.

12. Onset of Illness

Table12:

Onset	No. Of cases	Percentage
Gradual	23	57.5%
Sudden	17	42.5%
Total	40	100%



Observations:

Out of 40 patients, 23 cases (57.5%) had gradual onset of the disease and 17 cases (42.5%) had sudden onset of the disease.

13. Distributionsofvatham:

Table 13:

Vatham	Number of patients	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	-	-
Total	40	100%

Observation:

Among the 40 cases observed Viyaanan, Samanan and devadhathan were affected in almost all the cases (100%).

14.Distributionsof Piththam:

Table 14:

Pitham	No of patients	Percentage
Aakanal	0	0%
Vanna eri	0	0%
Aattralangi	40	100%
Olloli thee	0	0%
Nokkazhal	0	0%

Observation:

Among the 40 cases *Attralangi* was affected in almost all cases.

15. Distributionof kabam:

Table 15:

Kabam	**No of patients**	**Percentage**
Aliyaiyam	40	100%
Neerpiiyam	0	0%
Suvaiiyam	0	0%
Niraivaiyam	0	0%
Ontriiyam	40	100%

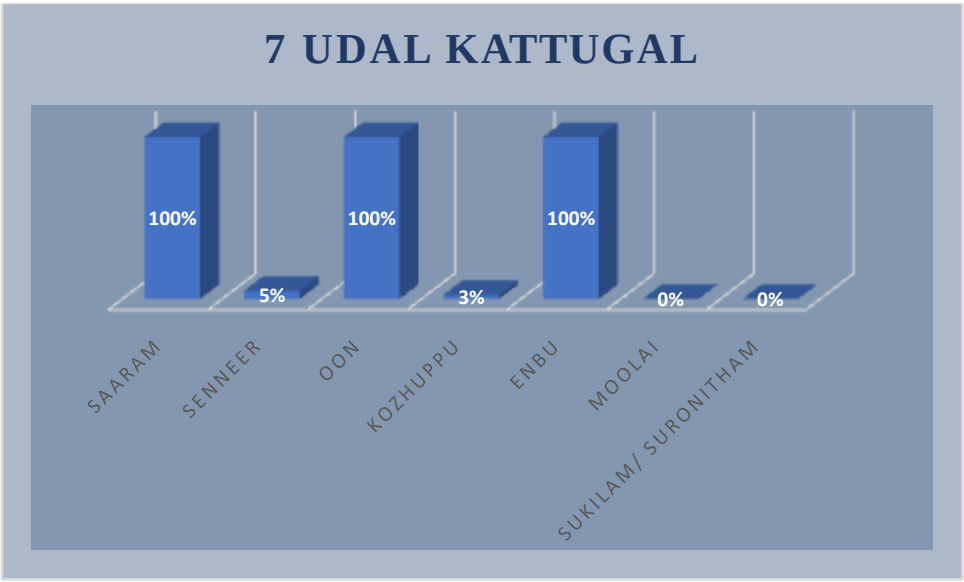
Observation:

Aliyaiyam and Ondriiyam was affected in all the 40 cases.

16. Examinations of udalThaathukkal:

Table 16:

Udalthadhukkal	No of cases	Percentage
Saaram	**40**	**100%**
Senneer	**02**	**5%**
Oon	**40**	**100%**
Kozhuppu	**01**	**2.5%**
Enbu	**40**	**100%**
Moolai	**0**	**-**
Sukkilam/Suronitham	**0**	**-**



Observation:

Saaram, oon, kozhupu, Enbu and moolai were affected in all the 40 cases (100%), *senneer* was affected in 02 cases (5%).

17.DISTURBANCES IN KANMENTHIRIUM:

Table 17:

Duration of illness	No of cases	percentage
Kai	0	0
Kaal	40	100%
Vaai	0	0
Eruvaai	0	0
Karuvaai	0	0

Observation:

Kaal affected in 40 cases (100%).

18.ENVAGAI THERVUGAL (EIGHT DIAGNOSTIC METHODS):

Table 18:

ENVAGAI THERVUGAL	NUMBER OF CASES	PERCENTAGE
Naadi:		
Vathapitham	03	7.5%
Pithavatham	35	87.5%
Pithakabam	02	5%
Naa	02	5%
Niram	0	0%
Mozhi	0	0%
Vizhi	0	0%
Sparisam	09	22.5%
Malam	0	0%
Moothiram	0	0%

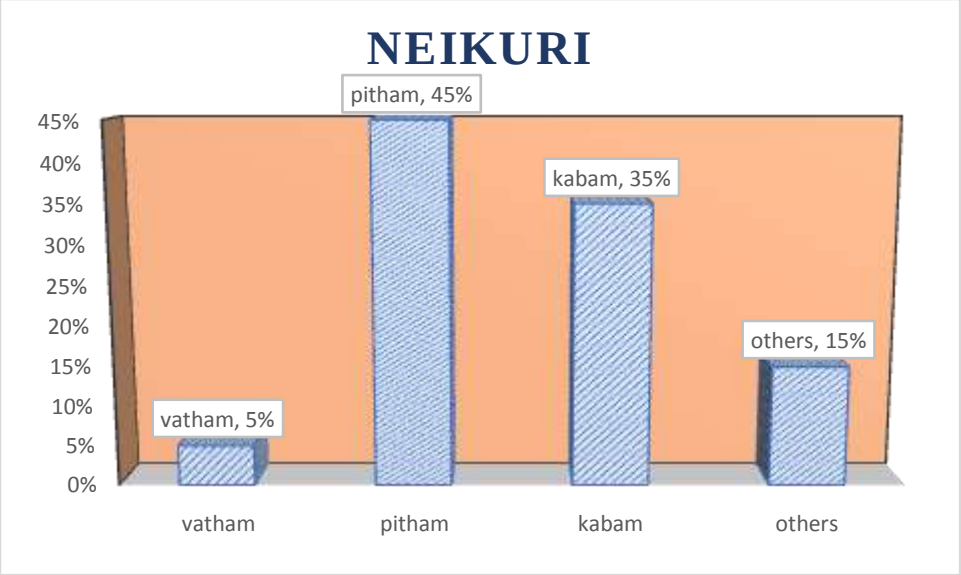
Observation:

Among the 40 patients recruited, Vathapithamnaadi was found in 03 cases (7.5%), Pithavathanaadi was found in 35 cases (87.5%), Piththakabanaadi was found in 2 cases (5%), Naa was affected in 02 (5%) cases and sparisam was affected in 09 (22.5%) cases, Niram, vizhi, Mozhi, Malam, Moothiram were not affected.

19. Neikkuri:

Table 19:

Spreading pattern	No of cases	Percentage
Aravenaneendathu - Vathaneer	02	5%
Aazhi pol paraviyadhu - Pithaneer	18	45%
Muthothunindrathu - Kabaneer	14	35%
Other pattern	08	15%



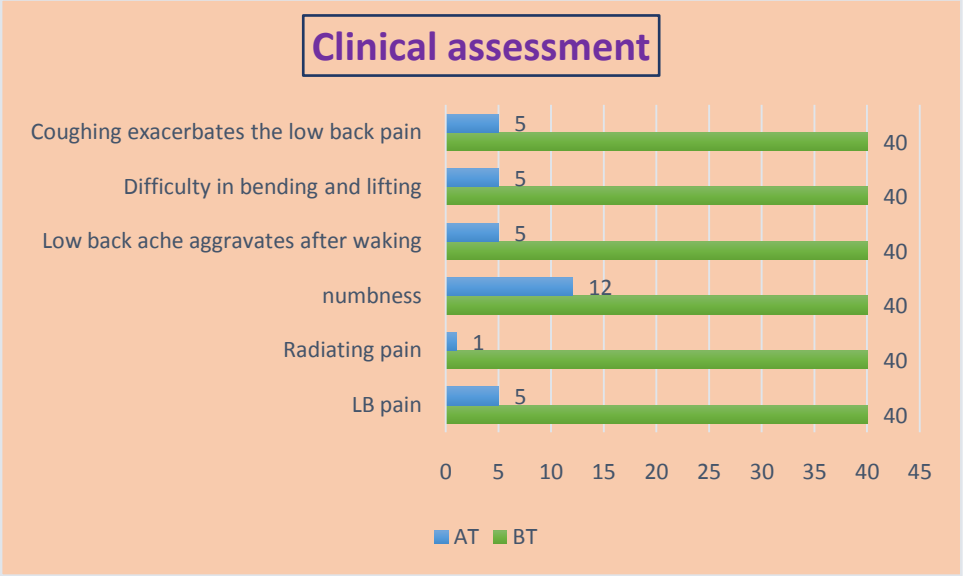
Observation:

Among 40 cases Vathaneer was found in 2 cases (5%), Pithaneer was found in 18 cases (45%), Kabaneer was found in 14 cases (35%), Other patterns were found in 06 cases (15%) cases.

20. Clinical symptoms:

Table 20:

Symptoms	Before treatment		After treatment	
	No of cases	Percentage	No cases	Percentages
Pain in low back region	40	100%	5	12.5%
Radiating pain to legs posterolaterally	40	100%	1	2.5%
Numbness	40	100%	12	30%
Low back ache aggravates after prolonged walking and standing	40	100%	5	12.5%
Difficulty in bending and lifting	40	100%	10	25%
Coughing exacerbates the low back pain	40	100%	5	12.5%



Observation:

Among 40 cases, all of them had all the inclusion criteria. After treatment, 5 cases (12.5%) had moderate low back pain, only one case (2.5%) had radiating pain, 12 cases (30%) had Grade 2 numbness (occasionally), 5 cases (12.5%) experiences the moderate low back pain while coughing, prolonged walking and standing, 10 cases (25%) had difficulty in bending and lifting

PAIN SCORE – TRIAL DRUG ONLY (Group A):

S. No	OP No	NAME	AGE/S EX	LUMBAR PAIN BT	LUMBAR PAIN AT	RADIATING PAIN BT	RADIATING PAIN AT	ROM BT	ROM AT	NUMBNESS BT	NUMBNESS AT
1	K46284	Mrs.N.Rajalakshmi	37/F	7	3	+	-	G3	G1	+	+
2	K05839	Mrs.K.Suseela	39/F	6	1	+	-	G2	G1	+	-
3	I18406	Mrs.R.Monika	20/F	8	1	+	-	G2	G1	+	-
4	K755793	Mr.A.Mahendran	48/M	6	2	+	-	G3	G1	+	-
5	K89095	Mrs.P.N.Poornima	30/F	8	1	+	-	G3	G1	+	-
6	K93183	Mr.D,David	48/M	7	2	+	-	G3	G1	+	-
7	J31225	Mrs.V.Amudha	36/F	7	2	+	-	G2	G1	+	-
8	K93196	Mrs.D.Usha	35/F	8	3	+	-	G3	G2	+	+
9	K97183	Mr.R.Thangavel	38/M	7	3	+	-	G3	G2	+	-
10	K97582	Mr.S.Sridhar	33/M	8	4	+	-	G3	G2	+	+
11	K98096	Mrs.J,Sasikala	38/F	7	2	+	-	G2	G1	+	-
12	K93479	Mrs.C.Padmavathy	48/F	6	3	+	-	G2	G1	+	-
13	K76850	Mrs.Jeya	48/F	7	4	+	-	G2	G1	+	-
14	K33679	Mrs. Amirtham	46/F	8	3	+	-	G3	G1	+	+
15	L04291	Mrs.E.Komala	43/F	8	4	+	-	G3	G1	+	-
16	L11391	Mrs.R.Jeyasutha	34/F	7	3	+	-	G3	G1	+	+
17	J53379	Mrs.J.Lakshmi	40/F	8	1	+	-	G3	G1	+	-
18	J12701	Mrs.S.Prema	45/F	8	3	+	-	G3	G2	+	+
19	K16726	Mrs.E.Ponniyammal	44/F	7	1	+	-	G2	G1	+	-
20	L09932	Mr.V.Anbazhagan	46/M	8	4	+	-	G3	G2	+	+

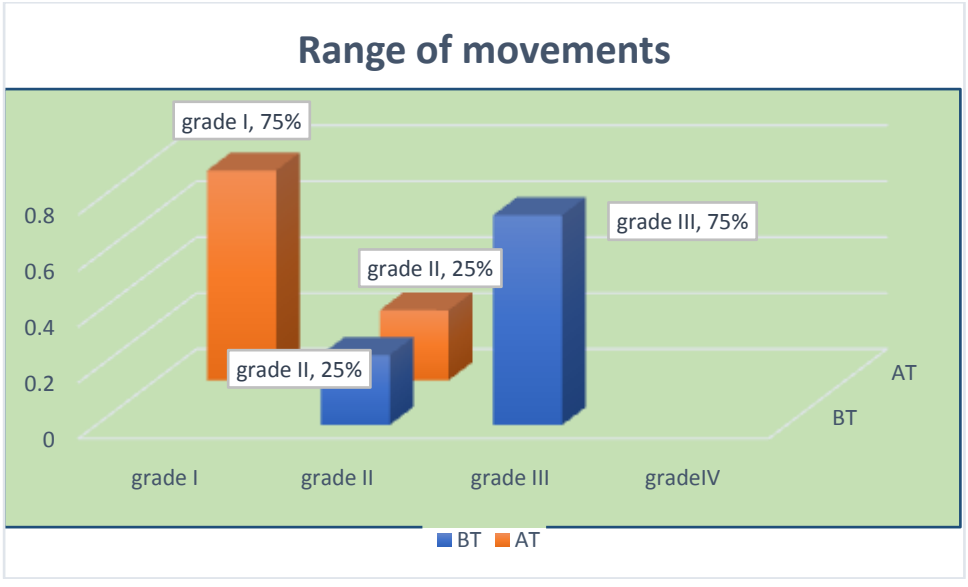
PAIN SCORE – (GROUP-B):

