CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN

Dissertation submitted to
THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY
CHENNAI – 32
For the partial fulfilment of the degree

DOCTOR OF MEDICINE
(Siddha)

By
Dr. R.Vinodini
PG Scholar
National Institute of Siddha
Chennai-47

Under the guidance of
Dr. A. M. Amala Hazel MD(S), Ph.D.,

Lecturer, Department of Kuzhandhai Maruthuvam

National Institute of Siddha
Chennai-47

Study Centre

Dept. of KUZHANDHAI MARUTHUVAM
National Institute of Siddha
Tambaram Sanatorium, Chennai – 47.

2015 - 2018

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN''** is a bonafide and genuine research work carried out by me under the guidance of **Dr.A.M.AMALA HAZEL M.D(S), Ph.D., Lecturer** Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title previously.

Date: 05.07.2018 **Signature of the Candidate**

Place: Chennai-47 (Dr. R.Vinodini)

CERTIFICATE

This is to certify that this dissertation work on **"CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN"** has been carried out by **Dr. R. VINODINI (Regd. No. 321514208)** Kuzhanthai Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai under my guidance and supervision in partial fulfilment of regulation laid by The Tamilnadu Dr.M.G.R Medical University, Chennai for the final M.D (Siddha), Branch IV –KUZHANTHAI MARUTHUVAM Examination to be held in OCTOBER – 2018. This dissertation work is not reprinted or reproduced from the previous dissertation work.

Dr.M.Meenakshi Sundaram, M.D(s),
Asso.prof/ HOD(i/c)

Dr.A.M.Amala Hazel M.D(S), Ph.D.,
Lecturer/ Guide

Prof. Dr.V.BANUMATHI M.D(S)
Director, National Institute of Siddha, Chennai.

Date: 05.07.2018
Place: Chennai-47

ACKNOWLEDGEMENT

- I am extremely grateful to the God who empowered his blessings and grace to complete this dissertation work successfully.
- I express my whole hearted gratitude to my parents for their valuable support and encouragement in my career from the very beginning.
- I express my honourable thanks to the 'Siddhars' who are our preachers.
- I express my sincere thanks to **Prof.Dr.V.Banumathi M.D(s),** Director, National Institute of Siddha for providing all the basic facilities in this dissertation work.
- I express my sincere thanks to **Dr.A.M.Amala Hazel M.D(s), Ph.D., Lecturer/Guide & Supervisor,** Department of Kuzhandhai Maruthuvam for her exemplary guidance, monitoring, unending patience and encouragement and hopeful support of my whole study and her expert advice, suggestions and supportive guidance for the frame work of the study.
- I express my sincere thanks to the **Vice-Chancellor**, The Tamilnadu Dr.MGR Medical University.
- I express my sincere thanks to **Dr.M.Meenakshi Sundaram M.D(s), Ph.D.,** Head of the Department (i/c), Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai-47.for his hopeful support and encouragement of my whole study.
- I express my sincere thanks to **Dr.K.Vetrivel M.D(s),** Associate Professor, **Dr.K.Suresh M.D(s), Ph.D.,** Lecturer, **Dr.P.Arul Mozhi M.D(s), Ph.D.,** Lecturer, **Dr.K.Vennila M.D(s), Ph.D.,** Lecturer, Department of Kuzhandhai Maruthuvam for their suggestions, hopeful support and encouragement of my whole study.
- I express my sincere thanks to **Dr.S.Visweswaran M.D(s),** Hospital superintendent and Head of the Department (i/c), Department of Gunapadam, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 for his kind help in identifying and authenticating mineral drug in my trial medicine.
- I express my sincere thanks to **Dr.D.Aravind M.D(s), M.Sc.,** Assistant Professor of Medicinal Botany, NIS, chennai-47, for his kind help in authentication of herbals in this study.
- I wish to thank **Dr.A.Muthuvel, M.Sc., Ph.D., Asst. Professor of Biochemistry,** National Institute of Siddha, for his guidance and help in conducting the biochemical analysis of the trial drug.

- I express my sincere thanks to **Mr.M.Subramanian M.Sc., (statistics)** Senior Research Officer.
- I express my cordial thanks to NOBLE RESEARCH SOLUTION PVT. LTD. for conducting the physicochemical analysis of the trial drugs.
- I wish to express my thanks to all the technicians of Department of Bio- chemistry, National Institute of Siddha, who helped in the experiments regarding this dissertation.
- With profound sense of gratitude and appreciation, I recall the constant support, help and co-operation by my dear friends in the completion of this work.
- I wish to express my thanks to my batch friends, juniors and seniors for their help and encouragement in clinical studies.
- Above all I owes my indebtedness to all the children who were backbone of the clinical trial and wishes them good health and well-being.
- Besides this, I extend my thanks to all the people who have knowingly and unknowingly helped me in the successful completion of this project.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

Introduction

Aim & Objectives

Review of Literature

Siddha Review

Modern Review

Drug Review

Materials & Methods

Observations & Results

Discussion

Summary

Conclusion

Annexure

Bibibliography

INTRODUCTION

Siddha system – The time honoured medicine which has been prevalent of yore is the foremost of all medical system in world.

The word Siddha comes from the word Siddhi which means an object to be attained perfection or heavenly bliss. It generally refers to the "Attamasiddhi" (i.e.) the eight supernatural powers. Those who attained these powers are called as Siddhars.

As the siddha medical works were authorised by the great Siddhars, they are considered excellent. These medical works were bestowed by the great Siddhars, after attaining spiritual knowledge through physical perfection and spiritual salvation, as explained by the saint YUGI in the following verse:

"அடைவான ஆயள்வே தந்தன் னைத்தான்
ஐயருமே அம்மைதனக் கருளிச் செய்ய
நடைவான அம்மையும்நந் திக்குச் சொல்ல
நந்தியும் சீடர்களுக் கருளிச் செய்யத்
தடைவான தன்வந்தரி அசுவி னிக்குச்
சமரசமாம் அகத்தியமுனி தேரை யர்க்கு
நடைவான ரிஷிதேவர் சொன்ன நூலின்
நேர்மையெல்லாம் விவரமாய் நிகழ்த்தி னேனே".

The works were passed on Lord Shiva to his consort and then to Nandhi, who in turn taught to Dhanvantari, who in turn to Aswini Devas, the twins and they narrated these works to Agathiar. Agathiar in turn told to saint Theraiyar and finally Theraiyar narrated these to Rishi Devar. The present form of medical works is adapted from the works of Rishi Devar.

According to Siddha medical science, the universe originally consisted by atoms which contributed to the five basic elements, viz., Nilam (earth), Neer (water), Thee (fire), Vali (wind) and Veli (space) which synchronise with the five senses of the human body, and they were the fundamentals of all the corporal things in the world. A close relationship is found existing between the external world and the internal system of human body. Siddhars maintain that the structure of the human body is a miniature of the world in itself. In other words, every substance visible or invisible, animate or inanimate is said to be formed of kinds of Panchaboothas, otherwise called the five elements which is said above. They might

have been formed by one, two, three, four or five elements noted above. This is the first principle or idea of a substance.

Also SATTAMUNI GNANAM says that,

"Microcosm reflects macrocosm"

"அண்டத்திலுள்ளதே பிண்டம்
பிண்டத்திலுள்ளதே அண்டம்
அண்டமும் பிண்டமும் ஒன்றே
அறிந்துதான் பார்க்கும் போதே"

- சட்டமுனி ஞானம்.

(i.e.) The universe is a macrocosm made up of five primordial elements or boothas and the human being is a microcosm made up of the same five elements.

The seers of ancient India propounded the Thiridhatu theory in accordance with which three vital elements namely the Vatha, Pitha and Kaba in their normal condition regulate all physiological activities and keep the body healthy. This Thiridhatu theory is also based on Panchaboothas.

When these Thridhatus became abnormal or when their mutual harmony is disturbed they bring about ill health. It is mentioned in Thirukural as follow,

"மிகினும் குறையினும் நோய்செய்யும் நூலோர்
வளி முதலா எண்ணிய மூன்று."

- திருவள்ளுவர்.

Siddha differs from western system of medicine in the method of approach to the medical problems which it views and interprets in terms of the three elemental theories and thus while considering the aetiology and treatment of disease, it gives more attention to the disorders of the body than to the extrinsic ones. A specific feature in Siddha care is the Kalpamurai also called as Kayakalpa where the human body can be fortified into rock like strength through serious of efforts with lifestyle, strengthening drugs and formulations.

The uniqueness of Siddha system of medicine is not only curing the ailments but also the mind to lead a peaceful life. In Thirukurral, it is stated as,

"மனநலம் மன்னுயிர் காக்கும்"

- திருவள்ளுவர்

The words of the Siddhars are indeed difficult to interpret and to be translated effectively in a foreign medium. It has been described that the number of diseases comes up to 4448. They have classified them as those affecting the different part of the body. Out of 4448 Skin diseases are 90 and Kuttam (Leprosy) is 18. According to our Siddha literature Venpulli (Vitiligo) comes under the 18 types of Kuttam. It is also called as Venkuttam, Venpadai and Suvetha kuttam.

Venpulli (Vitiligo) is a skin disorder in which there is focal failure of pigmentation may be in defined area or as dots in skin with or without the hair depigmentation. Last decade has witnessed an increasing interest in psychological effects and quality of life in patients suffering from this disease. A healthy normal skin is essential for a person's physical and mental well-being. It is an important aspect of their sexual attractiveness, a sense of well-being and a sense of self confidence. Hence any blemish on the skin visibly affects the person's onlooker and thus the patients affected profoundly.

It affects the general population worldwide with a variable frequency ranging from 0.38% to2.9%.42% male and 58% female, aged predominantly between six and ten years old (40%) were studied at the Martagao Gesteira Childcare and Pediatrics Institute between 2005 and 2011.Both the sexes were equally affected. Vitiligo's onset being most between the age of 40-60. About 50% of all patients with vitiligo have an onset before 18 year of age and 25% develop depigmentation before age 8.

Vitiligo is more acute in the case of young women and children. In India vitiligo commonly known as Leucoderma is unfortunately associated with some religious beliefs. It is believed that the person who did "Guru Droh" in his/her previous life suffers from vitiligo in this life. Many vitiligo patients feel distressed and stigmatized by their condition. They attract undue attention from the general public sometimes whispered comments, antagonism and ostracism. The self-image of the vitiligo patients drops considerably and may lead to depression. These patients often develop negative feeling about it. It may be embarrassing and the frustration of resistant lesions over exposed part of hands and feet can lead to anger and disillusionment.