S. No	OP No	NAME	AGE/S EX	LUMBAR PAIN		RADIATING PAIN		ROM		NUMBNESS	
				BT	AT	BT	AT	BT	AT	BT	AT
1	K63654	Mr.K.Selvam	31/M	9	1	+	-	G3	G1	+	-
2	1672-18	Mrs.G.Kajalakshmi	50/F	9	6	+	+	G3	G2	+	+
3	K76700	Mrs.K.Omana	52/F	7	1	+	-	G3	G1	+	-
4	K96058	Mrs.S.Sunimol	40/F	9	0	+	-	G3	G1	+	-
5	K56356	Mr.R.Magesh	20/M	9	1	+	-	G3	G1	+	-
6	L06454	Mr.Syednafees	26/M	8	0	+	-	G3	G1	+	-
7	C55087	Mrs.M.Ayireen	40/F	8	1	+	-	G3	G1	+	-
8	K86452	Mrs.D.Tamilselvi	37/F	6	0	+	-	G2	G1	+	-
9	K99250	Mrs.R.Vijayalakshmi	38/F	8	0	+	-	G3	G1	+	-
10	K99200	Mr.Praveen	24/M	8	1	+	-	G2	G1	+	-
11	J99015	Mrs.B.Geetha	38/F	8	1	+	-	G3	G1	+	-
12	L22719	Mrs.K.Ganthimathi	45/F	8	1	+	-	G3	G2	+	+
13	L17882	Mr.J.Krishnamoorthy	37/M	7	1	+	-	G3	G1	+	-
14	L15969	Mr.V.Muruganantham	37/M	8	1	+	-	G3	G1	+	-
15	L19387	Mr.R.Shanmugam	39/M	8	1	+	-	G3	G1	+	-
16	H05305	Mr.E.Sivakumar	46/M	9	0	+	-	G3	G1	+	-
17	L06071	Mrs.K.Muthulakshmi	48/F	7	3	+	-	G2	G2	+	+
18	K51236	Mrs.Latha	46/F	8	1	+	-	G3	G1	+	-
19	H07027	Mrs.Jeyanthi	36/F	8	0	+	-	G3	G2	+	+
20	H12365	Mrs.G.Rani	41/F	7	3	+	-	G3	G2	+	+

22. Outcome Measures

Restricted movement assessment scale:

Grading	Before treatment		After treatment		
	No of cases	Percentage	Grading	No of cases	Percentage
Grade I	-	0%	G3 – G1	21	52.5%
			G2 – G1	09	22.5%
Grade II	10	25%	G3 – G2	09	22.5%
			G2 – G2	01	2.5%
Grade III	30	75%	-		
Grade IV	-	0%	-		
Total	40	100%	-		

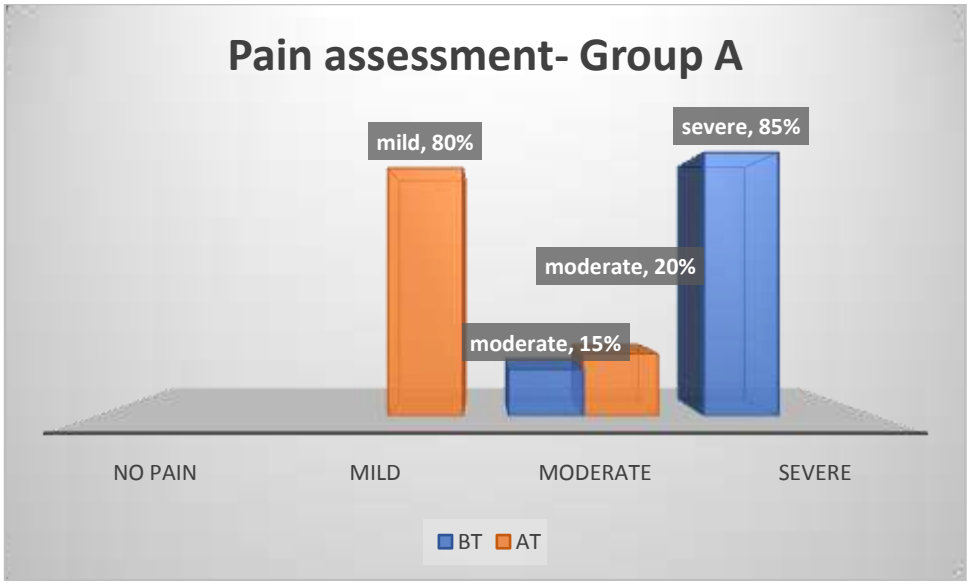


Observation:

After the treatment among the 40 patient's movement restriction was reduced in 30 cases (Grade I - 75%), mild restriction was found in 10 cases (Grade II - 25%).

Pain Assessment (Group A):

Pain assessment (varmam + trial drug)	Before treatment (BT)		After treatment (AT)	
	Number of patients	Percentage %	Number of patients	Percentage %
No pain 0	-	-	-	-
Mild (1-3)	-	-	16	80%
Moderae (4-6)	03	15%	4	20%
Severe (7-10)	17	85%	-	-
Total	20	100	20	100

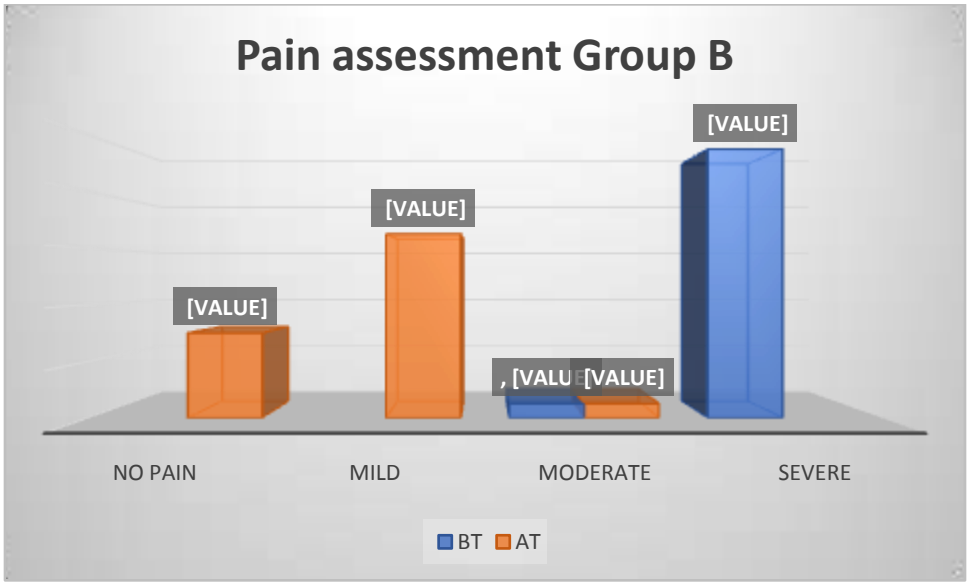


Obseravation:

After treatment among 20 patients, mild pain was present in 16(80%) of the cases, moderate pain was present in 4(20%) 0f the cases.

Pain Assessment (Group B):

Pain assessment (varmam + trial drug)	Before treatment		After treatment	
	Number of patients	Percentage %	Number of patients	Percentage %
No pain 0	-	-	06	30%
Mild (1-3)	-	-	13	65%
Moderate (4-6)	01	05%	1	5%
Severe (7-10)	19	95%	-	-
Total	20	100	20	100

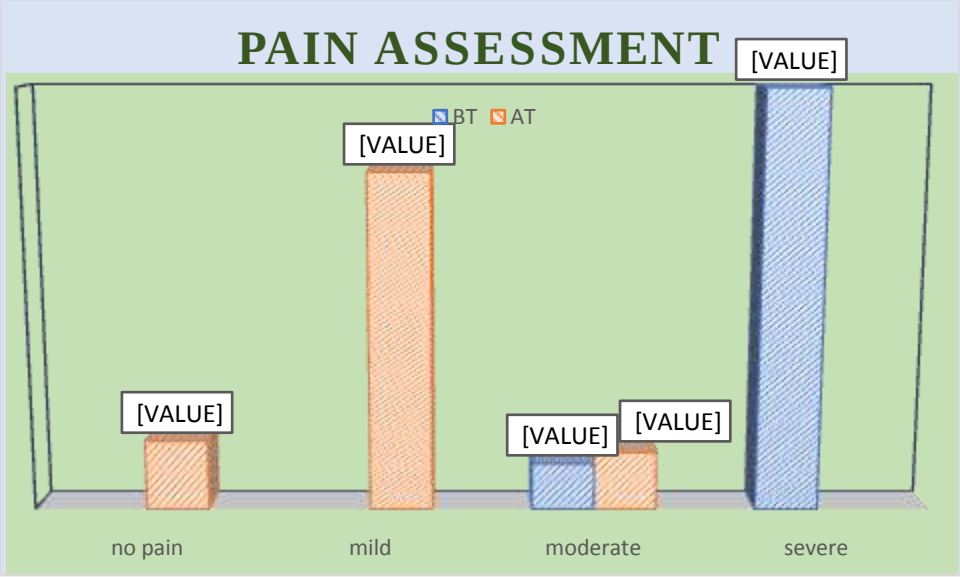


Observation:

Among the 20 cases, after the treatment no pain was present in 6 cases (30%) mild pain was present in 13 cases (65%) and moderate pain was present in 1 case (5%).

Pain assessment scale:

Pain assessment	Before treatment		After treatment	
	Number of patients	Percentage %	Number of patients	Percentage %
No pain 0	-	-	06	15%
Mild (1-3)	-		29	72.5%
Moderate (4-6)	04	10%	05	12.5%
Severe (7-10)	36	90%	-	-
Total	40	100%	40	100%

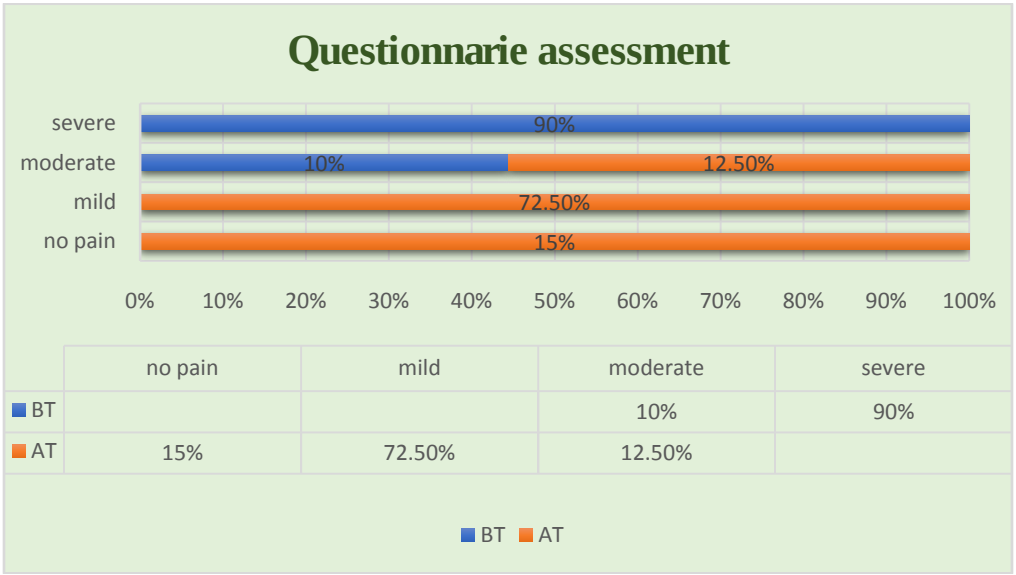


Observation:

Among the 40 cases, after the treatment, no pain was found in 6 cases (15%), mild pain was present in 29 cases (72.5%) and moderate pain was present in 5 cases (12.5%).

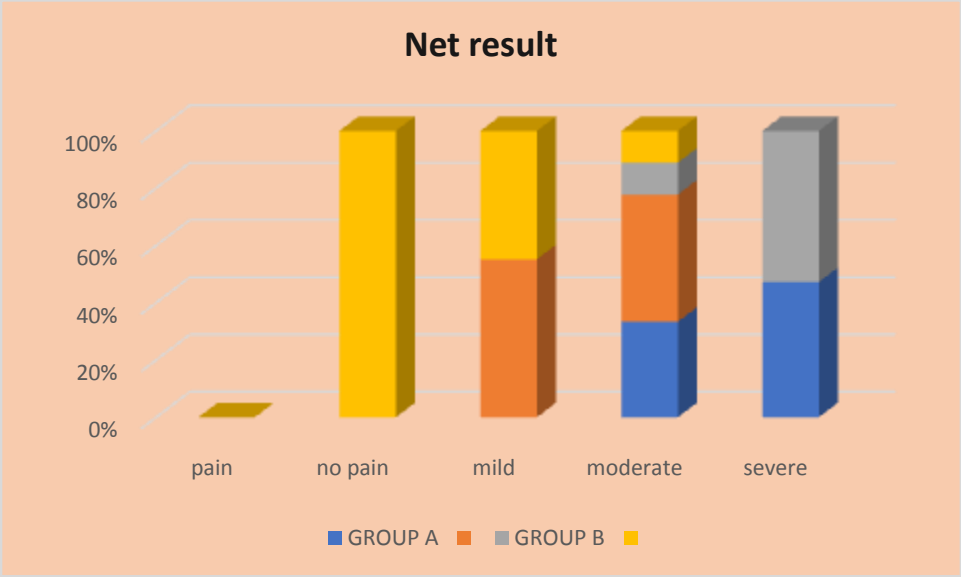
25. Questionnaire Assessment:

Questionnaire	Before treatment		After treatment	
	Number of patients	Percentage %	Number of patients	Percentage %
No pain 0	-	-	06	15%
Mild (1-3)	-	-	29	72.5%
Moderate (4-6)	04	10%	05	12.5%
Severe (7-10)	36	90%	-	-
Total	40	100%	40	100%



NET RESULT OF GROUP A AND GROUP B :

PAIN ASSESSMENT	GROUP A				GROUP B			
	BEFORE TREATMENT		AFTER TREATMENT		BEFORE TREATMENT		AFTER TREATMENT	
	No. of Patients	%	No. of Patients	%	No. of Patients	%	No. of Patients	%
No Pain (0)	-	-	-	-	-	-	06	30%
Mild (1-3)	-	-	16	80%	-	-	13	65%
Moderate (4-6)	03	15%	4	20%	01	5%	01	5%
Severe (7-10)	17	85%	-	-	19	95%	-	-
Total	20	100 %	20	100	20	100 %	20	100 %

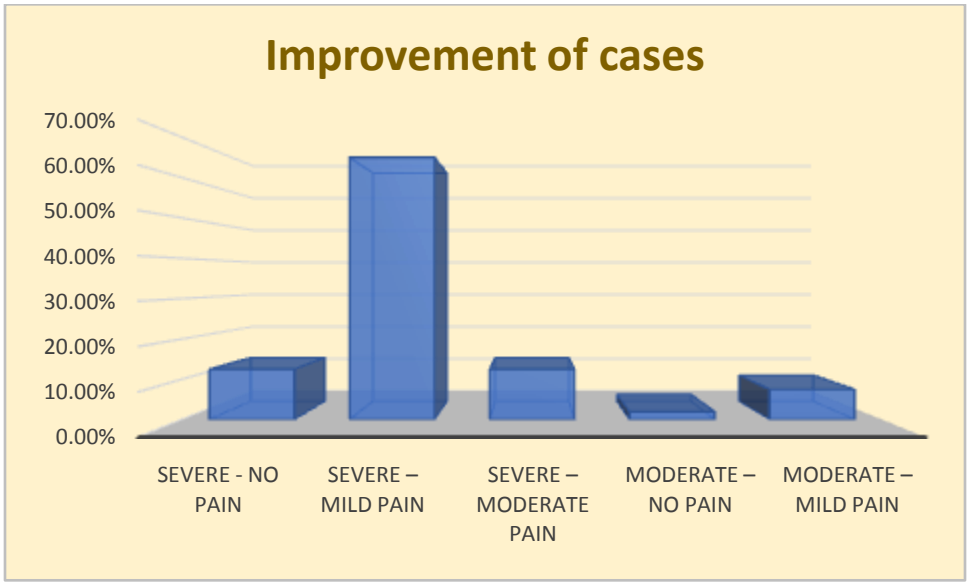


Observation:

Among 40 patients, in group A patients after the treatment about pain, 80% of the patient havemild pain and 20% of the patient have moderate pain. In Group B patients 30% of the patient have nopain, 65% of patients have mild pain, 5% of the patient have moderate pain.

IMPROVEMENT OF CASES:

Pain assessment	No of cases	Percentage
Severe - No pain	**05**	**12.5%**
Severe – Mild pain	**26**	**65%**
Severe – Moderate pain	**05**	**12.5%**
Moderate – No pain	**01**	**2.5%**
Moderate – Mild pain	**03**	**7.5%**
Total	**40**	**100%**



STATISTICAL 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

Pain scale	Sample size	Mean	Standard deviation	95% confidence interval	Significant
Before treatment	**40**	**7.62**	**0.82**	**7.37 to 7.87**	**0.0010**
After treatment	**40**	**1.825**	**1.4122**	**1.49 to 2.35**	

There is extremely significant difference between before and after treatment.

PAIN ASSESSMENT BETWEEN TWO GROUPS:

	Before treatment		After treatment	
	Group A	**Group B**	**Group A**	**Group B**
Sample size	20	20	20	20
Mean	7.3	7.95	2.5	1.15
SD	0.714	0.804	1.07238	1.38832
T value	2.702		3.442	
P value	0.0102		0.0014	
Significance	Significant		Very significant	

There is very significant difference between with and without varmam treatment groups before the end of treatment.

BATCH A:

LABORATORY INVESTIGATIONS BEFORE AND AFTER TREATMENT

S.No	OP No	NAME	AGE/SEX	Hb (gm/dl)		TOTAL RBC COUNT (million/ cu.mm)					
										TOTAL WBC	
								ESR (mm/hour)		COUNT	
				BT	AT	BT	AT	BT	AT	BT	AT
1	K46284	Mrs.N.Rajalakshmi	37/F	11.2	11.8	4.2	4.4	10/20	20/40	8100	8400
2	K05839	Mrs.K.Suseela	39/F	11.7	11.5	4.7	4.6	10/20	10/15	8300	8300
3	I18406	Mrs.R.Monika	20/F	11	11.5	4.1	4.2	10/20	10/20	9800	9600
4	K755793	Mr.A.Mahendran	48/M	13.7	14.3	4.6	4.9	4/12	4/10	7000	7300
5	K89095	Mrs.P.N.Poornima	30/F	10.1	11.3	4.0	4.1	10/20	30/10	9000	10400
6	K93183	Mr.D,David	48/M	13.6	13.8	5.3	5.3	20/30	10/20	6300	7400
7	J31225	Mrs.V.Amudha	36/F	12.1	12.6	4.4	4.4	4/10	10/20	6400	6600
8	K93196	Mrs.D.Usha	35/F	11.5	11.5	4.5	4.5	10/22	10/16	5900	4700
9	K97183	Mr.R.Thangavel	38/M	16.6	16.6	5.3	5.2	2/4	8/16	10800	10600
10	K97582	Mr.S.Sridhar	33/M	16.9	16.2	5.8	5.6	2/10	6/12	8800	6900
11	K98096	Mrs.J,Sasikala	38/F	12.3	11.5	4.0	3.8	10/22	6/12	4700	7200
12	K93479	Mrs.C.Padmavathy	48/F	11.7	11.6	3.7	3.6	40/80	32/64	7400	7300
13	K76850	Mrs.Jeya	48/F	8.1	8.3	4.5	4.4	30/46	20/34	7300	7600
14	K33679	Mrs. Amirtham	46/F	8.3	8.3	4.2	4.3	6/12	30/60	8000	7500
15	L04291	Mrs.E.Komala	43/F	11.6	11.7	4.3	4.5	20/42	20/40	11300	13600
16	L11391	Mrs.R.Jeyasutha	34/F	12.2	11.9	3.9	3.7	12/24	8/16	9700	6900
17	J53379	Mrs.J.Lakshmi	40/F	11.5	11.6	4.4	4.6	12/24	8/16	6300	6800
18	J12701	Mrs.S.Prema	45/F	12.1	11.6	4.4	4.2	4/10	30/60	7400	9800
19	K16726	Mrs.E.Ponniyammal	44/F	11.1	12	5.0	5.2	6/12	10/20	8700	8400
20	L09932	Mr.V.Anbazhagan	46/M	16.4	15.8	5.4	5.0	4/10	2/4	6400	7300

LABARATORY INVESTIGATIONS - BEFORE AND AFTER TREATMENT

S. No	OP No	NAME	AGE/ SEX	BLOOD GLUCOSE (F)		BLOOD GLUCOSE (P)		UREA		CREATININE		TOTAL CHOLESTEROL	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	K46284	Mrs.N.Rajalakshmi	37/F	81	91	120	118	15	12	0.8	0.8	147	165
2	K05839	Mrs.K.Suseela	39/F	108	100	160	142	20	18	0.8	0.8	156	150
3	I18406	Mrs.R.Monika	20/F	86	80	92	90	16	16	0.9	0.5	132	130
4	K755793	Mr.A.Mahendran	48/M	96	119	140	174	11	14	1.3	1.3	207	257
5	K89095	Mrs.P.N.Poornima	30/F	90	84	130	127	16	16	0.9	0.9	170	169
6	K93183	Mr.D,David	48/M	72	86	112	132	16	14	0.8	0.8	160	184
7	J31225	Mrs.V.Amudha	36/F	87	95	93	136	17	17	0.9	0.8	216	210
8	K93196	Mrs.D.Usha	35/F	99	86	128	156	23	14	1.0	0.9	147	` 140
9	K97183	Mr.R.Thangavel	38/M	120	114	160	174	29	28	1.1	0.8	189	196
10	K97582	Mr.S.Sridhar	33/M	91	96	126	132	15	14	1.1	1.0	235	243
11	K98096	Mrs.J,Sasikala	38/F	91	89	97	112	09	15	0.9	0.8	132	133
12	K93479	Mrs.C.Padmavathy	48/F	97	78	126	124	16	21	0.8	0,8	210	190
13	K76850	Mrs.Jeya	48/F	81	89	84	96	17	13	0.9	0.9	161	162
14	K33679	Mrs. Amirtham	46/F	97	97	111	130	14	19	0.8	0.8	157	171
15	L04291	Mrs.E.Komala	43/F	79	75	103	120	11	25	0.8	0.9	190	220
16	L11391	Mrs.R.Jeyasutha	34/F	81	72	112	120	16	14	0.9	0.9	200	175
17	J53379	Mrs.J.Lakshmi	40/F	84	82	114	110	15	19	0.7	0.7	190	180
-18	J12701	Mrs.S.Prema	45/F	100	104	146	160	15	17	0.8	0.9	150	155
19	K16726	Mrs.E.Ponniyammal	44/F	142	136	207	168	17	16	0.9	0.9	192	210
20	L09932	Mr.V.Anbazhagan	46/M	92	87	92	112	34	36	1.4	1.4	155	166

LABARATORY INVESTIGATIONS - BEFORE AND AFTER TREATMENT

S.No	OP No	NAME	AGE/ SEX	Total bilirubin		Calcium		Uric acid	
				BT	AT	BT	AT	BT	AT
1	K46284	Mrs.N.Rajalakshmi	37/F	0.6	0.9	9.1	7.7	6.0	4.8
2	K05839	Mrs.K.Suseela	39/F	0.2	0.2	10.4	10.6	4.3	4.4
3	I18406	Mrs.R.Monika	20/F	0.3	0.4	8.5	8.7	3.2	3
4	K755793	Mr.A.Mahendran	48/M	1.0	0.9	9.3	9.4	4.9	4.8
5	K89095	Mrs.P.N.Poornima	30/F	0.5	0.7	10	11	4.2	4.3
6	K93183	Mr.D,David	48/M	0.5	0.5	9.1	9.6	4	4
7	J31225	Mrs.V.Amudha	36/F	0.7	0.6	8.9	9.5	4.9	4.6
8	K93196	Mrs.D.Usha	35/F	0.2	0.3	8.6	8.8	3.4	3.2
9	K97183	Mr.R.Thangavel	38/M	0.5	0.5	10.2	10.5	3.6	3.6
10	K97582	Mr.S.Sridhar	33/M	-0.7	0.9	10.1	9.9	4.5	4.6
11	K98096	Mrs.J,Sasikala	38/F	0.4	0.3	9.1	9.2	3.5	3.1
12	K93479	Mrs.C.Padmavathy	48/F	0.4	0.4	9.8	9.3	3.3	3.0
13	K76850	Mrs.Jeya	48/F	0.5	0.5	9.2	9.3	4	4.5
14	K33679	Mrs. Amirtham	46/F	0.5	0.3	9.7	9.8	2.6	2.6
15	L04291	Mrs.E.Komala	43/F	0.4	0.3	8.4	9.1	5.3	5.1
16	L11391	Mrs.R.Jeyasutha	34/F	0.7	0.5	9.9	9.1	4.2	3.8
17	J53379	Mrs.J.Lakshmi	40/F	0.8	0.6	9.7	9.5	4	3.3
18	J12701	Mrs.S.Prema	45/F	0.5	0.4	9.8	10.1	5	4.6
19	K16726	Mrs.E.Ponniyammal	44/F	0.6	0.6	9.0	9.0	4.3	4
20	L09932	Mr.V.Anbazhagan	46/M	0.5	0.5	9.5	8.9	5.1	4.5

LABARATORY INVESTIGATIONS - BEFORE AND AFTER TREATMENT

S.No	OP No	NAME	SEX	SGOT		SGPT		Alkaline Phosphatise	
				BT	AT	BT	AT	BT	AT
1	K46284	Mrs.N.Rajalakshmi	37/F	20	19	21	19	103	102
2	K05839	Mrs.K.Suseela	39/F	16	16	15	16	71	81
3	I18406	Mrs.R.Monika	20/F	18	18	15	19	81	90
4	K755793	Mr.A.Mahendran	48/M	20	22	14	17	77	76
5	K89095	Mrs.P.N.Poornima	30/F	25	27	38	39	98	102
6	K93183	Mr.D,David	48/M	16	14	15	14	86	96
7	J31225	Mrs.V.Amudha	36/F	15	15	`15	17	71	76
8	K93196	Mrs.D.Usha	35/F	19	19	12	21	81	65
9	K97183	Mr.R.Thangavel	38/M	13	13	17	17	87	94
10	K97582	Mr.S.Sridhar	33/M	17	12	18	19	53	52
11	K98096	Mrs.J,Sasikala	38/F	19	13	16	13	89	102
12	K93479	Mrs.C.Padmavathy	48/F	12	13	06	13	87	68
13	K76850	Mrs.Jeya	48/F	15	13	10	13	62	73
14	K33679	Mrs. Amirtham	46/F	14	15	09	16	100	107
15	L04291	Mrs.E.Komala	43/F	16	13	14	10	93	93
16	L11391	Mrs.R.Jeyasutha	34/F	18	14	18	12	58	62
17	J53379	Mrs.J.Lakshmi	40/F	18	20	24	19	47	45
18	J12701	Mrs.S.Prema	45/F	16	17	10	16	63	69
19	K16726	Mrs.E.Ponniyammal	44/F	11	13	12	12	89	76
20	L09932	Mr.V.Anbazhagan	46/M	27	23	25	24	88	75

LABARATORY INVESTIGATIONS - BEFORE AND AFTER TREATMENT-11

S. No	OP No	NAME	AGE/ SEX	URINE SUGER (F)		URINE SUGER (PP)		ALBUMIN		DEPOSITS			
										Epithelial cells		Pus cells	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	K46284	Mr.Rajalakshmi	37/F	nil	Nil	nil	nil	nil	Nil	2-3	2-3	1-2	1-2
2.	K05839	Mrs.Suseela	39/F	nil	Nil	nil	nil	nil	Nil	2-5	2-3	1-2	1-2
3.	I18406	Miss.Monika	20/F	nil	Nil	nil	nil	nil	Nil	1-3	1-2	1-3	1-2
4.	K755793	Mr.A.Mahendran	48/M	nil	Nil	nil	nil	nil	nil	1-2	2-3	1-2	2-3
5.	K89095	Mrs.Poornima	30/F	nil	Nil	nil	nil	nil	nil	1-2	3-5	1-2	2-4
6.	K93183	Mr.David	48/M	nil	Nil	nil	nil	nil	nil	1-2	2-4	1-2	2-3
7.	J31225	Mrs.Amutha	36/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	1-2	2-3
8.	K93196	Mrs.Usha	35/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	1-2	1-2
9.	K97183	Mr.Thangavel	38/M	nil	Nil	nil	nil	+	+	1-3	1-2	2-4	2-3
10.	K97582	Mr.Srithar	33/M	nil	Nil	nil	nil	nil	nil	2-3	2-4	1-2	1-2
11.	K98096	Mrs.Sasikala	38/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	2-4	2-3
12.	K93479	Mrs.Padmavathy	48/F	nil	Nil	nil	nil	nil	nil	6-7	Plent -y	1-2	1-2
13.	K76850	Mrs.Jeya	48/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	1-2	1-2
14.	K33679	Mrs.Amirtham	46/F	nil	Nil	nil	nil	nil	nil	1-2	2-4	1-2	1-2
15.	L04291	Mrs.Komala	43/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	2-4	6-7
16.	L11391	Mrs.Jeyasudha	34/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	1-2	1-2
17.	J53379	Mrs.Lakshmi	40/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	1-2	1-2
18.	J12701	Mrs.Prema	45/F	nil	Nil	nil	nil	nil	nil	1-2	1-2	2-3	4-5
19.	K16726	Mrs.Ponniyammal	44/F	Nil	Nil	nil	nil	nil	nil	5-6	2-3	2-4	2-4
20.	L09932	Mr.Anbazhagan	46/M	Nil	Nil	nil	nil	nil	nil	1-2	1-2	2-4	2-3