In Siddha medicine child care has been considered so important that it is classified and subdivided into further branches depending on the age starting from early infancy to late childhood. Balavagadam is the branch of medical science of Siddhars which deals with

the diseases of children, their essential nature, especially on the functional changes together with planetary influence, morbid diathesis etc. on the treatment.

In NIS OPD a considerable number of patients in paediatric population are recorded with symptoms of Venpulli. Children are not aware of this condition because this doesn't cause any illness to them. But it may lead to a complex comparing to others skin complexion in the schools and their surrounding environment. They may be mentally affected and feel shy which reflects in their academic, attitude and in their performance skill.In Siddha vaithiya thirattu text, there is a preparation called Parangipattai Chooranam which has Venpulli as its indication. So, I wish to evaluate its efficacy as my dissertation work in our OPD and IPD patients in National Institute of Siddha, Chennai. Also we are suggesting Annabedhi Chenduram mixed with lemon juice as an external application along with OP medicines. So far it yields a good improvement by repigmentation of the lesion. Hence I had selected this medicine (Annabedhi Chenduram - externally) as a trial drug in my dissertation topic.

AIM AND OBJECTIVE

AIM:

The aim of the present clinical study is "TO EVALUATE THE EFFICACY OF THE TRIAL DRUG PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) IN THE TREATMENT OF VENPULLI (VITILIGO) IN CHILDREN".

OBJECTIVES:

PRIMARY:

To evaluate the efficacy of PARANGIPATTAI CHOORANAM (Internal) and ANNABEDHI CHENDURAM (External) in the treatment of VENPULLI (Vitiligo) in children.

SECONDARY:

To study occurrence of new lesion, anywhere else in the body after intake of trial medicine.Also,

- To collect the authorial measures and literature reviews of VENPULLI in ancient siddha and modern literatures.
- Have an idea of the incidence of the disease with regard to age, sex, precipitating factors socio economic status, food, kaalam and factors etc.
- To expose the efficacy of siddhar's diagnostic principles.
- To utilize the modern investigation methods to confirm the diagnosis and prognosis.
- To study the biochemical and physiochemical analysis of the trial drug.

SIDDHA ASPECT

In Siddha system skin diseases are classified under the name kuttam. Generally kuttam means “Group of skin diseases”.

Venpulli is a chronic skin disease characterized by various sizes of hypopigmentad patches in the skin. Synonym of Venpulli is Swetha kuttam. According to Yugi Munivar classification Swetha Kuttam is one among the 18 types of Kuttam.

Description of Kuttam by the Siddhar Dhanvanthiri in his literature “Dhanvanthiri Vaithiyam” is given below:

குட்ட நோயின் பூர்வ ரூபம்:

“தொட்டுப் பார்த்தால் நகம் வைத்தால் றோலினுணர்ச்சி தெரியாதே
கெட்டுச் சரீரந் தடித்ததிற் கிளறுந் தினவும் விரணமுமா
மட்டில் வியர்வை வரினம் வரு மாறியு வருகினு முலரும்
விட்டு விளங்கு மொரு வன்ன மேவுங் குட்டஞ் சீக்கிரமே”

“நிரத்த வுடம்பு சரசரத்து நெருப்புப் பொறி பட்டாற் புண்ணாய்
கறுத்தே இரத்த மயிர்க் கூச்சல் காணுங் குணங்களி துவாகிற்
பொறுத்தே நெடுநாளனு சரித்துப் பொங்கும் வியாதி யென்றறிக
மறுத்து முரைத்தோ மஹாகுட்டம் வளமை யேழும் புவிமீதே.”

- Loss of sensory function e.g., touches, pricking with nail.
- Erythema or wheal formation all over the body
- Itching and ulceration
- Sweating may occur, if occurs it dries up soon.
- Change in colour of skin
- Burns like ulcer.
- Hyperpigmentation

ELUCIDATION ABOUT SWETHA KUTTAM:

சுவேத குட்டம்

‘தடிப்பாகத் தவளநிறம் போல் வெளுத்துச்
சர்வாங்க மும் வெளுத்தாற் றான்றி ரும்பும்
மடிப்பாக மயிர்வெளுத்தால் சாத்ய மாகும்
வரிவாடு வுள்ளங்கைக் குதங்குய் யந்தான்
நெடிப்பாக நெருப்புப்பட்டது போற் புண்ணாய்
நிறமிருந்தா லசாத்திய மென்றே யுரைக்கலாழும்
வெடிப்பாக மேனி எல்லாம் வெளுத்து வீங்கில்
வெண்சுவேத குட்டமென்றே விளம்பலாமே’’

யூகி வைத்திய சிந்தாமணி (முதல் பதிப்பு)

பாடல் எண்: 514 பக்க எண்: 164

பொருள்:

சுவேதம்	-	வெண்மை, - Whiteness வியர்வை பாதரசம்
தடிப்பு	-	கண்டிப்பு –Strict விறைப்பு, கடைப்பு, வீக்கம்
தவளநிறம்	-	சாம்பல் நிறம் - Ash Colour Grey வெண்மைநிறம், கற்பூரம்
சர்வம்	-	முழுவதும் - Whole/ அங்கம் - இடம், பகுதி
வெளுத்து	-	வெண்மையாதல்,Growing White
மடிப்பாக	-	மெதுவாக - Sluggish,சோறு, வளைந்த
வெளுத்தாற்	-	வெண்மையாதல் - Growing white
அசாத்தியம்	-	குணப்படுத்த முடியாமை- Incurability
வரி உதடு	-	கோடுபோன்ற உதடு - Line like lips
உள்ளங்கை	-	Palm of the hand
குதம்	-	மலவாய் - anus, Anal Orifice
குய்யம்	-	ஆண்குறி / பெண்குறி - The genital organ of Male / Female
நெடிப்பாக	-	நெடுநேரம், காலநீட்சி/ நீடித்த காலமான –Chronic
நெருப்புட்டது போல் புண்ணாய்	-	தீக்காய தழும்பின் நிறம்,Pinkish white
வெடிப்பாக	-	பிளப்பு, வெடித்தல் சிறப்பு,Splendours

மேனியெல்லாம்	-	உடல், சர்மம், - Body
வெளுத்து	-	வெண்மையாதல் - Growing white
வீங்கில்	-	பெரிதாகுதல், வீக்கம் மிகுதியாக –Abundance

Reference: T.V.Sambasivam Pillai Dictionary, Tamil lexicon

தடிப்பாகத் தவளநிறம் போல் வெளுத்து

- கண்டிப்பாக சாம்பல் நிறம் போன்று வெளுத்து
- Strictly the lesion becomes grey white

சர்வாங்க மும்வெளுத்தாற் றான்றி ரும்பும்

- பாதிக்கப்பட்ட இடம் முழுவதும் வெண்மையாக மாறும்
- The whole place of the lesion turns to white

மடிப்பாக மயிர்வெளுத்தா லசாத்திய மாகும்

- மெதுவாக பாதிக்கப்பட்ட இடத்தில் உள்ள மயிர் வெண்மையாக மாறினால் குணப்படுத்தமுடியாது
- Slowly if the hair become grey, it is incurable

வரிவுதடு உள்ளங்கை குதங்குய் யந்தான்

- கோடு போன்ற உதடு, உள்ளங்கை, மலவாயை சுற்றியுள்ள இடம், இனப்பெருக்க உறுப்பு ஆகியவைகளில
- The Lesion present in lips palms, anus and genital area

நெடிப்பாக நெருப்பு பட்டதுபோற் புண்ணாய்
நிறமிருந்தா லசாத்திய மென்றே யுரைக்கலாகும்

- நீண்ட காலமாக, தீக்காய தழும்பின் நிறமாக இருந்தால் குணப்படுத்த முடியாது
- Chronically if the lesion present like burns scar color (Pinkish white), It is incurable

வெடிப்பாக மேணியெல்லாம் வெளுத்து வீங்கில்

- சிறப்பாக வெண்மையாதல் உடல் முழுவதும் அதிகரித்து காணில
- The pallor spreads all over the body

வெண்சுவேத குட்ட மென்றே விளம்பாலமே

- வெண்மையான வெண் குட்டம் என்று கூறலாமே
- called as Swetha kuttam

AETIOLOGY:

According to siddha system, the predisposing causes for this disease have been described as hereditary factor, stress, and strain, malnutrition and venereal exposure and no other specific causes have been mentioned for Venpulli.

ACCORDING TO THIRUMOOLAR KARUKKIDAIVAITHIYA NOOL:

"வியாதியுண் மூவாறு விளங்கிய குட்டங்கேள்
கயாதிக் கிரந்தி சுழன் மேகத்தாலாறும்
பயாதி மண்ணுளப் பலவண்டினா லெட்டும்
நியாதி புழுனாலான் நின்றதிக் குட்டமே."

- Six types of kuttam i.e skin disease are caused by kirandhi and megham.
- Eight types are caused by insects in the soil.
- Four types are caused by worms.

ACCORDING TO YUGHI VAITHIYA CHINTHAMANI 800:

"விளம்பவே மிகுந்த உஷ்ணந்தன் னாலும்
மிகுந்த சீதளத்தாலு மழற்சி யாலும்
விளம்பவே மந்தத்தாலும் வாந்தி யாலும்
மகத்தான பெண்ணோடு மருவலாலும்
கிளம்பவே கிலேசங்கள் மிகுதலாலும்
கெடியான வுறக்கங்கள டைத லாலும்
தளம்பவே மயிருகற்கள் தவிடு மண்கள்
சாதத்திற் பருகலால் மிகுக்குங் குஷ்டம்."

The above said literature clearly indicates that the predisposing factors of the diseases are

- Excessive heat and cold, allergy.
- Vomiting due to indigestion
- Hyper sexual indulgence.
- Mental disturbance

- Excessive sleep in day time
- Frequent intake of food mixed with polluted stone husk and hair

“குட்டந்தான் பதினெட்டு வரவே தென்னிற்
குருனிந்தை சிவனிந்தை மரையோர் நிந்தை
திட்டந்தான் தேவதையைத் தூஷனைக்கு ரோதம்
செப்பலாற் றிருடலாற் பரதா ரத்தை
அட்டந்தா னாசையால டைக்க லத்தை
அபகரித்த லகதிபர தேசி தன்னை
வட்டந்தான் வைத்தார் கற்பழித்தல்
வந்திடமே பதினெட்டு குட்டந்தான்.”

- Use of indecent and disrespectful words against god and highly religious and noble people.
- Neglecting phans and beggars
- Intention to spoil others.
- Raping
- Greed
- Cursing the elders and so on have also been given as predisposing causes by Yughi text.

These habits are supposed to be the factors which lower the immunity of the body (iyarkai vanmai) and make it vulnerable to the disease.

ACCORDING TO AGASTHIYAR KANMA KAANDAM:

“சேர்ந்தே குட்டமொடு குறைநோய்கள் வந்த
சேதி கேள் மலராத வரும்பு கொய்தல்
தாரிந் சீவசெந்து வதைகள் செய்தல்
தாய்தந்தை மனது நொந்து ரோந் தானே
தானென்ற தெய்வரு தனையழித்தல்
சார்வான பெரியோர்கள் தமைப் பழித்தல்
கானென்ற நந்தவனம் பூஞ்செடிகள் வெட்டல்
கருமமடா சரீரத்திற் காசுபோலே
ஊனென்ற வுடம்பெல்லாம் பொட்டு பொட்டா
யுடன் வெளுத்து குறைநோயுதிரஞ் சிந்தும்
வானென்ற கருமங்கள் தீர்ப்பதற்கு
வகையொன்று சொல்வேன்கேள்.”

மலராத அரும்புகொய்தல், சீவசெந்துகளை வதைகள்செய்தல், பெற்றோர் மனதை நோகும்படி செய்தல் பெரியோர்கள் தம்மை பழித்தல், நந்தவனம் பூச்செடிகள் வெட்டுதல் ஆகிய இக்காரணங்களால் குட்டநோய் வரும் என்று அகத்தியர் கன்ம காண்டத்தில் கூறப்பட்டுள்ளது.

ACCORDING TO PARARASASEKARAM:

‘அன்னவல் வினையி னாலே மொய்த் தெழுங் குட்டரோகம்
மைசேர் நெறியிலுய்க்க நற்றவக் குரைவை மெய்மை
மன்னிடு மன்பர் தம்மை யுதாசினம் பேசி நாளும்
இன்னல் செய் பாத கத்தோர்க் கெய்திடு மென்னும்
வேதமே யுரைக்கு மேலா நெறியினில் வலி நாளும்
ஏதமே புரியுந் தீயோர்க் கெய்துவ நல்லான் மேலோர்
சூதிய நெறியீ னின்றே யுயிர்களுக் குறுதி செய்யும்
மாதவர் நன்மைளற்றோய் வருந்த நாங் கண்டிலோமே
ஆனதோர் வாத பித்த சேற்பன மதனினாலும்
மானாய்ப் விடநீராலு மங்கையர் வருத்தத்தாலும்
ஈனமாங் கிரந்தியாலு மிழிவுறு குட்டரோகம்
தானமில் லாதே சாரு மெனமுனி சாற்றினானே
சாற்றிய வுணவின் பேதந் தன்னாலும் பால்நெய் வெல்லம்
ஏற்றமா யுண்ப தாலு மிறைச்சிமீ னதிகித் தாலும்
கோற்றொடி மடவா ரின்பங் குறைவறத் துய்க்கையாலும்
சோற்றிடு மலசலத்தைச் சுகமற வடக்கையாலும்’’

பழ வினைகள்:

- முக்குற்றமான வாத, பித்த கபத்தாலும
- கோபம் கொள்ளல்
- விடநீர்
- பெண்போகம்
- கிரந்தி
- உணவு பேதம்
- பால், நெய்,வெல்லம் அதிகம் உண்பதாலும்
- இறைச்சி, மீன் அதிகம் உண்பதாலும்
- மல சலம் அடக்கலாலும் குட்டம் உண்டாகும்.

CLASSIFICATION:

ACCORDING TO YUGI VAITHIYA CHINTHAMANI:

“ முத்தாகும் குட்டந்தான் பதினெட்டுக்கும்
முனியான யூகினான் சொல்லக் கேளாய்
புத்தாகும் புண்டரீக குஷ்டத்தோடு
பெருகின்ற விற்போடகக் குட்டமாகும்
பத்தாகும் பாமா குஷ்ட ஏகசர்ம குஷ்டம்
பரிவான கர்னகுஷ்டம் சர்மகுஷ்டம்
கித்தாகுங் கிருஷ்ண குட்டம் அவுதும்பர குட்டம்
கேடியான மண்டல குஷ்டமாகும் மென்னெ
குட்டமா மபரிச குஷ்ட மோடு
மருவலாங் கிடீப குஷ்டந் சர்மதல குஷ்டந்
திட்டமாற் தத்துரு குஷ்ட மோடு
தக்கான சித்துமா குஷ்டஞ் சதாரு குஷ்டந்
துட்டமாஞ் சுவேத குஷ்டதன் னோடொக்கச்
சுயம்பான பதினெட்டுக் குட்டமாச்சே.”

1. Pundareeka kuttam
2. Virpodaka kuttam
3. Baama kuttam
4. Gaja saruma kuttam
5. Karna kuttam
6. Sarma kuttam
7. Krishna kuttam
8. Avudhumbara kuttam
9. Mandala kuttam
10. Abarisa kuttam
11. Visarchika kuttam
12. Vibaathika kuttam
13.Kideeba kuttam
14. Sarmathala kuttam
15. Thethru kuttam
16. Sithuma kuttam
17. Sathaaru kuttam
18. Swetha kuttam (It is also called as Venpadai / Venpulli)

ACCORDING TO SIDDHAR ARUVAI MARUTHUVAM:

Venpadai has been classified into 3 types on the basis of Mukkutram, they are,

1. Vaatha venpadai
2. Piththa venpadai
3. Kaba venpadai

ACCORDING TO SIDDHA SIRAPPU MARUTHUVAM:

Venpulli has been classified into 4 types:

1. Vaatha venpadai
2. Piththa venpadai
3. Kabha venpadai
4. Mega venpadai

ACCORDING TO ATHMA RAKSHAMIRTHA VAIDHYA SARASANKIRAHAM:

Venpadai is classified into 4 types

1. Venkuttam
2. Senkuttam
3. Karunkuttam
4. Peru viyathi

CLINICAL FEATURES OF KUTTA ROGAM:

ACCORDING TO THANVANTHIRI VAITHIYAM:

"மீக்கௌத் தோறூமெலுமோர் முகம் வெளுக்குமாகில்
நோக்கியல் மரிக்குஞ் சொன்ன வெண்குட்டமாமே."

ACCORDING TO VAITHIYA SAARASANGIRAHAM:

- ✓ Venpulli is a disease characterised by white coloured patches which are circumscribed along with thickened border in sole, hands,lips,scalp,fingers and wrist joint.
- ✓ Blood, Muscles, and adipose tissue are also affected by this disease.
- ✓ Discolouration of hairs,absence of normal skin texture comparing the adjoining normal skin area and appearance of burns are indicates noncurable nature of disease.

ACCORDING TO ANUBHAVA VAITHIYA DEVA RAGASIYAM:

இந்நோயை குஷ்டமென கூறினும் இது குஷ்ட வகைகளின்று வேறுபட்டது என்பதையும் குஷ்டத்தைப்போல் அவ்வளவு கொடுமையான வியாதி அல்லவென்றும் உணரவேண்டும். இந்நோயில் திட்டுதிட்டாக வெண்மை நிறமான படைகள் உண்டாகி பிறகு தேகம் முழுவதும் பரவி உடலை விகாரப்படுத்துதல் முதலிய குணங்களை உடையது.

ACCORDING TO SIRAPPU MARUTHUVAM:

1. Vaatha venpadai
2. Piththa venpadai
3. Kaba venpadai
4. Mega venpadai

1.VAATHA VENPADAI:

It is characterized by the depigmented patches, which are dry, rough,reddish with somewhat pale black in colour.

2. PITHTHA VENPADAI:

It is characterized by the depigmented patches red in colour like lotus flower, spreading with burning sensation and loss of hairs on that area.

3. KABA VENPADAI:

Itis characterized by the depigmented patches white in colour like leucus flower spreads with rashes and itching.

4. MEGA VENPADAI:

It is due to the venereal disease syphilis and it occurs after 4 or 6 months after the onset of disease. It develops initially along the nape and the adjoining spaces.Also gradually it affects the shoulder joints; back of trunk. It is clinically characterized by hypopigmented patches with hyperpigmented margin which are few in number. They are pale, turmeric and dark in colour.These lesions are circumscribed with 2mm to 3mm diameter or above. The nature of hypopigmented and hyper pigmented skin resembles the appearance of sieve. Females are more prone to this mega venpadai, therefore anti-syphilitic therapy is mandatory in the early period of the treatment.

CHARACTER OF VENPULLI:

1. The imbalance of the three thadhus produces certain lesions in skin known as kuttam.
2. Skin colour will change to reddish black or reddish white or white colour with spreading nature.
3. Absence of perspiration and thickening of skin may produce the colour changes in skin.

தீரும், தீராதவை:

சாத்தியம் - 11:

‘‘பூண்டந் நுரவினோடு சதாரிகம் புண்டரீ கந்த
தாண்டு விற்போடம் பாமாவுடன் மைதலம் வெங்குட்டம்
கூண்டிடு காகறந்தி சிறுமை யசல குட்டம்
வேண்டுய வியாதியோடும் பதினொன்றாம் விரித்துக் கானே.’’

அசாத்தியம் - 7:

‘‘சொல்லுகுட்டம் எழுவகைபேர் சொல்லிக் கபால சர்மீகம்
வெல்லு முதும்பா மேகிடிபம் விசர்ச்சிமண்டலக் கிரமும்
மல்லல் தருமீசி யகுவை யாகும் பெயரோ ரேழாகும்
வல்லகியாதிக் குணமதனை வகுத்துப் பாரிலுறுரைப்பேன்.’’