LABARATORY INVESTIGATIONS - BEFORE AND AFTER TREATMENT

S.No	NAME	AGE/ SEX	Hb (gm/dl)		TOTAL RBC COUNT (millon/ cu.mm)		ESR (mm/hour)		TOTAL WBC COUNT	
			BT	AT	BT	AT	BT	AT	BT	AT
1	Mr.K.Selvam	31/M	17	16.5	5.5	5.5	10/20	10/20	7700	7600
2	Mrs.G.Kajalakshmi	50/F	8.4	9.5	4.0	4.2	20/40	15/32	7400	7300
3	Mrs.K.Omana	52/F	14.2	14.4	5.2	5.2	20/40	10/22	5300	6000
4	Mrs.S.Sunimol	40/F	11.4	12.1	4.2	4.2	30/60	10/20	6200	6200
5	Mr.R.Magesh	20/M	15.1	15.3	4.8	4.8	04/10	22/30	7100	7400
6	Mr.Syednafees	26/M	15.3	15.3	5.5	5.5	24/59	12/24	6600	6600
7	Mrs.M.Ayireen	40/F	10.9	11	4.1	4.1	10/20	16/32	7700	5800
8	Mrs.D.Tmailselvi	37/F	13.9	12.8	4.8	4.5	15/30	10/22	6200	4800
9	Mrs.R.Vijayalakshmi	38/F	11.9	12.2	4.0	4.1	34/70	15/30	6100	6300
10	Mr.Praveen	24/M	14.6	14.8	5.1	5.1	20/40	10/20	7400	7800
11	Mrs.Geetha	38/F	12.2	12.2	4.1	4.1	10/22	10/22	9300	8400
12	Mrs.Ganthimathi	45/F	13.1	12.6	4.5	4.3	30/60	16/32	12400	10900
13	Mr.Krishnamoorthy	37/M	14.5	14.9	5.0	5.0	30/60	10/22	11000	11600
14	Mr.Muruganantham	37/M	14.9	14.9	5.0	5.0	06/12	10/20	8300	8000
15	Mr.R.Shanmugam	39/M	16.5	14.8	5.0	5.3	10/22	2/4	6300	5200
16	Mr.E.Sivakumar	46/M	15.0	15.6	5.2	5.2	10/20	12/26	10600	12600
17	Mrs.K.Muthulakshmi	48/F	12.8	12.8	4.8	4.9	26/54	12/24	10500	9600
18	Mrs.Latha	46/F	10.2	10.2	4.2	4.2	10/20	6/10	9600	9400
19	Mrs.Jeyanthi	36/F	12.2	12	4.3	4.3	20/40	10/16	8200	8600
20	Mrs.G.Rani	41/F	12.8	12.8	4.2	4.2	14/30	10/20	11400	10100

LABARATORY INVESTIGATIONS - BEFORE AND AFTER TREATMENT

S. NO	NAME	SEX	SUGAR FASTING		PP SUGAR		UREA		CREATININE		TOTAL CHOL	
			BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	Mr.K.Selvam	31/M	90.7	95	94	96	20.7	20	1.35	1.02	176	180
2	Mrs.G.Kajalakshmi	50/F	90	95	130	140	14	16	0.5	0.8	185	170
3	Mrs.K.Omana	52/F	83	90	60	102	12	12	1.0	1.0	170	168
4	Mrs.S.Sunimol	40/F	90	80	96	110	10	14	0.9	0.5	164	170
5	Mr.R.Magesh	20/M	97	82	112	96	25	20	1.0	0.9	146	123
6	Mr.Syednafees	26/M	98	86	132	116	24	24	1.1	0.9	218	186
7	Mrs.M.Ayireen	40/F	92	91	120	136	16	13	0.8	0.9	231	222
8	Mrs.D.Tmailselvi	37/F	89	77	117	120	22	21	1.0	0.8	170	155
9	Mrs.R.Vijayalakshmi	38/F	102	100	131	110	16	14	1.0	1.0	255	100
10	Mr.Praveen	24/M	92	86	112	123	16	19	29	28	76	85
11	Mrs.Geetha	38/F	103	95	160	142	11	08	0.7	0.7	171	159
12	Mrs.Ganthimathi	45/F	101	97	140	158	20	21	0.8	0.7	284	282
13	Mr.Krishnamoorthy	37/M	86	93	133	154	20	20	1.0	0.9	138	184
14	Mr.Muruganantham	37/M	74	82	126	132	26	20	1.0	0.9	187	190
15	Mr.R.Shanmugam	39/M	85	84	112	132	21	17	1.0	0.9	215	226
16	Mr.E.Sivakumar	46/M	86	92	142	113	14	14	1.1	1.1	250	256
17	Mrs.K.Muthulakshmi	48/F	130	112	189	174	16	16	0.8	0.8	183	198
18	Mrs.Latha	46/F	110	102	146	154	14	14	0.8	0.8	168	172
19	Mrs.Jeyanthi	36/F	102	112	162	152	17	18	0.8	0.8	178	210
20	Mrs.G.Rani	41/F	80	82	134	146	18	16	1.0	1.0	217	220

LABARATORY INVESTIGATIONS IP - BEFORE AND AFTER TREATMENT

S.No	NAME	AGE/ SEX	Total Bilirubin		Calcium		Uric acid	
			BT	AT	BT	AT	BT	AT
1	Mr.K.Selvam	31/M	0.67	0.67	9.5	9.7	4	3.8
2	Mrs.G.Kajalakshmi	50/F	0.5	0.5	9.5	9.5	4.2	4.4
3	Mrs.K.Omana	52/F	0.5	0.5	8.9	9.0	5	4.5
4	Mrs.S.Sunimol	40/F	0.6	0.6	8.0	8.4	4.0	4.0
5	Mr.R.Magesh	20/M	0.7	0.7	9.1	9.1	4.0	4.0
6	Mr.Syednafees	26/M	0.8	0.8	9.2	9.1	7.1	6.1
7	Mrs.M.Ayireen	40/F	0.2	0.3	10	8.9	3.7	4.3
8	Mrs.D.Tmailselvi	37/F	0.3	0.3	8.5	8.5	4.2	4.2
9	Mrs.R.Vijayalakshmi	38/F	0.7	0.7	9.6	9.8	4.9	4.0
10	Mr.Praveen	24/M	0.6	0.6	9.8	9.8	5.0	5.0
11	Mrs.Geetha	38/F	0.8	1.1	9.3	9.4	3.9	3.2
12	Mrs.Ganthimathi	45/F	0.4	0.5	8.6	9.3	4.6	5.0
13	Mr.Krishnamoorthy	37/M	1.0	1.0	8.6	9.3	4.8	4.3
14	Mr.Muruganantham	37/M	o.7	0.6	9.1	9.3	5.6	4.7
15	Mr.R.Shanmugam	39/M	0.2	0.5	9.3	7.7	6.0	5.3
16	Mr.E.Sivakumar	46/M	0.4	0.4	9.3	10.3	5.9	6.3
17	Mrs.K.Muthulakshmi	48/F	1.1	1.1	8.6	8.8	4.0	4.2
18	Mrs.Latha	46/F	0.6	0.6	9.1	9.2	5.2	4.5
19	Mrs.Jeyanthi	36/F	0.4	0.4	8.5	9.1	4.8	4.3
20	Mrs.G.Rani	41/F	0.6	0.6	9.5	9.8	5.2	4.5

LABARATORY INVESTIGATIONS IP - BEFORE AND AFTER TREATMENT

S.No	NAME	AGE/ SEX	SGOT		SGPT		Alkaline phosphatase	
			BT	AT	BT	AT	BT	AT
1	Mr.K.Selvam	31/M	26.4	26	28.6	28	129	130
2	Mrs.G.Kajalakshmi	50/F	24	23	24	27	102	102
3	Mrs.K.Omana	52/F	17	17	15	15	86	90
4	Mrs.S.Sunimol	40/F	14	14	11	11	92	92
5	Mr.R.Magesh	20/M	29	29	49	32	92	93
6	Mr.Syednafees	26/M	22	20	24	18	75	76
7	Mrs.M.Ayireen	40/F	19	20	13	23	83	96
8	Mrs.D.Tmailselvi	37/F	17	17	24	24	47	48
9	Mrs.R.Vijayalakshmi	38/F	33	40	59	40	87	87
10	Mr.Praveen	24/M	33	34	29	25	71	76
11	Mrs.Geetha	38/F	16	15	15	15	43	41
12	Mrs.Ganthimathi	45/F	10	17	20	22	111	111
13	Mr.Krishnamoorthy	37/M	32	28	57	40	119	120
14	Mr.Muruganantham	37/M	23	22	26	24	75	87
15	Mr.R.Shanmugam	39/M	26	41	51	65	81	74
16	Mr.E.Sivakumar	46/M	26	26	30	30	126	120
17	Mrs.K.Muthulakshmi	48/F	13	14	17	17	100	92
18	Mrs.Latha	46/F	10	17	20	22	110	120
19	Mrs.Jeyanthi	36/F	15	17	18	22	86	97
20	Mrs.G.Rani	41/F	15	15	18	15	91	86

LABARATORY INVESTIGATIONS OP - BEFORE AND AFTER TREATMENT

S. No.	Name	Age/ Sex	URINE SUGER(F)		URINE SUGER (PP)		ALBUMIN		DEPOSITS			
									Epithelial cells		Pus cells	
			BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1.	Mr.K.Selvam	31 /M	nil	nil	nil	nil	nil	nil	1-2	1-2	1-2	1-2
2.	Mrs.G. Kajalakshmi	50/F	nil	nil	nil	nil	nil	nil	1-2	2-3	1-2	2-3
3.	Mrs. K. Omana	52/F	nil	nil	nil	nil	nil	nil	1-2	1-2	1-2	1-2
4.	Mrs.S. Sunimol	40/F	nil	nil	nil	nil	nil	nil	1-2	1-2	1-2	1-2
5.	Mr.R. Magesh	20/M	nil	nil	nil	nil	nil	nil	1-2	3-5	1-2	2-4
6.	Mr.Syednafees	26/M	nil	nil	nil	nil	nil	nil	1-2	1-2	2-4	1-3
7.	Mr. M.Ayireen	40/F	nil	nil	nil	nil	nil	nil	1-2	1-2	2-4	1-2
8.	Mrs.D.Tamilselvi	37/F	nil	nil	nil	nil	nil	nil	3-4	2-4	1-2	1-2
9.	Mrs.R.Vijayalakshmi	38/F	nil	nil	nil	nil	nil	nil	2-3	2-3	1-3	2-3
10.	Mr.Praveen	24/M	nil	nil	nil	nil	nil	nil	1-2	2-4	1-2	2-3
11.	Mrs. Geetha	38/F	nil	nil	nil	nil	nil	nil	1-2	3-4	1-2	1-2
12.	Mrs. Ganthimathi	45/F	nil	nil	nil	nil	nil	nil	1-2	1-2	1-2	3-5
13.	Mr.Krishnamoorthy	37/M	nil	nil	nil	nil	nil	nil	1-2	2-4	2-3	2-3
14.	Mr. Muruganantham	37/M	nil	nil	nil	nil	nil	nil	1-2	1-2	1-3	2-4
15.	Mr.R. Shanmugam	39/M	nil	nil	nil	nil	nil	nil	1-2	2-3	1-2	2-3
16.	Mr.E. Sivakumar	46/M	nil	nil	nil	nil	nil	nil	1-2	2-4	1-3	2-4
17.	Mrs. K. Muthulakshmi	48/F	nil	nil	nil	nil	nil	nil	4-6	2-3	4-6	1-2
18.	Mrs. Latha	46/F	nil	nil	nil	nil	nil	nil	2-3	1-3	2-4	1-2
19.	Mrs. Jeyanthi	36/F	nil	nil	nil	nil	nil	nil	2-4	2-4	2-4	2-4
20.	Mrs. G. Rani	41/F	nil	nil	nil	nil	nil	nil	1-2	1-2	1-2	2-3

DISCUSSION

The retrospective review of the disease *Vathasthambam* mentioned in Siddha literatures begins from the correlation of it to signs and symptoms of the disease Sciatica.

The drugs which possess anti-*vatha* 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 under the supervision of the members of the teaching faculty and guided by the Head of the Department of *SirappuMaruthuvam* of the National Institute of Siddha, Chennai - 47.

40 patients of both genders were recruited for this study. Among 40 patients, 20 patients were treated with *Varmam* treatment along with the trial drugs, remaining 20 patients with trial Medicines only.

The treatment was aimed to normalizing the deranged *Thodams* and providing relief from symptoms. Before treatment the patients were advised to take *Meganatha kuligai*-2 with warm water in empty stomach at early morning for purgation. The patient was advised to take rest without internal medicine and other activities on that day.

The patients were treated with trial drugs *RAAJAMAARTHANDHA ILAGAM* twice a day in a dosage of 6gm, and *VAATHAKAJAKESARI THYLAM* external for 45 days. Patients were instructed to take the Medicines regularly advised to follow the dietary regimen and advised to avoid weight bearing, long travelling and strenuous activities. Out-Patients were asked to visit the hospital once in 7 days. For Out-Patients the drugs were given for 45 days and the clinical assessment was done under the supervision of the faculty on 0^{th} day, 7^{th} day, 14^{th} day, 21^{st} day, 28^{th} day, 35^{th} day, 42^{nd} day and 45^{th} day.

For In-Patients the drugs were given for 45 days and the clinical assessment was done daily. 20 Patients were treated with *varmam* along with trial drugs. The results were

compared at the end of the study. For In-Patients, who are not in a situation to stay in the hospital for a long time, were advised to attend the Out-Patient Department of *SirappuMaruthuvam* for further follow- up.

Regarding age, 45% of the affected patients comes under the age group between 31-40 years.40% of the patients comes under the age group between 41-50 years .12.5% of them are between 20-30 and the remaining 5% patients comes under the age the group of 51-60 years. This present study reports coincides with the recent incidence that indicates that the onset is most frequent during third, fourth decades of life. About 80% of all patients developing this disease between the ages 31 -50.

On screening the **gender distribution,** the present study showed that a maximum of 67.5% of the patients fall upon females and only 32.5% were males. This indicates the prevalence of this disease more in females among the 40 patients.

While seeing the **socio-economic status** of the reported patients the data revealed that 25% of the patients were from low income group, 55% of them from middle income group and only 20% of them came from high income group, this condition invariably affects all socio- economic groups.

Dietary habits of all the reported patients were noted down and it is inferred from that all the 100% of the patients were non-vegetarians. Diet doesn't seem to possess any influence over the disease according to modern science. But the non-vegetarian diet increasing the symptoms of vatham disease according to siddha literature.

In the ***kaalam* distribution**, about 47.5% of the cases are repoted in *Munpanikaalam (margazhi,thai)*, 17.5% in *pinpanikalam (maasi,panguni)*,25% in *Koothir kalam (ipasi,karthigai)* and remaining 10% of the patients reported in *kaar kalam (avani, puratasi*).

Naadiexamination in all the 40 patients showed that *vathapithamnaadi* was felt in7.5% of the cases, 87.5% of them had *Pithavathamnaadi*, 5% of the cases had *pithakabam*.