CURABLE-11:

1. Thethuru kuttam
2. Sadhaaru kuttam
3. Pundareega kuttam
4. Virpodaga kuttam
5. Sarmathala kuttam
6. Baama kuttam
7. Kaha nandhi kuttam
8. Venkuttam
9. Sithuma kuttam
10. Alasa kuttam
11. Vibaathiga kuttam

INCURABLE -7:

1.Kabaala kuttam

2. Sarumamega kuttam

3. Kideeba kuttam

4. Avudhumbara kuttam

5. Visarchika kuttam

6. Aguvai kuttam

7. Mandala kuttam

IN YUGI CHINTHAMANI-800:

“குட்டந்தனை பதினெட்டில் சாத்தியந்தான்
கூறக்கேள் விற்போடக பாமா குட்டம்
திட்டந்தான் கெசசர்ம குட்டமொடு
கிருட்டிண குட்டமவுதும்பர குட்டந்தானும்
திட்டமாந் தேதிதிருக் குட்டமொடு
செய்சித்துமா குட்டங் கிடிப குட்டம்
தட்டந்தான் மிகுந்த சதாரு குட்டம்
சமகிருட்ண குட்டம் சாத்தியமா மென்னெ.”

CURABLE -10:

1.Virpodaga kuttam

2. Baama kuttam

3. Gaja saruma kuttam

4. Krishna kuttam

5. Avuthumbara kuttam

6. Thethuru kuttam

7. Sithuma kuttam

8. Kideepa kuttam

9. Sathaaru kuttam

10. Sarmathala kuttam

INCURABLE -8:

1. Pundareeka kuttam
2. Karna kuttam
3. Sikura kuttam
4. Mandala kuttam
5. Abarisa kuttam
6. Visarchika kuttam
7. Swetha kuttam
8. Vivadhika kuttam

MUKKUTRA VAERUPADUGAL (PATHOGENESIS):

Disease occurs due to the derangement in

- Uyir thathukka
- Udal thathukkal
- Kalamarupadu (seasonal changes)
- Thinai (living lands)
- Udal vanmai

MUKKUTRA IYAL:

The function of the three uyir thathus

a) Vali – Kattru + Veli

b) Azhal – Thee

c) Iyyam – Neer + Mann

The alteration of three thathu in their reaction to extrinsic or intrinsic factors results in disharmony. This altered harmony and balance variation of the three results in disease. Their natural ratio (1:1/2:1/4) to each other is discerned by the physician at the wrist and each nadi is individually assessed for its strength, speed and regularity.

VATHAM:

The term vatham denotes vayu, dryness, pain and flatulence. Based on functions and locations it is classified into ten types. They are tabulated below.

S.No	Vatham	General Features	Changes in Venpulli
1	Piranan (Uyirkkaal)	Responsible for respiration and it is necessary for proper digestion.	Normal
2	Abanan (Keel nokkukkaal)	Responsible for all the downward forces such as voiding of urine, stools, semen, menstrual flow.	Normal
3	Viyanan (Paravukaal)	Dwells in the skin and is concerned with the sense of touch, extension and flexion of the parts of the body and distribution of the nutrients to various parts of the body.	Affected (skin colour changed into white)
4	Uthanan (Melnokkukaal)	Responsible for all kinds of upward motion such as nausea, vomiting etc.,	Normal
5	Samanan (Nadukkaal)	Start from the umblicial cord, Samanan spread out upto the lower limbs and responsible for the balance of other four vadha and digestion.	Affected (It cannot control the other vayus)
6	Nagan	Helps in opening and closing of eyelids.	Normal
7	Koorman	Responsible for vision, lacrimation and yawning.	Normal
8	Kirugaran	Induces appetite, salivation, all secretions in the body including nasal secretion and sneezing.	Normal
9	Thevathaththan	Induces and stimulates a person to become alert, get anger, to quarrel, to sleep etc.,	Normal
10	Dhananjeyan	Resides in the cranium and produces bloating of the body after death. This leaves from the body after 3 days of death, forming a way through the skull.	Normal

PITHAM:

It is the thermal life force of the body. It is sub divided into five types. They are

S.No	Pitham	General Features	Changes in Venpulli
1	Anarpitham	Peps up the appetite and aids in digestion.	Normal
2	Ranjagapitham	Responsible for the colour and contents of blood.	Affected
3	Saathagapitham	Controls the whole body and is held responsible for fulfilling a purpose.	Normal
4	Pirasagapitham	Dwells in the skin and concerned with the shine, glow, texture and its complexion.	Affected (skin colour Changed into white)
5	Alosagapitham	Responsible for the perception of vision.	Normal

KABHAM:

It is responsible for the stream line functions of the body and maintains body's defence mechanism intact. It is again classified into 5 types.

S.No	Kabham	General Features	Changes in venpulli
1	Avalambagam	Lies in the respiratory organs, exercises authority over other kabhas and control the heart and circulatory system.	Normal
2	Kilethagam	Found in stomach as it seat, moistens the food, softens and helps to be digested.	Normal
3	Pothagam	Responsible for the perception of taste	Normal
4	Tharpagam	Presents in the head and is responsible for the coolness of the eyes, sometimes may be referred to as cerebrospinal fluid.	Normal
5	Santhigam	Necessary for the lubrication and the free movements of joints.	Normal

PARUVAKALAM:

S.No	Perum pozhuthugal	Mukkutra marupaadugal
1	Kaar kaalam (Aavani & Purattasi) Mid-August to Mid-October	VATHAM - Vaetrunilai valarchi PITHAM – Thannilai valarchi
2	Koothir kaalam (Iypasi & Karthigai) Mid-October to Mid-December	VATHAM – Thannilai adaidhal PITHAM - Vaetrunilai valarchi
3	Munpani kaalam (Margazhi & Thai) Mid-December to Mid-February	PITHAM – Thannilai adaidhal
4	Pinpani kaalam (Masi & Panguni) Mid-February to Mid-June	KABHAM – Thannilai valarchi
5	Elavenir kaalam (Chithirai & Vaikaasi) Mid-April to Mid-June	KABHAM – Vaetrunilai valarchi
6	Mudhuvenir kaalam (Aani & Aadi) Mid-June to Mid-August	VATHAM– Thannilai valarchi KABHAM – Thannilai adaidhal

THINAI (LAND):

Siddhars classified the lands into five types. They are

1. Kurunji – Mountain range
2. Mullai – Pastoral area of the forest
3. Marudham – The fertile river bed
4. Neidhal – The coastal region
5. Paalai – Arid desert

- Kabha diseases will occur in Kurinji land. Pitha diseases occur in Mullai land. Vadha diseases occur in Neidhal land. Staying in Paalai land is not good to health. Marudham land is the fertile area where no disease occurs. So, Marudham land is the best one to stay in.

- The winter season gives good health to the man, early summer and later rainy gives moderate health. Whereas early rainy and later summer are more prone to diseases, that's why siddhars called it as Aanaga kaalam.

RELATION BETWEEN MUKKUTRAM, KAALANGAL AND THINAIGAL:

Mukkutram	Paruvakaalam (Seasons)			Thinai
	Thannilai valarchi (Accumulation)	Vaetrunilai valarchi (Aggravation)	Thannilai adaidhal (Alleviation)	
VATHAM	Mudhuvenil kaalam	Kaar kaalam	Koothir kaalam	Vatha disease is more prevalent in Neidhal land.
PITHAM	Kaar kaalam	Koothir kaalam	Munpani kaalam	Pitha disease is more prevalent in Mullai land
KABHAM	Pinpani kaalam	Elavenil kaalam	Mudhuvenil kaalam	Kabha disease is more prevalent in Kurunji land

UDAL VANMAI (IMMUNITY):

Siddhars classify udal vanmai into three types. They are

1. Iyarkai vanmai
2. Kala vanmai
3. Seyarkai vanmai.

UDAL KATTUGAL:

S.No	Udal kattugal	General Features	Changes in Venpulli
1	Saaram (Digestive essence)	Responsible for the growth and development. It keeps the individual in good temperament and it enriches the body.	Affected
2	Senneer (Blood)	Responsible for the color of the blood and for the intellect, nourishment, strength of the body.	Affected
3	Oon (Muscle)	Gives lookable contour to the body as needed for the physical activity. It feed the fat next day and gives a sort of plumpness to the body.	Normal

4	Kozhuppu (Fat)	Lubricates the organs to facilitate frictionless functions.	Normal
5	Enbu (Bones)	Supports and protects the vital organs, gives the definite structure of the body and responsible for the posture and movements of the body.	Normal
6	Moolai (Bone marrow)	Nourishes the bone marrow and brain which is the centre that controls other system of body.	Normal
7	Sukkilam/Suronitham (Sperm/Ova)	Responsible for reproduction	Normal

PINIYARI MURAIMAI (DIAGNOSIS):

Four steps are followed in diagnosing the disease. They are

1. Poriyaal aridhal
2. Pulanal therdhal
3. Vinaadhal
4. Envagai thervugal

PORIYAAL ARIDHAL:

In this, the physician should carefully observe the changes that occur in the five sensory organs (porigal) of the patient.

PULANAL THERDHAL:

The physician carefully applies his five senses of perception, smell, taste, vision, touch and sound to understand the condition of the patient.

VINAADHAL:

The physician should interrogate about the patients name, age, occupation, socio-economic status, food habits, history of past illness, history of present illness, family history and frequency of pain.

ENVAGAI THERVUGAL:

“ நாடிப்பரிசம் நாநிறம் மொழிவிழி
மலம் மூத்திரமிவை மருத்துவராயுதம்”

Nowadays advanced diagnostic tools have been developed by modern bio medical scientists. But siddhars have given eight diagnostic methodological tools. They are called as Envagai thervu.

Eight fold system of clinical assessments:

Siddhars have given eight diagnostic methodological tools. They are

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

GENERAL FINDINGS:

NAADI:

Naadi is responsible for the existence of life, can be felt one inch below the wrist on the radial side by means of palpation with tips of index, middle and ring finger, corresponding to vatham, pitham, kabham.

Three humours Vatham, Pitham, and Kabham are in the ratio 1:1/2:1/4 normally. Derangement in these ratio leads to various disease conditions.

Naadi nadai in Venpulli,

Vathapitham or Pithakabam.

SPARISAM:

By sparisam, the temperature of skin (thatpam- cold or veppam – heat), smoothness, roughness, sweating, dryness, hard patches, swelling, abnormal growth of organs and tenderness can be felt.