In the reported 40 patients 100% of patients had *Rajogunam*.

In ***Vatham****: Viyanan, Samanan*were affected in all the 40 cases.

In ***Pitham****: Saathagam* was affected in all the 40 cases.

In ***Kabam****: Avalambagam*and*santhigam* was found to be affected in all 40cases.

In ***Kanmendriangal****: Kaal* affected in all 40 patients.

In **7** ***Udalkattukal****: Saaram, seneer, oon, kozuppu and enbu*were affected in most of the cases.

In 32.5% of the patient's **duration of illness** is within 1 month, 40% in 1-3 months, 20% in 3-6 months, 2.5% in 6months to 1 year and remaining 5% of patients affected more than 1 year.

The clinical study reveals that **the onset** is gradual in 57.5% of the patients and sudden in 42.5% of patients.

According to clinical features low back pain, radiating pain in limbs, numbness, paraesthesia, pain aggravates after coughing and sneezing occurred in most of the cases. Clinical features vary according to age and duration of illness. Among 40 cases, all of them had all the inclusion criteria. After treatment, 5 cases (12.5%) had moderate low back pain, one case (2.5%) had radiating pain, 12 cases (30%) had Grade 2 numbness (occasionally), 5 cases (12.5%) experiences the moderate low back pain while coughing, prolonged walking and standing, 10 cases (25%) had difficulty in bending and lifting.

Occupation of the patients is also an important cause for sciatica.Among the 40 patients recruited, the prevalence were more in Housewives 10 (25%), 6 (15%) were in construction work, 4 (10%) were in farmers and company, sales department, 2 (10%) were in tailor, students, cooking job and business man and 1 (5%) were in driver, accountant, IT sector, security, civil engineer, nurse and painter.

Laboratory investigations of blood and urine were done for all 40 cases. There were no significant changes in blood and urine parameters before and after treatment.

The radiographic studies of the cases showed narrowed IV-disc space and presence of osteophytes in some cases.

The trial drug showed improvement in prognosis of the disease clinically.

The total study showed that out of the 40 patients, **65% of the patients had move from severe to mild pain, 12.5% of patients move from severe pain to no pain, 2.5% of the patients move from moderate to no pain, 12.5% of patients move from severe to moderate pain and remaining7.5% of the patients move from moderate to mild pain. improvement.**

20 patients were given *Varmam*treatment along with the trial drug. The results were compared at the end of the study. Patients treated with *Varmam* showed good results since there was reduction in the Symptoms of patients in this clinical trial. The mean pain score before treatment was 7.95; after treatment it was reduced to 1.15. **Hence, this study reveals that *varmam*treatment along with trial medicine has better effect in the treatment of sciatica.**

SUMMARY

The 40 cases of *Vathasthambam* were diagnosed clinically and 20 cases of them were treated with the trial drugs and the rest of the 20 cases were treated with trial drugs and *varmam* therapy in inpatient ward and outpatient unit, department of *SirappuMaruthuvam* in AyothidossPandithar Hospital attached to National Institute of siddha, Tamabaram Sanitorium, Chennai - 47.

The Study Protocol was approved by Institutional Ethics committee (NIS/13-IEC/2017-1-07/22-11-2017). Before initiating the clinical trial, it was registered in Clinical Trials Registry of India and the registration number Ref No Is: CTRI/2018/08/015538.

Among the 40 patients, 20 patients were treated by *varmam* treatment along with the trial medicine for 45 days. Rest of 20 patients were treated with trial drug for 45 days.

The various Siddha methods of examination of the disease were carried out and the data were recorded in the prescribed Proforma for the 40 selected cases.

Initially before starting the treatment, purgation was given by administering Meganathakulgai -2 with warm water in empty stomach at early morning to bring the Thirithodam to equilibrium.

From the second day onwards *RAAJAMAARTHANDHA ILAGAM – KOTTAI PAAKALAVU (*6gm twice a day) was given internally and *VAATHAKAJAKESARI THYLAM* for external use were given to the patients.

During the period of treatment all the patients were advised for *Pathiyam* (specific dietary regimen chart for the disease given to each patients).

Laboratory investigations were done periodically 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 and external drugs were effective in relieving the pain in *Vathasthambam* patients. During the study period, there was no serious adverse event reported. As per the Siddha Literature and recent research articles, the ingredients of the trial drugs were found to have anti-inflammatory, analgesic, anti-spasmodic, immunomodulator and anti-oxidant properties owing to the disease manifestations

The mean pain score before treatment is 7.62, after treatment it is reduced to 1.825. Hence this study reveals patients treated with trial drugs and *varmam* showed good improvement when compared to those who were treated only with trial drugs. Statistical analysis showed extremely significant reduction in the pain score and questionnaire before and after treatment.

CONCLUSION

The clinical trial attests the efficacy of the trial drugs by reducing the clinical signs and symptoms like low back pain, radiating pain, numbness and restricted movements and provides better improvement. **The study results show that improvement of severe to no pain in 5 cases (12.5%), severe to mild pain in 26 cases (65%), severe to moderate pain in s cases (12.5%), moderate to no pain in 1 case (2.5%), moderate to mild pain in 3 cases 1(7.5%)**.

Thus, these results revealed good relief from the disease after treatment.The trial medicines were prepared from easily available ingredients and the palatability of medicine is better and the dosage is also convenient. **Patients treated with trial drugs and*varmam* showed better improvement when compared to those who were treated only with trial drugs.** When these affected individuals get a better management with this trial drug and *Varmam*, it would be a great useful medication.

In preclinical study, acute and 28 days repeated oral toxicity study trial drug does not produce any toxicity in animal model. So, the drug is safe to use in human population. In this trial there was no serious adverse effect were reported. Hence the drugs were proven for their safety. The clinical trial conducted in selected patients was satisfactory encouraging. Further elaborative studies may be taken up to establish the efficacy of the drug.

BIO-CHEMICAL AND ELEMENTAL ANALYSIS

Qualitative Analysis

S.No	EXPERIMENT	OBSERVATION	RESULT
1.	Apperance of the sample	Dark brown in colour	
2.	**Solubility:** a. A little of the sample is shaken well with distilled water. b. A little of the sample is Shaken well with con. Hcl Con. H_2SO_4.	Sparingly soluble Completely soluble	Insoluble Presence of Silicate
3.	**Action of Heat:** A small amount of the sample is taken in a dry test tube and heated gently at first and then Strong.	Brown fumes not evolved	Absence of Nitrate.
4	**Ash Test:** A filter paper is soaked into a mixture of sample and cobalt nitrate solution and introduced into the Bunsen flame and ignited.	No Yellow colour flame.	Absence of Sodium.

Preparation of the Extract

5 gm of ***Raajamaarthandhailagam*** was weighted accurately and placed in a 250 ml clean beaker. Then 50 ml distilled water was added and dissolved well. Then it is boiled well for about 10 minutes. It was cooled and filtered in a 100 ml volumetric flask and then it was made up to 100 ml with distilled water. This fluid was taken for analysis.

SL. NO.	EXPERIMENT	OBSERVATION	INFERENCE
TEST FOR ACID RADICALS			
1.	**Test For Sulphate:** a. 2 ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution. b. 2ml of the above prepared extract is added with 2 ml of dil-Hcl is added until the effervescence ceases off. Then 2ml of Barium chloride solution is added.	Cloudy appearance present A white precipitate Insoluble in con.HCl present	Presence of Sulphate. Sulphate is confirmed
2.	**Test For Chloride:** 2 ml of the above prepared Extract is added with dil. HNO_3 till the effervescence ceases. Then 2 ml of silver nitrate solution is added.	Cloudy Appearance present.	Presence of Chloride.
3.	**Test For Phosphate:** 2 ml of the extract is treated with 2ml of ammonium molybdate solution and 2 ml of con. HNO_3	Cloudy yellow Appearance present	Presence of Phosphate.
4.	**Test For Carbonate:** 2m1 of the extract is treated with 2m1 magnesium sulphate solution	Cloudy appearance	**Presence of Carbonate.**

II. TEST FOR BASIC RADICALS			
1	**Test For Lead:** 2 m1of the extract is added with 2m1of potassium iodide solution.	Yellow precipitate is obtained	Presence of Lead.
2.	**Test For Aluminium:** Take the 2m1of the extract sodium hydroxide is added in drops to excess.	characteristic Changes present	Presence of Aluminium.
3.	**Test For Iron: (Ferrous)** To the 2 ml of extract 2m1 ammonium thiocyanate solution and 2m1of con.HNO_3 is added.	Blood red colour Appearance	Presence of Iron.
4.	**Test For Zinc:** To 2m1 of the extract sodium hydroxide solution is added in drops to excess.	White precipitate is Formed	**Presence Of Zinc.**
5.	**Test For Calcium:** 2m1 of the extract is added with 2m1 of 4% ammonium oxalate	Cloudy appearance and white	Presence of Calcium.

	Solution.	precipitate is obtained	
6.	**Test For Magnesium:** To 2ml of extract sodium hydroxide solution is added in drops to excess.	White precipitate is obtained.	**Presence of Magnesium**.
7.	**Test For Ammonium:** To 2ml of extract few ml of Nessler's reagent and excess of sodium hydroxide solution are added.	No brown colour appeared.	**absence of Ammonium**.
8.	**Test For Potassium:** A pinch of substance is treated with 2ml of sodium nitrite solution and then treated with 2m1 of cobalt nitrate in 30% glacial acetic acid.	No Yellowish precipitate is obtained	Absence of Potassium.
9.	**Test For Mercury:** 2m1 of the extract is treated with 2ml of sodium hydroxide solution.	Yellow precipitate is obtained	Presence of Mercury.

10.	**Test For Arsenic:** 2m1 of the extract is treated with 2m1 of sodium hydroxide solution.	brownish red Precipitate is obtained	Presence of Arsenic.
III. MISCELLANEOUS			
1.	**Test for Starch:** 2ml of extract is treated with weak iodine solution.	Blue colour developed	**Presence of Strarch.**
2.	**Test For Reducing Sugar:** 5. ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.	Brick red colour developed	**Presence of Reducing sugar**.

3.	**Test For The Alkaloids:** a. 2m1 of the extract is treated with 2ml of potassium Iodide solution. b. 2m1 of extract is treated with 2ml of picric acid. c. 2m1 of the extract is treated with 2ml of phosphotungstic acid.	No red colour developed Trace Yellow colour developed No White precipitate developed	**Presence of Alkaloid.** **Trace of Alkaloid present.** **Presence of Alkaloid.**
4.	**Test for Tannic Acid:** 2ml of extract is treated with 2ml of ferric chloride solution.	Black precipitate is obtained	**Presence of Tannic acid.**

5.	**Test For type of Compound:** 2ml of the extract is treated with 2 ml of ferric chloride solution.	No Green colour developed No Red colour developed No Violet colour developed blue colour developed	Absence of oxy quinole epinephrine and pyro catechol. Anti pyrine, Aliphatic amino acids and Meconic acid are absent. Apomorphine, Salicylate and Resorcinol are absent. Morphine, Phenol cresol and hydro quinone are Present

RESULT:

The Bio-chemical analysis of *Raajamaarthandhailagam*had shown the presence of Carbonate, Zinc, Magnesium, Ammonium,Reducing sugar, Tannic acid, starch, unsaturated compound and Alkaloids

2.	**Solubility:** a. A little of the sample is shaken well with distilled water. b. A little of the sample is Shaken well with con. Hcl Con. H_2SO_4.	Completely soluble Completely soluble	 Absence of Silicate
3.	**Action of Heat:** A small amount of the sample is taken in a dry test tube and heated gently at first and then Strong.	White fumes not evolved Brown fumes not evolved	Absence of Carbonate. Absence of Nitrate.
4.	**Flame Test:** A small amount 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.	White flame is appeared	Absence of Copper.
5	**Ash Test:** A filter paper is soaked into a mixture of sample and cobalt nitrate solution and introduced into the Bunsen flame and ignited.	No Yellow colour flame.	Absence of Sodium.

Preparation of the Extract

5 gm of ***Mudakkuvathalegium*** was weighted accurately and placed in a 250 ml clean beaker. Then 50 ml distilled water was added and dissolved well. Then it is boiled well for about 10 minutes. It was cooled and filtered in a 100 ml volumetric flask and then it was made up to 100 ml with distilled water. This fluid was taken for analysis.

SL. NO.	EXPERIMENT	OBSERVATION	INFERENCE
TEST FOR ACID RADICALS			
1.	**Test For Sulphate:** a. 2 ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution. b. 2ml of the above prepared extract is added with 2 ml of dil-Hcl is added until the effervescence ceases off. Then 2ml of Barium chloride solution is added.	Cloudy appearance not present A white precipitate not present	Absense of Sulphate. Absense of Sulphate.
2.	**Test For Chloride:** 2 ml of the above prepared Extract is added with dil. HNO_3 till the effervescence ceases. Then 2 ml of silver nitrate solution is added.	No Cloudy appearance	Absence of Chloride.
3.	**Test For Phosphate:** 2 ml of the extract is treated with 2ml of ammonium molybdate solution and 2 ml of con. HNO_3	No Cloudy yellow appearance	Absence of Phosphate.
4.	**Test For Carbonate:** 2m1 of the extract is treated with 2m1 magnesium sulphate solution	Cloudy appearance	**Presence of Carbonate.**

5	**Test For Nitrate:** 1gm of the substance is heated with copper turnings and concentrated H_2SO_4 and viewed the test tube vertically down.	Brown gas is not evolved	Absenceof Nitrate.
6.	**Test For Sulphide:** 1 gm of the substance is treated with 2m1 of con. Hcl.	No Rotten egg smelling gas evolved	Absence of Sulphide.
7.	Test for fluoride & oxalate 2 m1 of The Extract Is Added With 2m1of Acetic Acid and 2 m1 calcium Chloride solution and heated.	No Cloudy appearance.	Absence of Fluoride & Oxalate
8.	Test for Nitrite: 3drops of extract is placed on a filter paper,on that 2 drops of acetic Acid and 2 drops of benzidine solution is placed.	No characteristic Changes.	Absence of nitrite.
9.	**Test For Borate:** 2 pinches of the substance is made into paste by using sulphuric acid and alcohol (95%) and introduced into the blue flame.		Absence of borate.

II. TEST FOR BASIC RADICALS			
1	**Test For Lead:** 2 m1of the extract is added with 2m1of potassium iodide solution.	No Yellow precipitate is obtained	Absence of Lead.
2.	**Test for Copper:** a. One pinch of substance is made into paste with con. Hcl in a watch glass and introduced into the non-luminous part of the flame. b. 2 ml of extract is added with excess of ammonia solution.	No Blue colour flame precipitate No Blue colour precipitate	Absence of Copper. Absence of Copper.
3.	**Test For Aluminium:** Take the 2m1of the extract sodium hydroxide is added in drops to excess.	No characteristic changes	Absence of Aluminium.
4.	**Test For Iron: (Ferrous)** To the 2 ml of extract 2m1 ammonium thiocyanate solution and 2m1of con.HNO_3 is added.	No Blood red colour Appearance	Absence of Iron.
5.	**Test For Zinc:** To 2m1 of the extract sodium hydroxide solution is added in drops to excess.	White precipitate is Formed	**Presence of Zinc.**
6.	**Test For Calcium:** 2m1 of the extract is added with 2m1 of 4% ammonium oxalate	Cloudy appearance and white	Absence of Calcium.