In Venpulli – Affected area may be or may not loss of sensation.

NAA:

Signs and symptoms in the tongue are noted here. Colour, salivary secretion, ulcers, coating, inflammation, taste changes, deviation and its nature are generally noted.

In Venpulli – In anaemic condition tongue may be Pallor.

NIRAM:

The colour of the skin is noted here.

In Venpulli – The natural colour becomes pale or diminished.

MOZHI:

Character of the speech is noted, mainly uraththa oli (high pitched), thazhndha oli (low pitched), or resembles the sound of any instrument.

In Venpulli – No changes in voice.

VIZHI:

Character of the eye is noted. Colour, warm, burning sensation, irritation, visual perception are generally noted.

In Venpulli- Not affected.

MALAM:

The stools are examined for quantity, hardening (malakattu), loose motion (bedhi), colour and smell.

In Venpulli – Normal

MOOTHIRAM:

a) NEERKURI (Urine examination):

Urine examination is good diagnostic method compared to naadi and other Envagai thervugal. Theraiyar mention it as.

"அருந்துமா றிரதமும் அவிரோதமதாய்
அக்கல் அலர்தல் அகாலவூண் தவிர்த்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிகலசத் தாவியே காதுபெய்
தொருமுகூர்த்தக் கலைக்குட்படு நீரின்
நிறகுறி நெய்குறி நிருமித்தல் கடனே."

The early morning urine sample is collected and sample should be examined within 90 minutes.

SIRUNEERIN POTHU GUNAM:

“வந்த நீர்கரி எடை மணம் நுரை எஞ்சலென
றைந்தியலுளவை யறைகுது முறையே.”

The urine is examined for its Niram (colour), Eadai (Specific gravity), Nurai (Froth), Natram (Smell), Enjal (Deposits).

NIRAM (COLOUR) NIRA THOGAI

“ பீதம் செம்மைபைங் கருமை வெண்மையென்
றோதையங் கொழுமையை யொத்துகு நீரே.”

1. Yellow
2. Red
3. Green
4. Black
5. White.

Urine may be any colour as mentioned above.

EADAI (SPECIFIC GRAVITY):

Urine, not thick is considerably healthy. This is mentioned as

“மிக தடிப்பும் மிகத் தேறலும் இன்றேனில்
சுகத்தைத் தரும் மெய்ச் சுபாவ நீர் நன்றே.”

NURAI (FROTH):

Urine may be frothy in nature, if it is reduced, vali, azhal and ayyam are said to be deranged. This is mentioned as

“பந்தமெய்ப் பசையிளகபடும் பருவத்
தந்தர்ப் பூதமாய் அனில மூத்திரத்தில்
சம்பந்தபடும் ததினுரைப் புனலே.”

NEIKURI:

The early morning urine of the patient is analysed by dropping a drop of gingelly oil on the surface of the urine sample. The accumulation, formations, changes, and dispersal under the sunlight without any external disturbances of the urine sample can be noted. The urine kept on the kidney tray in sun light, on non-wind condition, should be examined by dropping a drop of gingelly oil. If oil spread like snake, it indicates vali neer; a ring

indicates azhal neer and float like a pearl indicates iyya neer and sinks in urine indicates mukkutram.

“அரவென நீண்டின.்தே வாதம்
ஆழி போற் பரவின் அ.்தே பித்தம்
முத்தொத்து நிற்கின் மொழிவதென் கபமே.”

- Vatha neer – The oil spreads like snake
- Pitha neer – The oil spreads like ring
- Kabha neer – The oil spreads like pearl
- If the oil spreads gradually, it indicates good prognosis
- If the oil spreads fast or gets mixed completely with urine or sinks in urine, it suggests bad prognosis

MANAGEMENT OF VENPULLI:

REJUVENATION:

KALPA MARUNTHU:

Pothu kalpam, Ponnangaani karpam (Alternanthera sessilis)(Used as recipes along with milagu (Piper nigvum),kariuppu(Sodium chloride).

SIRAPPU:

- KITTIKIZHANGU (Acalypha fruticosa) used as daily dishes like curry, vatral,etc.., Lemon used as pickle or juices (To be continued for six months).
- Ayapirungaraja karpam
- Ayajambeera karpam

KALPA YOGAM:

- Sarvangaasana is most useful for this complained shirasana is also useful, whereas the other asanam have been included for general health and fitness.
- Pranayamam

THE COMMON BENEFITS OF YOGAM:

SARVANGASANAM USES:

It prevents narai, thirai and moopu (i.e) prevents ageing .By stimulating the thyroid gland it gives strength to all the organs of the body .It cures kutta noi.

UNAVU:

TO BE ADDED:

- Drink adequate water
- Carrot
- Coriander
- Soya beans
- Pumpkin
- Fig fruit
- Banana flower
- Black dates
- Green vegetables/spinach
- Watermelon
- Beetroot
- Walnuts
- Apple
- Honey
- Pomegranate

TO BE AVOIDED:

- Bitter gourd
- Sea foods
- Chicken
- Chocolate
- Tamarind
- Packaged food
- Curd
- Coffee
- Raw onion
- Brinjal
- Pickles
- Papaya
- Green chilli
- Citrus fruits (Grapes, Orange, Lemon)
- Tinned foods or drinks
- Raw tomato
- Raw garlic

OTHER ADVICES:

- OLEATION: Oil bath should be taken twice a week which is advisable.
- It is better to add bitter tasted herbs like azadirachta indica, acacia catechu etc..,
- Eechaam paai a type of mattress prepared from the leaves of phoenix sylvestris.
- Food stuff that bring the vaatha ,piththa and kabha dhoshas to the normal physiology level have to be consumed.

MODERN ASPECTS

THE SKIN:

Dermatology is the study of skin diseases. Disease of the skin, are a common occurrence, account for a great deal of misery, suffering in capacity and economic loss. A very few skin diseases are contagious.

Hippocrates, Father of Medicine described many skin diseases and divided them into two groups according to their exogenous or endogenous causes. He attributed the origin of disease to abnormal mixing of black and yellow bile, blood and phlegm. The theory of abnormally mixed humors played a major role in dermatology for a long time.

Dermatology is a branch of medicine dealing with the skin. Its roots reach back to antiquity. The obviously manifested skin diseases have drawn the attention of men since time immemorial.

SKIN ANATOMY

The human skin is the outer covering of the body and is continuous with the mucous membranes in the region of the mouth, nose, urogenital organs and the anus. In an adult the skin surface measures 1.5 - 2 m while the thickness of the skin varies from fractions of a millimetre to 4 mm. The thickness of the epidermis varies from 0/06 - 0.9 mm to 0.5 - 0.6 mm. The thickness of the subcutaneous fat varies considerably. Some areas are devoid of fat while in others (on the abdomen and gluteal regions), it is several centimetres thick. The mass of skin of an adult accounts for approximately 5 % while together with subcutaneous fat for about 10 to 17.7 % of the total body mass.

NORMAL SKIN STRUCTURE:

The colour of the skin may change because the amount of the pigment in it varies due to external and internal factors. The skin surface is covered with hairs over a great area. The areas devoid of hairs are the lips, palms and soles, glans penis, inner surface of the prepuce and the inner surface of the labia majorum and minorum.

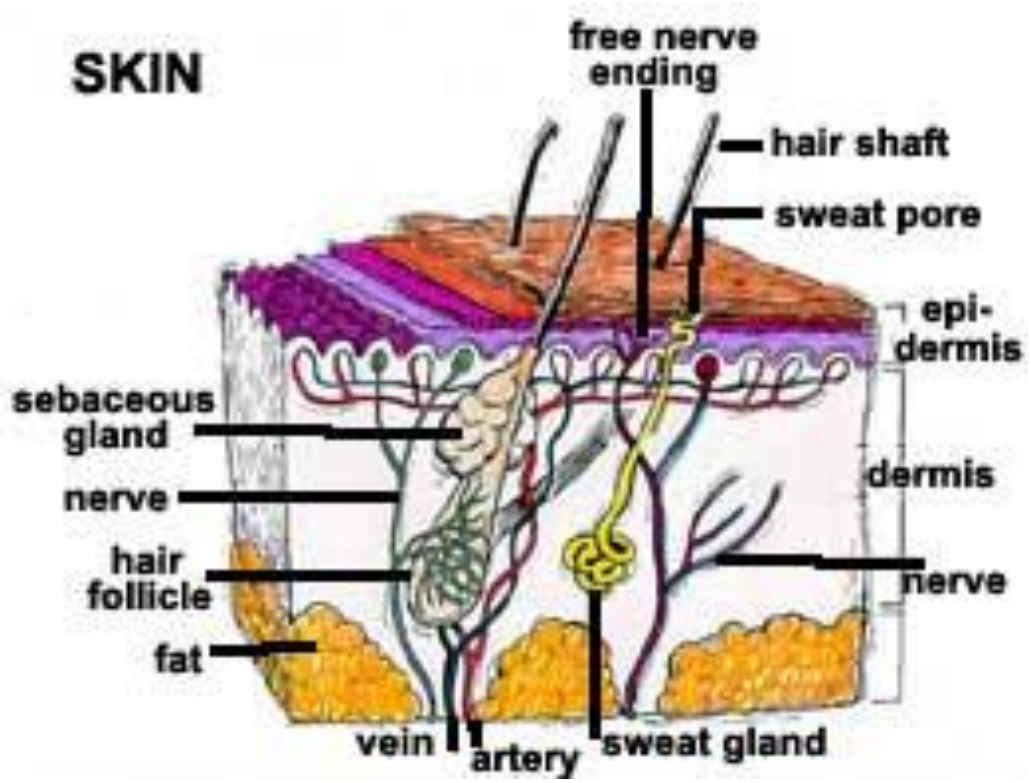


Figure 1 : Structure of skin

SKIN HISTOLOGY:

The skin develops from two germinative zones. The ectoderm which is represented by the epidermis (the most superficial skin layer) and the mesoderm (the middle embryonal layer) represented by two layers namely the true skin, or dermis (the middle layer) and the subcutaneous fat or hypoderm the deepest skin layer.

The boundary between the epidermis and dermis forms a wavy line because of the presence of skin papilla (special out growth on the surface of the true skin) the spaces between which are filled with epithelial processes.

VASCULAR SYSTEM OF SKIN:

Vascular system of the skin is formed of several networks of blood vessels. Large arterial vessels stretch from the bascia through the subcutaneous fat and give off small branches to the fat lobules. On the boundary of the dermis and hypoderm, they divide into branches which stretch horizontally and anastomose with one another. A deep arterial plexus of skinforms, which gives rise to branches supplying the holes of the sweat glands, the hair follicles and the fat lobules. The epidermis is devoid of blood vessels. The most

powerful network of blood vessels is located in the skin of the face, palms, soles, lips, genitals and in the skin around the anus.

LYMPHATIC SYSTEM OF SKIN:

The lymphatic system of the skin forms superficial and deep networks. The superficial lymphatic network arises on the papillary layer as blind rounded dilated capillaries between which there are numerous anastomoses. The second network of lymph vessels is in the lower part of the dermis and already has valves. There is a network of wide loops forming lymphatic plexus and deeper parts are continuous with lymph trunks

LAYERS OF THE SKIN:

EPIDERMIS:

The epidermis is stratified epithelium undergoing keratinization; it consists of the following layers:

i) Germinative layer of stratum basale

ii) Prickle - cell layer or stratum spinosum

iii) Granular layer or stratum granulosum

iv)Stratum lucidum

v) Horny layer or stratum corneum

There are many nerve endings in the epidermis but no blood vessels and the cells are supplied with nutrients by the lymph flowing in the intercellular slits.

DERMIS:

The dermis is located between the epidermis and the subcutaneous fat. Two layers are distinguished in it, the papillary or subepithelial layers and the reticular layer. The papillary layer is that part of the dermis which is found between the epidermis and the superficial network of blood vessels. The reticular layer merges with the subcutaneous fat and is not demarcated from it sharply.The dermis is supportive connective tissue, mainly collagen, elastin and glycosaminoglycan.

SUBCUTANEOUS LAYER:

The subcutis consists of loose connective tissue and fat (upto 3 cm thick on the abdomen).

BLOOD AND LYMPHATIC VESSELS:

The skin also has a rich and adaptive bloodsupply. Arteries in the subcuits branchupwards, forming a superficial plexus at the papillary/ reticular dermal boundary. Branches extend to the dermal papillae .each of which has a single loop of capillary vessels, one arterial and one venous, Veins drain from the venous side of the loop to form the mid dermal and subcutaneous venous networks. In the reticular and papillary dermis there are arteriovenous anastomoses which are well innervated and concerned with thermoregulation.

The lymphatic drainage of the skin is important, and abundant meshes of lymphatics originate in the papillae and assemble into larger vessels which ultimately drain into the regional lymph nodes.

PIGMENTATION OF THE SKIN:

The colour of the skin may be brown or even black according tothe amount of pigment present and it varies due to external and internal factors.Even in white races most parts of the skin contain brown pigment granules in the deepest layer of the germinative zone of the epidermis. In dark races they are more abundant and extend throughout the whole zone.The degree of racial pigmentation does not depend on the number of melanocytes present but on their metabolic activity and the size and shape of their melanin producing organelles the melanosomes.

Brownness of the skin depends upon the transfer of melanosomes from melanocytes into keratinocytes.Melanosomes are cytoplasmic particle formed in melanocytes and then distributed among the basal cells of the epidermis.Each melanocytes in the epidermis secrete melanosomes are site of melanin synthesis by the action of tyrosinase upon tyrosine.

MELANIN:

Melanin - Derived from the Greek word Melas, meaning black.

Melanin is endogenous nonhaemoglobin derived brown or black pigment formed when the enzyme tyrosinase catalyses the oxidation of tyrosin to dihydroxy phenylalanine (DOPA) in melancocytes.

DISTRIBUTION:

It is widely distributed in the body but peculiarly enough it is limited only to those structures which have got an ectodermal origin, for eg: skin, hair, choroid coat of retina and substantia nigra of the brain. It is formed from tyrosine by oxidation, metabolism and polymerization.

FUNCTIONS:

The function of melanin in the choroids is namely to convert the eye ball into a perfect dark chamber. Since nervous tissue is derived from ectoderm, the melanin in the substantia nigra may represent the vestigial remnants of the melanin in the substantia nigra may represent the vestigial remnants of the melanin forming properties. Melanin is the great protector of the skin against the actinic rays of the sun.

MELANIN FORMATION:

Melanin, wherever it is found, is formed in the local cells by the enzyme tyrosinase (or) melanase. The mother substance, upon which the enzyme acts, is a tyrosine derivative (DOPA) believed to be formed in the adrenals.

Melanin formation in both human and amphibian skin is augmented by the harmone known as intermedian or melanocyte - stimulating harmone (MSH) secreted by the pars intermedia of the pituitary gland. Adrenocartico tropic harmone (ACTH) secreted by Anterior Pituitary has melanocyte - stimulating activity similar to MSH although to a much lower degree. In Addison’s disease ACTH is secreted in a large amount and there is brownish black pigmentation of the exposed parts of the skin eg. hands, feet and mucous membrane.

Melatonin extract from bovine pineal gland, causes concentration of melanin near the nuclei of melanocytes in frog and as a result of this the skin becomes pale. Its role in the human is not known. MSH causes the serum copper to rise and this is accompanied by in the melanin formation. Diminished formation of melanin is seen in albinism and leucoderms. In melanocytic sarcoma, melanin may be found in the urine.

TYPES OF PIGMENTARY DISORDER:

Excessive pigmentation is known as hyper pigmentation and decreased pigmentation is known as hypo pigmentation. Both may be localized or generalized. In addition, increased pigmentation may result from deposits of abnormal non melanin pigments in the skin, E.g: Haemosiderin from broken down haem pigment in extravasated blood.

Homogentisic acid deposited in cartilage particular in the inherited metabolic defect known as alkaptonuria.Drugs and heavy metals toxicity. Silver, Gold, Mercury, Arsenic poisoning, Amiodarone and phenothiazine causes slate grey, dusky skin pigmentation in exposed sites.

VITILIGO:

The name ‘vitiligo’ is derived from the Latin word skin eruption, victim meaning a blemish (spoil the beauty of) happens to be a synonym for it.White skin is the literal meaning of leucoderma, derma being derived from the Greek words, leucas and dermis. Leucas means white and dermis means skin.Celeus was the first Roman physician of the 2nd century to coin the word vitilligo, because the disease resembles the white patches of a spotted calf (vitelus).

Vitiligo is characterized by the presence of non-pigmented areas of irregular shape, which develop on the epidermis of skin and hair. In this condition there is absence of deficiency of melanin, a dark pigment of the skin produced by melancytes under the stimulation of the sun light and possibly, under the control of a melanin stimulating hormone of the hypophysis.It is also regarded to develop through eczema scar of prick by injection needle, injury by burn or from other accidents, by friction of foot, wearing tight clothes. It has also been observed in persons who have suffered serious illness due to typhoid, jaundice, liver diseases, diabetes, worms, constipation and diarrhoea.

The non-pigmented patches whitish or reddish are round or oval in shape with smooth surface and slowly grow into large, irregularly outlined areas. It may be the result of skin diseases or it may be a harmless condition of unknown cause.

DEFINITION:

Vitiligo is a disorder of the skin especially due to loss of pigment without any disturbances and textural alterations.A condition due to failure of melanin formation in the skin produces sharply demarcated, milky white patches with hyperpigmented borders.

It is an extremely common depigmentary disorder of great medico social significance among the dark people, aetiology is uncertain association with variable penetrance; no age is except, both sexes. A symptomatic puncture linear, oval, circular or irregular, discrete or confluent depigmented and or hypopigmented macules on otherwise normal skin is confined to mucocutaneous functions dermatomal unilateral or bilateral, symmetrical or asymmetrical generalized or universal over laying hair retain pigment or turn white, no autonomic or sensory disturbances, sub burn or chronic solar damage in longstanding cases, unpredictable and capricious course, stationary, self-healing or progressive.

It is quite clear that vitiligo is due to some derangement in the pigment metabolism resulting in appearance of white patches in the skin. It is hard to say whether the site of derangement is usually general or local, but the main affected part is the skin, which is the most exposed part of the body. It can be examined by naked eye and can furnish a lot of information about the person and the disease. In certain cases the changes are not clear. Hence the study of the skin structure and its physiology is essential for proper assessment.

EPIDEMIOLOGY:

Vitiligo is an acquired idiopathic depigmentary condition which, though worldwide in distribution, is most common in India, Egypt and other tropical countries. It is a source of great social embarrassment of dark-skinned people. It affects all age groups with no predilection to either sex.

GROSS ANATOMICAL CHANGES IN VITILIGO:

Vitiligo represents an acquired patchy loss of pigments of the skin. There are no gross changes seen except irregularly demarcated, depigmented patches of varying size, usually surrounded by hyperpigmented skin. These are seen distributed symmetrically or asymmetrically at various parts of the body.

HISTOPATHALOGIC CHANGES IN VITILIGO:

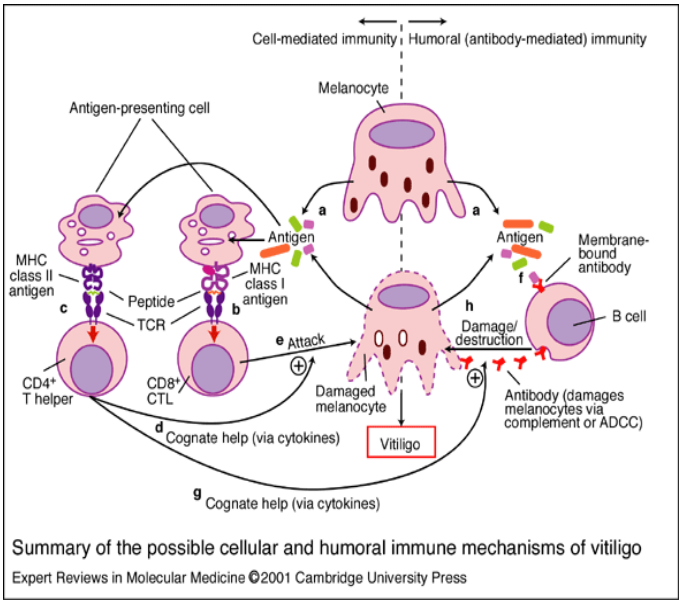
Marked histological changes do not occur in cases of vitiligo. All the layers of the epidermis and dermisappear normal except a few changes which can be seen after special stains.