	Solution.	precipitate is obtained	
7.	**Test For Magnesium:** To 2ml of extract sodium hydroxide solution is added in drops to excess.	White precipitate is obtained.	**Presence of Magnesium**.
8.	**Test For Ammonium:** To 2ml of extract few ml of Nessler's reagent and excess of sodium hydroxide solution are added.	Brown colour appeared.	**Presence of Ammonium**.
9.	**Test For Potassium:** A pinch of substance is treated with 2ml of sodium nitrite solution and then treated with 2m1 of cobalt nitrate in 30% glacial acetic acid.	No Yellowish precipitate is obtained	Absence of Potassium.
10.	**Test For Sodium:** 2 pinches of the substance is made into paste by using HCL and introduced into the blue flame of Bunsen burner.	No Yellow colour Flame appeared.	Absence of Sodium.
11.	**Test For Mercury:** 2m1 of the extract is treated with 2ml of sodium hydroxide solution.	Yellow precipitate is not obtained	Absence of Mercury.

12.	**Test For Arsenic:** 2m1 of the extract is treated with 2m1 of sodium hydroxide solution.	No brownish red Precipitate is obtained	Absence of Arsenic.
III. MISCELLANEOUS			
1.	**Test for Starch:** 2ml of extract is treated with weak iodine solution.	Blue colour developed	**Presence of Strarch.**
2.	**Test For Reducing Sugar:** 5. ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.	Brick red colour developed	**Presence of Reducing sugar**.

3.	**Test For The Alkaloids:** a. 2m1 of the extract is treated with 2ml of potassium Iodide solution. b. 2m1 of extract is treated with 2ml of picric acid. c. 2m1 of the extract is treated with 2ml of phosphotungstic acid.	Red colour developed Trace Yellow colour developed White precipitate developed	**Presence of Alkaloid.** **Trace of Alkaloid present.** **Presence of Alkaloid.**
4.	**Test for Tannic Acid:** 2ml of extract is treated with 2ml of ferric chloride solution.	Black precipitate is obtained	**Presence of Tannic acid.**
5.	**Test for Unsaturated Compound:** To the 2ml of extract 2ml of Potassium Permanganate solution is added.	Potassium Permanganate is decolourised	**Presence of Unsaturated Compound.**
6.	**Test For Amino Acid:** 2 drops of the extract is placed on a filter paper and dried well and 2 ml of biuret reagent is added	No Violet colour developed	Absence of Amino acids.

7.	**Test For type of Compound:** 2ml of the extract is treated with 2 ml of ferric chloride solution.	No Green colour developed No Red colour developed No Violet colour developed No blue colour developed	Absence of oxy quinole epinephrine and pyro catechol. Anti pyrine, Aliphatic amino acids and Meconic acid are absent. Apomorphine, Salicylate and Resorcinol are absent. Morphine, Phenol cresol and hydro quinone are absent

RESULT:

The Bio-chemical analysis of *Mudakkuvathalegium*had shown the presence of Silicate, sulphate, Cloride, Phosphate, Carbonate, lead, aluminium, mercury, Zinc, Magnesium, calcium, arsenic, starch, reducing sugar, alkaloid, tannic acid.

CERTIFICATES

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. K. AARTHY

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. K. AARTHY 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

(2)

CERTIFICATE

This is certify that the project title **To evaluate the safety profile of "*Raajamaarthandailagam*" – acute and subacute toxicity study** hasbeen approved by the IAEC. Total No. of animals approved: 46 Rats (20M+26F)

IAEc approval No: NIS/IAEC.VI/24042018/08

Professor.Dr.V.Banumathi	**Dr.K.Nachimuthu**
Name of Chairman/Member Secretary IAEC:	**Name of CPCSEA nominee**

Signature with date:

V. Banumathi 24/4/2018

Chairman/Member Secretary of IAEC:

24/4/2018

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.K.Aarthy, II[nd] PG scholar.
Name of the Department	:	Sirappu Maruthuvam
Name of the guide	:	Dr.M.V.Mahadevan, Lecturer, Department of Sirappu Maruthuvam, National Institute of Siddha.

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Raajamaarthanda Ilagam"** (Internal) and **"Vaatha Kaja Kesari Thylam"** (External) taken up for Post Graduation Dissertation studies by **Dr.K.Aarthy** M.D.(S), II year, Department of Sirappu Maruthuvam, 2018, are identified Botanically as

Elettaria cardamomum Maton (Zingiberaceae), Seed
Syzygium aromaticum (Linn.) Merr. & L.M. Perry (Myrtaceae), Flower bud
Ferula foetida Regel. (Apiaceae), Gum-oleoresin
Piper longum Linn. (Piperaceae), Fruit
Piper longum Linn. (Piperaceae), Root
Myristica fragrans Houtt. (Myristicaceae), Nut
Clerodendrum serratum Linn. (Verbenaceae), Root
Cyperus rotundus Linn. (Cyperaceae), Tuber
Cuminum cyminum Linn. (Apiaceae), Fruit
Nigella sativa Linn. (Ranunculaceae), Seed
Mesua ferrea Linn.(Clusiaceae) Flower
Maranta arundinacea Linn. (Marantaceae), Rhizome
Azima tetracantha Lam. (Salvadoraceae), Root
Solanum surattense, Burm.f (Solanaceae), Fruit
Piper nigrum Linn. (Piperaceae), Root
Pavonia zeylanica Cav. (Malvaceae), Root
Vettiveria zizanoides (Linn.) Nash (Poaceae), Root
Plumbago zeylanica Linn. (Plumbaginaceae), Root & Root bark
Tinospora cordifolia (Willd.) Meirs (Menispermaceae), Stem
Aegle marmelos (L.) Corr.Serr. (Rutaceae), Root
Curculigo orchioides Gaertn. (Amaryllidaceae), Rhizome
Zingiber officinale Rosc. (Zingiberaceae), Dried Rhizome
Piper nigrum Linn. (Piperaceae), Fruit
Carum copticum Benth & Hook. f. (Apiacea), Fruit
Datura metel Linn. (Solanaceae), Leaves
Cinnamomum camphora Linn. (Lauraceae), Resin
Sesamum indicum Linn. (Pedaliaceae), Seed oil

CHENNAI 600 047

Certificate No: NISMB3402018
Date: 02-07-2018

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

Clinical Trial Details (PDF Generation Date :- Wed, 17 Jul 2019 18:46:07 GMT)

CTRI Number	CTRI/2018/08/015538 [Registered on: 30/08/2018] - **Trial Registered Prospectively**
Last Modified On	28/08/2018
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 low back ache through siddha system of medicines and varmam therapy in adult.
Scientific Title of Study	Pre clinical and comparative clinical trial of siddha drugs Rajamaarthaanda Ilagam internally and Vaathakajakesari Thylam externally in the treatment of Vathasthambam (Sciatica) with and without varmam therapy

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
Name	Dr Aarthy K
Designation	PG Scholar
Affiliation	National Institute of Siddha
Address	National Institute of Siddha, Tambaram sanatorium, Chennai-47, Tamil Nadu. _ Kancheepuram TAMIL NADU 600047 India
Phone	9095897133
Fax	-
Email	aarthybsms@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr MV Mahadevan MDs
Designation	Lecturer
Affiliation	National Institute of Siddha
Address	National Institute of Siddha, Tambaram sanatorium, Chennai-47, Tamil Nadu. - Chennai TAMIL NADU 600047 India
Phone	9789633690
Fax	-
Email	mahasiddha2009@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Aarthy K
Designation	PG scholar
Affiliation	National Institute of Siddha
Address	National Institute of Siddha, Tambaram sanatorium, Chennai-47, Tamil Nadu. - Chennai TAMIL NADU 600047

		India
	Phone	9789633690
	Fax	-
	Email	aarthybsms@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> National Institute of Siddha, Tambaram sanatorium, Chennai-47.

Primary Sponsor

Primary Sponsor Details	
Name	Dr Aarthy K
Address	National Institute of Siddha, Tambaram sanatorium, Chennai-47.
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Aarthy K	Ayothidoss pandithar hospital, National Institute of Siddha	Op no-3, Dept of Sirappu Maruthuvam, Kancheepuram TAMIL NADU	9095897133 - aarthybsms@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	Rajamaarthaanda Ilagam Vaathakajakesari Thylam Varmam	Rajamaarthaanda Ilagam Internally Vaathakajakesari Thylam Externally Varmam (external therapy)
Comparator Agent	NIL	NIL

Inclusion Criteria

Inclusion Criteria	
Age From	20.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	Low back pain radiating to lower limb posterolaterally Numbness and paresthesia Low back ache aggravates after prolonged standing and walking Difficulty in bending and lifting Coughing exacerbate the low back pain Patients willing to undergo radiological investigation and Laboratory investigations. Patients willing to sign the informed consent stating that he/she will conscientiously stick to the treatment during 45 days but can opt out of the trial of his/her owns conscious discretion.

Exclusion Criteria

Exclusion Criteria	
Details	H/o Type 1 Diabetes mellitus H/o uncontrolled dyslipidaemia Spondylolisthesis Rheumatoid arthritis Tuberculous arthritis Pyogenic bone infection Vertebral fracture Tumor in vertebral body Osteochondritis Metabolic bone disease Limb weakness and foot drop Ankylosing spondylitis Spinal deformity Sexually transmitted disease Bowel and bladder incontinence

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
To relieve the pain and it will be assessed by universal pain assessment scale	45 days

Secondary Outcome

Outcome	Timepoints
NIL	NIL

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	10/09/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**1 **Days=**10
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	To evaluate the therapeutic efficacy of siddha drugs ***RAJAMAARTHANDA ILAGAM*** (Internal) and ***VAATHAKAJA KESARI THYLAM*** (external) in reducing the pain of ***VATHASTHAMBAM*** (SCIATICA) through clinical study.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUGS***"RAJAMAARTHAANDA ILAGAM"*** (INTERNAL) AND **"VAATHAKAJAKESARI THYLAM"** (EXTERNAL) IN THE TREATMENT OF ***"VATHASTHAMBAM"*** (SCIATICA) WITH AND WITHOUT VARMAM THERAPY.

Principal Investigator: Dr.K.Aarthy

FORM I - SCREENING & SELECTION PROFORMA

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

INCLUSION CRITERIA:

- ✓ Age: 20 - 60 Yrs. YES/ NO
- ✓ Sex: male, female and transgender YES/ NO
- ✓ Low back pain radiating to lower limb posterolaterally YES/ NO
- ✓ Numbness and paresthesia YES/ NO
- ✓ Low back ache aggravates after prolonged standing and walking YES/ NO
- ✓ Difficulty in bending and lifting YES/ NO
- ✓ Coughing exacerbate the low back pain YES/ NO
- ✓ Patients willing to undergo radiological investigation and Laboratory investigations. YES/ NO
- ✓ Patients willing to sign the informed onsent stating that he/she will conscientiously stick to the treatment during 48 days but can opt out of the trial of his/her own conscious discretion. YES/ NO

EXCLUSION CRITERIA

- H/o Type 1 Diabetes mellitus YES/ NO
- H/o uncontrolled dyslipidemia YES/ NO
- Grade 3 and 4 Spondylolisthesis YES/ NO
- Rheumatoid arthritis YES/ NO
- Tuberculous arthritis YES/ NO
- Pyogenic bone infection YES/ NO
- Vertebral fracture YES/ NO
- Tumor in vertebral body YES/ NO
- Osteochondritis YES/ NO
- Metabolic bone disease YES/ NO
- Limb weakness and foot drop YES/ NO
- Ankylosing spondylitis YES/ NO
- Spinal deformity YES/ NO
- Sexually transmitted disease YES/ NO
- Bowel and bladder incontinence YES/ NO
- Pregnant women and lactating mothers 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

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Principal Investigator: Dr.K.Aarthy

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

OCCUPATION:
MARITAL STATUS :1. Married 2. Unmarried

DATE OF INTIAL ASSESSMENT:

COMPLAINTS & DURATION:

FORM II-A – HISTORY TAKING PROFORMA

PERSONAL HISTORY:

PERSONAL HABITS NO	**YES**		**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	
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. Vathaudal ☐
2. Pithaudal ☐
3. Kabaudal ☐
4. Thonthaudal ☐

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. Kaarkaalam (Aavani-Purattasi) ☐
2. Koothirkaalam (Ippasi-Kaarthigai) ☐
3. Munpanikaalam (Maargazhi-Thai) ☐
4. Pinpanikaalam (Maasi-Panguni) ☐
5. Ilavenilkaalam (Chithirai-Vaigasi) ☐
6. Muthuvenilkaalam (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**
Annamayakosam	Normal /Affected	Normal /Affected
Pranamayakosam	Normal /Affected	Normal /Affected
Manomayakosam	Normal /Affected	Normal /Affected
Vignanamayakosam /Affected	Normal /Affected	Normal
Ananthamaya kosam	Normal /Affected	Normal /Affected

8. EZHU 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	**7th day**	**14th day**	**21st day**	**28th day**	**35th day**	**42nd day**	**46th day**
Praanan								
Abaanan								
Samaanan								
Udhaanan								
Viyaanan								
Naagan								
Koorman								
Kirukaran								
Devathathan								
Dhananjeyan								

B) AZHAL

	0th day	7th day	14th day	21st day	28th day	35th day	42nd day	46th day
Analakam								
Ranjakam								
Saathakam								
Prasakam								
Aalosakam								

C) IYYAM

	0th day	7th day	14th day	21st day	28th day	35th day	42nd day	46th day
Avalambagam								
Kilethagam								
Pothagam								
Tharpagam								
Santhigam								

10. ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

NAADI	0th day	7th day	14th day	21st day	28th day	35th day	42nd day	46th day

II. SPARISAM: [PALPATION]

Day	SPARISAM
0th day	
7th day	
14th day	
21st day	
28th day	
35th day	
42nd day	
46th day	

III. NAA: [TONGUE]

NAA	0th day	7th day	14th day	21st day	28th day	35th day	42nd day	46th 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**	**7th day**	**14th day**	**21st day**	**28th day**	**35th day**	**42nd day**	**46th day**

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		
EdaiNur		
ai		
Enjal		

NEIKKURI:

Neikkuri	Before treatment	After treatment
Aravenaneendathu/ Snake like pattern		
Azhipolparaviyathu Annular/Ringedpattern		
Muththothuninrathu Pearlbeadepattern		
Other patterns		

CLINICAL EXAMINATION:

LOCOMOTOR SYSTEM:

CLINICAL SYMPTOMS:

pain and stiffness :- ☐ ☐

(low back region) YES NO

Radiating pain :- Right leg Left leg

Numbness & paraesthesia :- YES NO

Onset :- Sudden Gradual

CLINICAL EXAMINATION

I.INSPECTION:

	0^{th}day	7^{th}day	14^{th}day	21^{st}day	28^{th}day	35^{th}day	42^{nd}day	46^{th}day
SPINE POSTURE								
GAIT								
Scobers test								

II.PALPATION:

	0^{th}day	7^{th}day	14^{th}day	21^{st}day	28^{th}day	35^{th}day	42^{nd}day	46^{th}day
Tenderness								
Local heat								

III. MOVEMENTS

	0^{th}day	7^{th}day	14^{th}day	21^{st}day	28^{th}day	35^{th}day	42^{nd}day	46^{th}day
Flexion								
Extension								
Lateral flextion								
Rotation								

IV. JOINT MESUREMENT:

A. HEALTH ASSESSMENT QUESTIONNAIRE:

` **QUESTIONNAIRE:**	Before Treatemnt	After Treatment
PAIN Lowback pain		
Early morning stiffness		
Nature of pain		
Aggravating factor Movement (Yes/No)		
Relieving factor Rest		
Tenderness		
Restriction of Movement		

CLINICAL TEST:

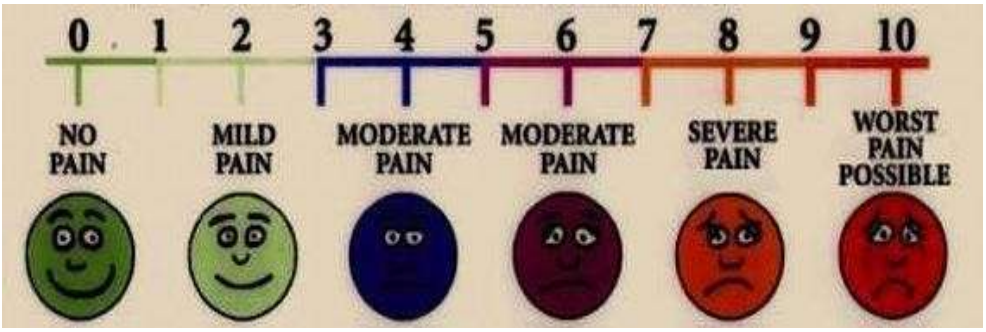
	0th day	7th day	14th day	21st day	28th day	35th day	42nd day	46th day
SLR: straight leg raising test								
Bragards test								
Lassique test								
Flip test EHL weakness								
(extensor hallusis longus) Faber test								
Femoral nerve stretch test								

OTHER EXAMINATION:

Neurological examination:	0th day	7th day	14th day	21st day	28th day	35th day	42nd day	46th day
Power: (Gluteal,thighs Legs)								
Reflex: 1.knee 2.ankle 3.plantar								
Sensation: (touch, pain, temperature)								

PAIN ASSESMENT SCALE:

1. UNIVERSAL PAIN ASSESMENT SCALE:



Grade 0 : No Pain

Grade 1-3 : Mild pain

(nagging,annoying,interferinglittlewithADLs)

Grade 4-6 : Moderate pain

(interfering significantly with ADLs)

Grade 7-10 : Severe pain

(disabling, unable to perform ADLs)

SCALE	**0thday**	**8thday**	**15thday**	**22ndday**	**29thday**	**36thday**	**43rdday**	**49thday**

Date:

Place:

Signature of the investigator:

Signature of the faculty : signature of the HOD

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Principal Investigator: Dr.K.Aarthy

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)	1/2hr			
	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		
	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-0.2		
	Indirect bilirubin	0.2-0.7		
	SGOT (IU/L)	0-40		
LFT (mg/dl)	SGPT (IU/L)	0-35		
	Alkaline phosphatase	80-290		
	Serum calcium	9-11		
	Serum phosphorus	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: LUMBOSACRAL REGION

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

Date:

Station:

Signature of the Investigator:

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

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Principal Investigator: Dr.K.Aarthy

FORM –IV- DRUG COMPLIANCE FORM

SERIAL NO:

NAME:

DRUG NAME:

On 0st day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 7th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 14th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 21st day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 28th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)
On 35th day-Date: Drugs issued: (Gms) Drugs returned: (Gms)

On 42nd day-Date: Drugs issued: (Gms) Drugs returned: (Gms)

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

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FORM-V– INFORMATION SHEET

Name of Principal Investigator : Dr .K.Aarthy
Name of the institute : National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL:

I, Dr.K.Aarthy Studying as M.D(Siddha) at National Institute of Siddha, Tambaram Sanatorium is doing a trial on the study of Vathasthambam (sciatica).Sciatica 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 **"Rajamaarthandailagam"** (Internal medicine-, Twice a Day with water for 48 days) and **"vaathakajakesarithylam"** (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.K.Aarthy, PG Scholar, Phone no:9095897133** 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.

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FORM –V தகவல்படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நோய்க்கான சித்த மருந்துகளின் ராஜமார்த்தாண்ட இளகம் (உள்மருந்து) மற்றும் வாதகஜகேசரி தைலம்(வெளிமருந்து)பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர் :கு.ஆர்த்தி

நிறுவனத்தின்பெயர் : தேசிய சித்த மருத்துவ நிறுவனம் தாம்பரம் சானடோரியம், சென்னை47

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர்:கு.ஆர்த்தி)வாதஸ்தம்பம் என்னும் நோய்க்கான மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இது பரவக்கூடிய நோய் அல்ல.இந்தஆராய்ச்சி சம்பந்தமாக சில கேள்விகளை கேட்கவும்,தேவையான ஆய்வக பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன் இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக ராஜமார்த்தாண்ட இளகம், 5கி, 2 வேளை காலை, மாலை) உணவுக்கு பின் 45 நாட்களுக்கு உட்கொள்ள வேண்டும் வெளிமருந்தாக வாதகஜகேசரி தைலம் 48 நாட்களுக்கு நோயுள்ள இடங்களில் வெளியே தடவ வேண்டும். வெளிநோயாளர் 7 நாட்களுக்கு ஒரு முறை மருத்துவமனைக்கு வரவேண்டும்.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கபடும் என உறுதி அளிக்கிறேன் இதில் பயணபடி முதலிய எந்த உதவி தொகையும் வழங்கபடமாட்டாது. இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவ மனையில் தக்க மாற்று சிகிச்சை அளிக்கப்படும்.இந்த ஆராய்ச்சியில் தங்களை உட்படுத்திய பிறகு உங்களுக்கு விருப்பமில்லையெனில் எப்போது வேண்டுமாணலும் விலகிக்கொள்ள முழு உரிமைஉள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மையை பற்றியும் முதன்மை ஆராய்ச்சியாளரான கு.ஆர்த்தி (பட்டமேற்படிப்பாளர் மருத்துவ பிரிவு) அணுகவும். கைப்பேசிஎண் 9095897133. மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறப்பட்டுள்ளது.

தேதி :
கையொப்பம் :
இடம் :
பெயர் :
சாட்சிக்காரர்கையொப்பம் :
பெயர் :
உறவுமுறை :
விரிவுரையாளார் கையொப்பம் :
துறைத்தலைவர் கையொப்பம் :

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

DEPARTMENTOFSIRAPPUMARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUG***"RAJAMAARTHAANDA ILAGAM"*** (INTERNAL) AND **"VAATHAKAJAKESARI THYLAM"** (EXTERNAL) IN THE TREATMENT OF ***"VATHASTHAMBAM"*** (SCIATICA) WITH AND WITHOUT VARMAM THERAPY.

Name of Principal Investigator: Dr.K.Aarthy.

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:

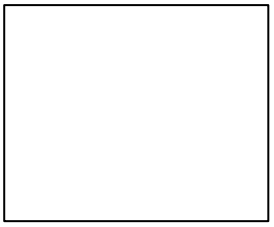
Signature of the participant

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

ஆய்வாளரால்சான்றளிக்கப்பட்டது

நான்வாதஸ்தம்பம்என்னும் நோயின்ஆய்வைக் குறித்தஅனைத்துவிபரங்களையும் நோயாளிக்குப்புரியும் வகையில் எடுத்துரைத்தேன் எனஉறுதியளிக்கிறேன்.

தேதி:
கையொப்பம்:

இடம்:
பெயர்:

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும்மருத்துவவழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும்மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்திஅளிக்கும் வகையில் ஆய்வு மருத்துவரால்விளக்கிக் கூறப்பட்டது. நான் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும்கூறாமல், எப்பொழுதுவேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னைவிடுவித்து கொள்ளும் உரிமையைத்தெரிந்திருக்கின்றேன்.

நான் என்னுடைய சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு"வாதஸ்தம்பம்"என்னும்நோய்க்கு"ராஜமார்த்தாண்டஇளகம்"(உள் மருந்து) மற்றும் "வாதகஜகேசரிதைலம்" (வெளி மருந்து) மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி:
கையொப்பம்:

இடம்:
பெயர்:

சாட்சிக்காரர் கையொப்பம்:

பெயர்:
உறவுமுறை:

விரிவுரையாளார்கையொப்பம் துறைத்தலைவர்கையொப்பம்

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

DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUG ***"RAJAMAARTHAANDA ILAGAM"*** (INTERNAL) AND **"VAATHAKAJAKESARI THYLAM"** (EXTERNAL) IN THE TREATMENT OF ***"VATHASTHAMBAM"*** (SCIATICA) WITH AND WITHOUT VARMAM THERAPY.

Name of Principal Investigator: Dr.K.Aarthy

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 / Pharmacovigilance Form)

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

DEPARTMENTOFSIRAPPUMARUTHUVAM

COMPARATIVE CLINICAL STUDY OF SIDDHA DRUG ***"RAJAMAARTHAANDA ILAGAM"*** (INTERNAL) AND ***"VAATHAKAJAKESARI THYLAM"*** (EXTERNAL) IN THE TREATMENT OF **"VATHASTHAMBAM: (SCIATICA)"** WITH AND WITHOUT VARMAM.

Name of Principal Investigator: Dr.K.Aarthy

FORM VII - A – ADVERSE REACTION FORM / PHARMACOVIGILANCE FORM

SERIAL NO :

OP/IP NO :

NAME : AGE:

GENDER :

DATE OF TRIAL COMMENCEMENT :

DATE OF THE ADVERSE REACTION OCCUR :

DESCRIPTION OF ADVERSE REACTION :

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DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND COMPARATIVE CLINICAL TRIAL OF SIDDHA DRUGS***"RAJAMAARTHAANDA ILAGAM"*** (INTERNAL) AND **"VAATHAKAJAKESARI THYLAM"** (EXTERNAL) IN THE TREATMENT OF ***"VATHASTHAMBAM"*** (SCIATICA) WITH AND WITHOUT VARMAM THERAPY.

Principal Investigator: Dr.K.Aarthy

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])	புளிப்பு (Sour) உப்பு (Salt) வாயுப் பொருட்கள் (Vatha diet) உருளைக் கிழங்கு (Potato) வாழைக் காய் (Plantain) புகையிலை (Tobacco) மது அருந்துதல் (Alcohol) பெண்போகம் (இச்சா பத்தியம்) [Sexual intercourse]

மருத்துவ அறிவுரை:

சமமான தரையில் படுத்தல் வேண்டும்.

To be lied flat(neutral position).

உடல் அதிக எடை இருப்பின் எடையைக் குறைக்க வேண்டும்.

Advised to reduce over weight

அதிக பளு தூக்குதலை தவிர்க்கவும்.

should not lift over weight

நீண்ட தூரம் பயணம் கூடாது.

long travel should be avoided.

அதிக தூரம் நடத்தல், அதிக நேரம் நிற்றல் தவிர்க்கவும்

Prolonged walking and standing should be avoided

ஒழுங்கான நிலையில் அமர வேண்டும்.

To be seated in a correct posture.

FORM IX- 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 the
RRC-ASU/ PPC-ASU

The Director
National Institute of Siddha,
(Pharmacovigilance Regional Centre For Siddha Medicine),
Tambaram Sanatorium, Chennai-600 047.
☏ (O) 044-22381314 Fax : 044 – 22381314
Website : www.nischennai.org
Email: nischennaisiddha@yahoo.co.in

* *

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

Who Can Report?

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

What to Report?