In the affected area the basal cells and the keratinizing cells of the other layers of epidermis do not contain melanin pigment granules in them. The contrast can be seen at a junction of the normal and vitiliginous areas of the skin, especially by silver staining or DOPA reaction. The pigment cells, the melanocytes are not seen in the affected area but they are present in the adjacent normal skin. At the border of the patches of vitiligo the melanocytes often appear large and possess long dendritic process filled with melanin granules. Electron microscopic studies confirm the absence of melanocytes in areas of long standing vitiligo.

There are collections of mononuclear cells at dermo epidermal junction at the border between vitiliginous and normal skin. These cells are predominately small lymphocytes. In the long standing cases where the skin has become thick and scaly, varying amount of the keratosis is seen.

POSSIBLE CELLULAR AND HUMORAL IMMUNE MECHANISMS OF VITILIGO

Fig 2:



Summary of the possible cellular and humoral immune mechanisms of vitiligo

ETIOLOGY – VITILIGO:

- Melanocytes in areas of depigmented skin are destroyed and the cause is unknown. Anti-melanocytic anti-bodies directed against intra cellular components of melanocytes have been shown. The presence of organ specific auto immune disease occurs in about 10 % of patients. Such conditions are more common in their families than in a normal population. A neurogenic defect has been postulated for the rare dermatomal pattern of vitiligo which affects principally the limbs.
- Endocrines - Association with thyrotoxicosis and diabetes.
- Trophoneurosis and autonomic imbalance - emotional stress and strain.
- Infections and toxic products, Enteric fever ill health, focal sepsis.
- Drugs and chemicals - like quinines, guano furacin, amylphenol, chlorthiazide, broad spectrum antibiotics and chloroquin.
- Auto-immune thyroid disease is one of a group of organ specific auto immune diseases that include pernicious anaemia, Addison's disease and hypo para - thyroidism.

HEREDITARY FACTORS:

Hereditary is one of the factors supposed to be related with this disease to some extent. Familal incidence has been reported in 7.5 to 21 % in India and 33 to 40 % in western countries.

EMOTIONAL FACTORS:

It is every day knowledge and observation that emotional factors affect the skin as shown by the blushing of embracement, the pallor of fear and the pallor or redness of Change, depending on the subject and his emotional state. Experiments have demonstrated that emotional change can affect the following, which has direct relevance in the aetiology of certain skin disorders.

- Control of vascularity of the skin
- Control of sebaceous gland secretion.
- Influencing the degree of oxidation.
- Influencing the tendency of pruritus.

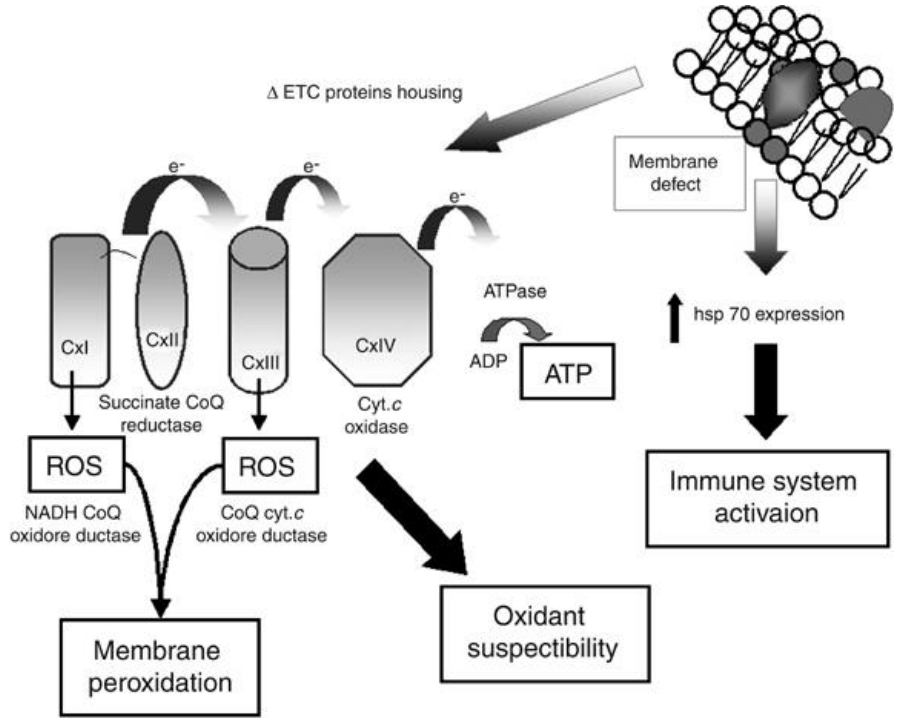
III PATHOLOGY:

Chemically melanin pigment is a group of chromo proteins with colored prosthetic groups, which is derived from the precursor tyrosine in the following way Tyrosine, Tyrinase Dihydroxy phenylanin (DOPA), Melanogenase, Melanin (Dopa oxidase).

Melanin + Protein = Melano protein.

THE POSSIBLE PATHOGENETIC MECHANISM: A SCHEMATIC PICTURE OF THE CAUSAL AND TEMPORAL SEQUENCE LEADING TO THE MELANOCYTE FUNCTIONAL IMPAIRMENT DURING VITILIGO

Fig 3:



In the skin, the pigment is produced by the melanocytes from their precursor's melanoblasts. The melanoblasts are supposed to be derived from the cells of neuro ectodermal origin during the embryonic life. After birth, these cells migrate to their definitive position. The melanocytes appear as clear cells within the basal cell layer of the epidermis and show dendritic processes after special staining. These processes come in contact with similiar process of other melanocytes and epithelial cells through which the melanin pigments are donated to the basal cells of epidermis. The dermis of normal skin also shows macrophages containing melanin pigments known as melanophores, which are incapable to produce the melanin pigments.

CAUSES OF HYPOPIGMENTATION:

Generalised depigmentation is found mostly in albinos. In this case, the characteristic dendritic melanocytes are present in the skin, but they are unable to produce melanin pigment due to defective tyrosinase activity. In albinism, the skin looks milky white, the hairs are pale looking and the iris is transparent. The generalized pallor is also noticed in panhypopituitiarism, male eunuchoidism and phenyl ketonuria.

Localised depigmentation is often noticed in the skin of patterned leucoderma. The white patches on the skin may be quite extensive and the condition is inherited as an autosomal dominant character.Sometimes sharply defined focal depigmented areas are found on skin of persons suffering from vitiligo. In the affected areas, melanocytes are absent and there is no trace of melanin. The condition is an acquired one and shows some familial tendency.

Vitiligo in patients in whom the disease spreads very fast or those having halo-navi or malignant melanoma is believed to be based on auto-immune mechanisms, where auto antibodies or sensitized lymphocytes are supposed to act on the melanocytes. Trauma on the skin including that produced by scratching can lead to depigmentation of the skin even when it does not lead to ulceration. Leucoderma is also commonly seen on the flanks of ladies wearing tight petticoat strings where the prolonged pressure is presumed to lead to depigmentation. Sometimes vitiligo can be caused by the action of monobenzyle either on hydroquinone present in the slippers, gloves (or) other articles made of rubber or used as a depigmenting agent in the form of an irritant for pigmentary disorders. Recently vitiligo has also been observed to occur from plastic slippers as well as plastic ‘hindis’.

However most people with vitiligo have no other autoimmune disease. Vitiligo may also be hereditary, that is, it can run in families. Children whose parents have the disorder are more likely to develop vitiligo. However, most children will not get vitiligo even if a parent has it, and most people with vitiligo do not have a family history of the disorder.

CLINICAL FEATURES:

- In this condition patches of skin lose their pigment and become perfectly white, though no other changes take place in them and particularly there is no scaling.
- Vitiligo may occur in either sex.

- The white patches may appear on any part of the skin but commonest on the face, neck, hands and wrist, lower abdomen and thighs and may be precipitates by trauma to the skin.
- They may be of any size or shape and are usually though not always, roughly symmetrical.
- They slowly increase in size until large areas of the skin are completely discoloured.
- The remaining small patches of normal skin may then be mistaken for pigmented areas. The mistake may be avoided by remembering that the vitiligo areas have convex margins and the normal areas therefore have concave ones.
- When vitiligo occurs on a hairy area such as eyebrows or pubis the hair on the white patch may also become white.
- The depigmented areas are sometimes surrounded by an excess of pigmentation in the immediately adjoining skin but this appearance is often illusory and the result of visual contrast.
- Vitiligo is most noticeable in the summer when the normal skin is tanned by the sun.
- Vitiligo sometimes disappears spontaneously after months or years but more usually the conditions spreads slowly and may eventually involve nearly whole of the skin.
- It is characterized by completely depigmented macules and patches of varying sizes and shapes.
- There are no other changes except depigmentation.
- Early lesions may be pale white and ill defined. At this stage, Wood's lamp helps to confirm the diagnosis. Patches enlarge slowly and may affect the whole body.
- Any part of the body can be affected but the sites of predilection are the face, dorsa of fingers and hands, wrist and the legs.
- Involvement of mucous membrane especially the lip is not uncommon; it can precede cutaneous involvement by years.

CLINICAL CRITERIA FOR CLASSIFICATION OF VITILIGO:

Stages of Clinical Features:

Active (V1)	(i) New lesions developing
	(ii) Lesions increasing in size
	(iii) Border ill-defined
Quiescent (V2)	(i) No new lesions developing
	(ii) Lesions stationary in size
	(iii) Border hyper pigmented and well-defined.
Improving (V3)	(i) Lesions decreasing in size
	(ii) No new lesions developing
	(iii) Border defined and signs of spontaneous regimentation

Zosteriform: Unilateral distribution of lesions, preferably along the course of nerves. Besides typing the stage of disease, it is useful to decide the variety (acral,Vulgaris,Zosteriform), severity (Localized or extensive) and acuity (insidious or galloping) of vitiligo.