⇒ All reactions, Drug interactions,

Confidentiality

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

⇒ 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

BIBILIOGRAPHY

1. Pranarakshamirthasindhu
2. Kannusamyparambaraivaidhyam
3. Siddha Maruthuvam (Pothu) –Dr.N.KuppusamyMuthaliyar
4. Siddha Maruthuvam (Sirappu)- Dr.R.Thiyagarajan
5. Anupogavaithiyanavaneetham
6. SarabenthirarVaithiyaMuraikal(vatharogasikichai)
7. Agathiyargunavagadam
8. GunapadamMooligaiVaguppu
9. GunapadamThathu Jeeva Vaguppu - Dr.R.Thiyagarajan
10. Noi Nadal NoiMudhalNaadalThiratu Part I and II – Dr.M.Shanmugavelu
11. MarunthuSeiIyalumKalaiyum
12. UdalThathuvam
13. SarakkuSutthi Sei Muraigal –Siddha maruthuvanoolveliettupirivu
14. Siddha MaruthuvaangaSurukkam- Dr.K.S.Uthamarayan
15. Siddha priniciples of social and preventive medicine – Dr.G.Durairasan
16. Siddha VaithiyaPatharthaGunaVelakkam – C .Kannusamypillai
17. ThaerayarVaagadam
18. AgathiyarAyulVedham 1200
19. AgathiyarVaidhiyaKaviyam 1500
20. T.V.Sambasivam Pillai Dictionary, Volume 4, Part I
21. VarmamMaruthuvamsirappu - T.KannanRajaram
22. VarmamPullikalinIruppidam
23. VarmamKannadi
24. Varma Vithi
25. VaagadaNithanam
26. Varmammaruthuvathinadippadaikal - T.KannanRajaram
27. Varma odivumurivusarasuthiram
28. VathaNoiMaruthuvam –Dr.S.Chidambarathaanupillai
29. YugiVaithiyaChinthamani
30. Siddha VaithiyaThirattu
31. Siddha Formulary of India

32. Essential orthopaedics by J.Maheswari.
33. Text Davidson" sprinicIples and practice of medicine -chirstober, haslet..
34. Book of orthopedics and traumatology – John Ebnezar
35. Text book of orthopedics and trauma – Kulkarni
36. Handbook of medicinal botany
37. The Wealth Of India Vol.2 National Institute Of Science Communication And Information Resources Dr.K.Skrishnan Marg, Csir
38. Indian Herbal Pharmacopoeia, P – 424
39. Indian Materiamedica, K.M.Nadkarnivol I, Ii, 2nd Reprint of 3rd Revised and Enlarged Edition 2005.
40. T.V.SambasivamPillai, Tamil,English Dictionary Of Medicine, Chemistry, Botany, Allied science, Vol I, V, IV(Part)
41. P.J.Mehta" s Practical Medicine, 18th Edition 2007.
42. Text Book Of Orthopaedics And Traumatology, Prof.Mayilvahanan Natarajan, 6th Edition
43. Harrison" s Principles Of Internal Medicine, Vol II, 17th Edition.
44. Development Of Standard Siddha Terminologies, National Institute Of Siddha, Www.Emedicinehealth.Com.
45. Al Zuhair H, el Sayeh B, Ameen HA,etal.Pharmacological studies of cardamom oil in animals.Pharmacol Res 1996;34(1-2):79-82.8981560.
46. SapraB,GuptaS,Tiwaly AK, Role of volatile oil pretreatment and skin cholesterol on permeation of ion-paired diclofenac sodium. Indian J Exp Biology 2000,58(9):895-900, 1256/947.
47. Jamal A,Javed K, Aslam M, et al, Gasteroprotective effect of Cardamom, Ethanopharmacol 2006;103(2):149-153, 16298093.
48. Hosseini M, Asl MK, Rakhshandeh H, Analgesic effect of clove essential oil in mice. Avicenna J Phytomed 2011; 7(1) : 1-6
49. Raghavenra H, Diwakar BT, Lokesh BR, Naidu KA.Eugenol-The action principle from cloves inhibits 5-lipoxygenase activity and leukotriene-C_4 in human PMNL cells.J prostaglandins Leukot Essent fatty acids 2006;74:23-7
50. Kozam G. The effect of eugenol on nerve transmission.J oral Surg oral Med oral Pattol.1977;44;799-805.
51. Aoshima H, Hamamoto K, Potentiation of GABA A receptors expressed in Xenopus oocytes by perfume ndphytocide.JBiosciBiotechnolBiochem 1999;743-8.

52. Oxturk A, Ozbek H. The Anti- inflammatory activity of Eugenia caryophylataessoil.An animal model of anti-inflammatory activity .Eur J Gen Med 2005;2(4);159-63

53. Kim EH, Kim HK, Ahn YJ, Acaricidal activity of clove bud oil compounds against Dermatophagoides farina and Dermatophagoidespteronyssinus (Acaripyroglypidae). Agric food chem 2003:51(4):885-9

54. Gülçin I, Elmastaş M, Aboul-Enein HY. Antioxidant activity of clove oil-A powerful antioxidant source. Arab J Chem. 2012;5(4):489–499.

55. Gülçina İ, Şatb İ G, Beydemira Ş, Elmastaş c M, Küfrevioglu Öİ . Comparison of antioxidant activity of clove (*Eugenia caryophylata* Thunb) buds and lavender (*Lavandula stoechas* L.) Food Chem. 2004;8(3):393–400.

56. Rollinger JM, Steindl TM, Schuster D, Kirchmair J, Anrain K, Ellmerer EP, et al. Structure-base virtual screening for the discovery of natural inhibitors for human rhinovirus coat protein Jmed chem 2008;51:842-51

57. Dandagi PM, Patil MB, Mastiholimalh VS, Gadad AP, Dhumansure RH. Development and evaluation of hepatoprotective polyherbal formulation containing some indigenous medicinal plants Indian J pharm sci 2008;70:265-8.

58. Lawan A, Katsaya UA, Yaro AH. Anti-inflammatory and anti-nociceptive effects of the methanolic extract of the stem bark of Ficusvallischoudaedelile (Moraceae) Afr J Pharm Pharacol. 2008;2:200–203.

59. Mandegary A, Sayyah M, Heidari MR. Antinociceptive and anti- inflammatory activity of the seed and root extracts of *Ferulagummosa* Boiss in mice and rats. DARU. 2004;12:58–62.

60. Vedhanayagi G, Shashtri GV, Kuruvilla A. analgesic activity of Piper longumLinn.root. Indian J Exp Biol, 2003;41:649-51.

61. Kumar S, Arya P, Mukherjee C, Singh BK, Singh N, Parmar VS, et al.Novel aromatic ester from Piper longum and its analogues inhibit expression of cell adhesion molecules on endothelial cells.Biochemistry,2005;6;44;15944-52.

62. ChodharyGP.Mast cell stabilizing activity of Piper longumLinn.Indian J Allergy Asthma Immunol, 2006;20:112-6.

63. Atal CK, Zutshi, Rao PG (1981).Scientific evidence on the role of Ayurvedic herbals on bioavailability of drugs. J Ethnopharmacol.4(2) 229-232.

64. Zaveri M, Khandar A, Patel S, et al.(2010) chemistry and pharmacology of Piper longumLinn.IJPSRR, 5(1): 67-76.

65. Ozaki Y, Soedigdo S, Wattimena YR, Suganda AG, Anti inflammatory effect of mace, aril of MyristicafragransHoutt, and its active principles, Jpn J Pharmacol 1989;49:155-63

66. Lee JY, Park W, Anti-inflmmatory effect of Myristicin on RAW 264.7 macrophages stimulated with polyinosinic-polycitidylic acid. Molecules 2011;16:7132-42

67. Elliott S and BrimacombeJ:The medicinal plants of GunungLeuser National Park, Indonesia.J.Ethnopharmacol.19,285-317(1987).

68. Assa JR, Widjanarko SB, Kusnadi J, berhimponS.Antioxidant potential of flesh seed and mace of Nutmeg (MyristicafragransHoutt).Int J Chem Tech Res 2014;6:2460-8.

69. Gupta AD, Bansal VK, Babu V, MaithilN.Chemistry, the antioxidant and antimicrobial potential of nutmeg (MyristicafrgransHoutt).J Genet EngBiotechnol 2013;11:25-31.

70. Vaidya SM et al.Evaluation of hepatoprotective activity of ClerodendrumserratumL.Indian Journal of experimental biology 2007;45:538-542 csitted on 5.9.2014.

71. Narayanan N et al. Antinociceptive, Anti-inflammatory and Anti pyretic effect of ethanol extract of Clerodendrumserratum roots in experimental animals.Journal of ethanopharmacology 1999;65 (3):237-241.Cited on 5.9.2014.

72. Bhangare NK, Pansare TA, Ghongane BB, NesariTN.Screening for Anti-inflammatory and Anti allergic activity oofBharangi {Clerodendrumserratum.(Linn) Moon} in animals. International Journal of Pharma and Biosciences 2012;3(4):245-254.cited on 5.9.2014.

73. Bhujbal S, Kewatkar S, More L, and Patil M, Anti-oxidant effect of Clerodendrumserratum Linn, 2009.1,294-298.

74. Kapadia, V.H; Naik, v.g; Wadia,M.s;Dev,S.sequesterpenoids from essential oil of C.rotandus,Tetrahedron Lett.1967,4661.

75. Singh N,Kulshrestha VK, Gupta MB and Bhargava KP, Pharmacological studies n Cyperusrotandus, Indian J Med , Res, 1970,58,103-109.

76. Singh N, Kulshrestha VK, Gupta MB and Bhargava KP, Pharmacological studies n Cyperusrotandus, Indian J pharm, 1969,1(2), 9.

77. Singh N and Gilca M, Herbal Medicine – Science embraces tradition – A new insight ito the ancient Ayurveda, Lambert Academic Publishing, Germany, 2010, PP.139-148.

78. Ahmad M, Rehman AB, Mahummad R, and Wazir A. Assesment of Anti-inflammatory, Anti- ulcer and Neuro Pharmacological activities of Cyperusrotandus L. PJPSC.2014;27(6):2241-2246.

79. Shama A, Singh N, Bharadwaj R. Ethno-pharmaco therapeutic activities of Cyperusrotandus.IJMAS.2016;3(2):186-194.

80. Sirivastav S, Cyperusrotandus (Nagarmotha)-An Important Medicinal Plant:AReview.IJPR. 2015;1(1):11-22

81. Bhat SP, Rizvi W and Kumar A. Effect of Cuminumcyminum Linn seed extracts on pain and inflammation .Journal of Natural Remedies 2014;14(2):186-192.

82. Saini N,Singh GK, Nagori BP. Spasmolytic potential of some medical plants belonging to Family Umbelliferae: A Review. Int J Ris Ayurveda Pharm.,2014;5:74-83.
83. Gohari AJ, Saeidnia S. A Review on phytochemistry of Cuminumcyminum seeds and its standards from Field to Market. Pharmacognosy journal, 2011;3(25):1-5

84. Kapoor S. Emerging clinical and therapeutic applications of Nigella sativa in gastroenterology. World J Gastroenterol.2009;7:2170-2171.

85. Vohora S.B and Dandiya P.C., Herbal analgesic drugs, 1992, Fitoterapia, 63:195-207

86. Khan M.T.H.., Shailajabbar, Choudhuri M.S.K. and Ghafur M.A., Analgesic and Anti inflammatory activity of Nigella sativa Linn, Hamdard Medicus, 1999, 42:22-29.

87. Hassan MT, Ali MS, Alimuzzaman M, Raihan SZ. Analgesic activity of Mesuaferrea Linn. Dhaka univ. Pharm Sci, 2006; 5: 73-5

88. Gopalakrishnan C, Shankaranarayanan D, Nazimudeen SK, Viswanathan S, Kameswaran C. Anti-inflammatory and C.N.S. depressant activities of xanthomes from Calophylluminophyllum and Messuaferra. Imdian J Pharmacol, 1980,12:181-91.

89. Yamahara J, Miki K, Chisaka T, Sawada T, Fjimura H, Tomimatsu T, Nakano K, and Nohara T. Cholagogic effect of ginger and its active constituents. J. Ethnophharmacol.1985;13(2):217-225.

90. Chrubasik S, Pittler MH and Routogalis BD. Zingiberis rhizome: A comprehensive review on the ginger effect and efficacy profiles phytomdedicine.2005;12(9):684-701

91. Srivastava KC and Mustafa T. Ginger (Zingiberofficinale) and rheumatic disorders Med Hypotheses. 1989;29(1):25-28.

92. Mat, Jin X, Yang L, and LiuZL. Diarytheptanoids from the rhizomes at Zingiberofficinale. Phytochemistry. 2004;65(8):1137-1143.

93. Hsiang CY., Lo HY., Huang HC., et al. ginger extract and gingerone ameliorated trinitrobenzenesulphonic acid-induced colitis in mice via modulation of nuclear factor-B activity and interleukin 1 signelling pathway, Food chemistry.2013;136(1):170-177.

94. Illahami gulcin.et al. International Journal of Food science and Nutrition vol 56,2005-issue 7. 6 Jul2009.

95. Kottarapatjeena, VijayastelterB.Liju, N.P. Umadevi&Ramadasankuttan international journal of food science and Nutrition. 10 feb 2014.

96. Dipa Khanam, Debashish Deb, Shrabanti Dev et al, Analgesic and Anti-inflammatory activities of Ethanol extract of Clerodendruminerme, Bangladesh pharmaceutical Journal, 17(1):62-66,2014.

97. S.Somasundram and J.Sadique, Anti-haemolytic effect of Flavonoidal Glycosides of Clerodendruminerme: An *invitro* study, fitoterapia, 103-110 (1986)

98. Neeta Shri vasstava and Tejas Patel, Clerodendrum and Healthcare: An Overview, Medicinal and Aromatic Plant Science and Biotechnology,1(1), 142-150 (2007)

99. Siddharthan S, Yi-zhong C, Harold C, and Mei S. (2007). Systematic evaluation of natural phenolic antioxidants from 133 Indian Medicinal Plants. Food nd Chemistry 102: 938-953.

100. Anwikar S, Bhitre M. Study of the synergistic anti-inflammatory activity of *Solanum xanthocarpum*Schrad and Wendl and *Cassia fistula* Linn. Int J Ayurveda Res. 2010;1:167– [PMC free article][PubMed]

101. Tamaddonfard E, Farshid AA, Hosseini L. Crocin alleviates the local paw edema induced by histamine in rats. Avicenna J Phytomedicine. 2012; 2:97–104. [PMC free article] [PubMed]

102. Hepcykalarani D, Dinakar A, Senthil Kumar N,.Internationla Journal of Pharma and Biosciences review and research, Nov, 2012 17(1):77-80.

103. Subhadradevi V, Asokkumar K, Umamaheswari M, Sivashanmugam A, SankaranandR,In vitro antioxidant activity of VetiveriaZizanioides root extract,Tanzan J Health Res. 2010 Oct;12(4):274-9.

104. Sheeja E, Voshi SB, Jain DC, Bioassay guided isolation of anti-inflammatory and antinociceptive compound from Plumbago zeylanica, Pharma Bid;48.2010,381-387.

105. Yedapo, Studies on bioactivity of root extract of Plumbago zeylanica, Pharm Biol,34,1996,365-369

106. Yedapo SJ, Chang SC, Wen HC, Chen Ching-Yu, Jyh-Fei Lieo, Chang CH(2010). Plumbagin activities . Pharm. Biol., 34:365-369.

107. Oyedapa OO, Studies on the bioactivity of the extract of Plumbago zeylanica. Phytother Res., 13,1996,346-348.

108. Nile SH, Khobragrade CN, Anti-oxidant activity and flavonoid derivatives of Plumbago zeylanica, J Natural Products,3, 2010,130-133

109. Patgiri B, Umretia BL, Prajapati PK, Shukla VJ.Anti inflammatory activity of aquoues extract of T.cordifolia. Ayurveda 2014;35:108-10.

110. Bishayi B, Roychowdhery S, Ghosh S, Sengupta M. Hepatoprotective and immunomodulatory properties of Tinosporacardifolia in CCl4 intoxicated mature albino rats. The Journal of Toxicological Sciences.2002;27(3):139-146.

111. Pendse VK etal., Anti-inflammatory, immune suppressive and some related Pharmacological actions of the water extract of Tinosporacardifolia; A preliminary report. Ind.J.Pharmac. 1977; 9(3):221-224.

112. Narayanasamy R, Leelavinothan P: In-vivo and in-vitro antioxidant activities of coumarin on chemical induced hyperglycemic rats. International Journal of Pharmaceutical Sciences and Research 2011; 2(4); 968-978.

113. Rajadurai, PSM Prince: Comparative effect of *Aegle marmelos* extract and alpha- tocopherol on serum lipid, lipid peroxides and cardiac enzyme levels in rats with isoproterenol – induced myocardial infarctio. Singapore Med. J 2005; 46(2); 70.