DIAGNOSIS:

- The distribution, the age of onset and the hyperpigmented border will suggest the diagnosis.
- It is usually apparent; in doubtful and early case, Wood's lamp is of great help in diagnosis.
- In piebaldism the lesions are present at birth, are usually confined to the head and trunk and rarely show a hyperpigmented border.
- Careful examination of the texture of the unpigmented skin should exclude lichen sclerosus and scleroderma.
- Post-inflammatory leucoderma, which is frequent in the darker races, shows an irregular mottling of hyperpigmented and hypopigmented blotches.
- Hypomelanosis of the affected skin is commonly seen in pityriasis alba, producing slightly scaly areas with rather ill-defined edges of children's faces.
- Hypopigmented, slightly scaly macules are seen in pityriasis versicolor.
- Vitiliginous areas are milky white while other lacks this milky white colouration.
- Stationary patches are well-defined and have hyperpigmented borders.

- Absence of scaling, crusting and itching help to eliminate seborrhoeids and pityriasis versicolor.
- These areas often fluorescence a golden yellow when examined under a Wood's lamp. The hypomelanotic macules in leprosy are anaesthetic.
- Examination of the skin in long wave UVR helps distinguish whether there is total depigmentation (as in Vitiligo) or not. It may also detect areas of depigmentation not easily seen in ordinary daylight, as well as detecting a lemon-yellow fluorescence seen in some cases of pityriasis versicolor.

PROGNOSIS:

It has improved considerably in recent years because of better understanding of etiological factors and advances made in therapy.

Following conditions are said to be of poor prognosis.

1) Poor nutritional state or digestion, use of broad - spectrum antibiotics over long period, emotional stress and nervous debility.
2) Presence of vitiligo on resistant sites like the hands and the feet, front of wrists, the elbow, the waist, the eyelids and lips.
3) Depigmented hair in vitiliginous areas.

Causes of Localised Hypopigmentation

Vitiligo	Destruction of melanocytes; common; acquired, multiple sharply defined nonpigmented patches anywhere.
Pityriasis versicolor	Superficial fungus infection leading to disturbance in pigment production, common multiple pale scaling patches on trunk
Pityrisis alba	Mild patchy eczema of the face in children causing a disturbance in pigment production.
Leprosy	One or several paler macules on trunk or limbs that are hypo aesthetic.
White macules of affecting tuberous sclerosis	Uncommon development of anomaly of CNS, connective tissue and skin; several "maple leaf" shaped hypopigmented macules.
Post inflammatory hypopigmentation	After inflammatory skin disease (after eczema or trauma to the skin; irregular in shape and in depth of pallor).
Naevous anaemicus	Rare developmental solitary white patch usually on trunk; thought to have vascular basis.
Chemical toxicity	May look very much like vitiligo; seen in workers in rubber industry exposed to parateriary benzyltoluence.

DIFFERENTIAL DIAGNOSIS OF THE IMPORTANT DEPIGMENTARY DISORDERS:

Distinguish Features	Albinism	Naevus Depigmentosus	Vitiligo	Leprosy	Pityriasis
Age	Congential present at birth	Congential-present at birth	Acquired	Any age	Any age
Distribution	Complete (or) partial	Unilateral	Any area	Any area	Trunk, Neck, and Face
Course	Stationary	Does not increase in size or changing shape	Progressive	Progressive	Progressive, worse in monsoon and summer
Hyperpig mentary border	Nil	Nil	Present	Inflammatory	Nil
Heredofamilial	Hereditary	Not hereditary	Nil	Nil	Nil
Other features	Hair and eyes may be affected	Nil	Nil	Anaesthesia thickened nerves, nasal, bleeding slit smear and biopsy	Furfuraceous like dandruff, scaling in head macules and large patches.

VITILIGO AREA SEVERITY INDEX (VASI)

Its name is an adoption from PASI score in psoriasis. The percentage of vitiligo involvement is calculated in terms of hand units. One hand unit is approximately equivalent to 1% of the total body surface area. The degree of pigmentation is estimated to the nearest of one of the following percentages: 100% - complete depigmentation, no pigment is present; 90% - specks of pigment present; 75% - depigmented area exceeds the pigmented area; 50% - pigmented and depigmented areas are equal; 25% - pigmented area exceeds depigmented area; and 10% - only specks of depigmentation present. The VASI for each body region is determined by the product of the area of vitiligo in hand units and the extent of depigmentation within each hand unit measured patch.Total body VASI = S All body sites [Hand Units] ´ [Residual depigmentation].

DEPIGMENTATION VISUAL SCALE:

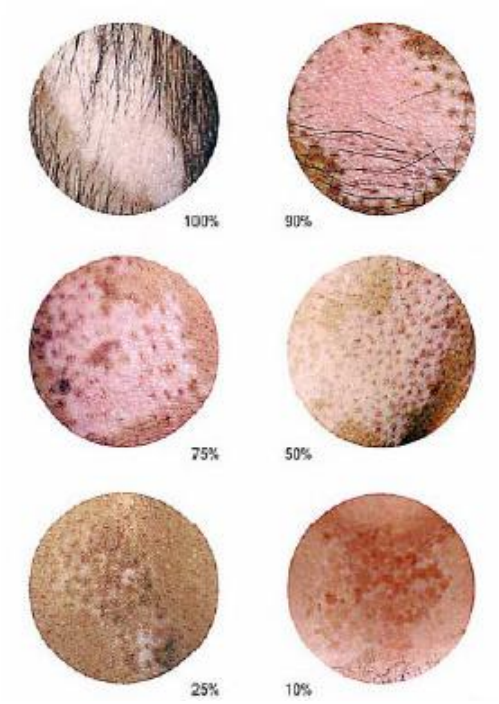


Fig 4: Depigmentation visual scale

VASI score	~−50	Very much worse
VASI score	-50 to -25	Much worse
VASI score	-25 to -10	Worse
VASI score	-10 to 0	Minimally worse
VASI score	0 to +10	Minimally improved
VASI score	+10 to 25	Improved
VASI score	25 to 50	Much improved
VASI score	+50~	Very much improved

DRUG REVIEW

I. PARANGIPATTAI CHOORANAM:

i) PARANGI PATTAI:

Botanical name : *Smilax china* Linn.

English name : China root

Family : Liliaceae

Part used : Tuber

Organoleptic Characters:

Suvai : Inippu

Thanmai : Thatpam

Pirivu : Inippu

பொது குணம்:

தாகம் பலவாதந் தாதுநட்டம் புண்பிளவை
மேகங் கடிகிரந்தி வீழ்மூலந் - தேகமுடன்
குட்டை பகந்தமேற் கொள்வமனம் போம்பறங்கிப்
பட்டையினை யுச்சரித்துப் பார்.

-தேரையர் குணவாகடம்.

Chemical constituents:

Saponins, D - mannitol, Stigmasterol, oleanolic acid, Queretaroic acid, Serratagenic acid, Sitosterol, Clerosterol identified as 5, 25- stimastadien-3β o, Clerodone as 3β- hydroxyl- lupan 12- one, B- sitosterol, Lupeol, A steroidal glycoside, Phytosterols, Ferulic acid, Arabinose, Scutellarcin, Baicalein , Serratin and Ursolic acid.

Ref: *Praveen Kumar A et al / Int. J. Res. Ayurveda Pharm. 4(2), Mar – Apr 2013.*

Actions:

- Alternative
- Antisyphilitic
- Aphrodisiac

ii) KARUNTHULASI:

Botanical name : *Ocimum tenuiflorum* Linn.

English name : Holy basil

Family : Lamiaceae

Part used : Leaf

Organoleptic Characters:

Suvai : Karppu

Thanmai : Thatpam

Pirivu : Karppu

பொதுக் குணம்:

“இருமலொடு நெஞ்சி லிழுப்புச்சு வாசம்
கிருமி சலதோடம் கேவல் - மருமச்
சளிரூட்சை சூலைவிடம் சன்னியிவை போக்கும்
தளிரார் கருந்துளசி தான்.”

Chemical constituents:

- Linoleic, lauric, myristic, oleic, palmitic and stearic acids
- β sitosterol.

Actions:

- Stimulant
- Expectorant
- Diaphoretic

II. ANNABEDHI CHENDURAM:

i) ANNABEDHI (IRON SULPHATE):

Other Names:

- Green vitriol
- Ferrous sulfate
- Iron Vitrol
- Copperas
- Melanterite
- Szomolnokite

Natural occurrences:

- Mikasaite, a mixed iron-aluminium sulfate of chemical formula (Fe3+, Al3+)2(SO4)3[3] is the name of mineralogical form of iron(III) sulfate.
- This anhydrous form occurs very rarely and is connected with coal fires.

- The hydrates are more common, with coquimbite (nonahydrate) as probably the most often met among them.
- Paracoquimbite is the other, rarely met natural nonahydrate. Kornelite (heptahydrate) and quenstedtite (decahydrate) are rarely found.
- Lausenite (hexa- or pentahydrate) is a doubtful species. All the mentioned natural hydrates are unstable compounds connected with Fe-bearing primary minerals (mainly pyrite and marcasite) oxidation in ore beds.
- In the solutions of the ore beds oxidation zones the iron(III) sulfate is also an important oxidative agent.
- Ironsulfate is the chemical compound with the formula Fe2(SO4)3, the sulfate of trivalent iron.
- Usually yellow, it is a rhombic crystalline salt and soluble in water at room temperature.
- It is used in dyeing as a mordant, and as a coagulant for industrial wastes.
- It is also used in pigments, and in pickling baths for aluminum and steel.
- Medically it is used as an astringent and styptic.

Physical Properties:

- Molecular formula : FeSO4
- Molar mass : 151.908g/mol (anhydrous)
  169.92g/mol(monohydrate)
  278.05 g/mol (heptahydrate)
- Appearance : Blue/green or white crystals
- Odour : Odourless
- Density : 2.84g/cm3 (anhydrous)
  2.2g/cm3 (pentahydrate)
  1.898 g/cm3 (heptahydrate)
- Melting point : 70 °C (dehydration of heptahydrate)
  400 °C (decomp)
- Solubility in water : 25.6 g/100mL (anhydrous)
  48.6 g/100 mL (heptahydrate) (50 °C)
- Solubility : Negligible in alcohol
- Refractive index (nD) : 1.536 (pentahydrate)
  1.478 (heptahydrate)

GUNAPADAM ASPECT:

- அன்னபேதி சுதேச மருந்துக் கடைகளில் கிடைக்கும்
- இரும்புக் கம்பியுடன், கந்தகத் திராவகம் சேர்த்துச் செய்கின்ற இச்சரக்கு கட்டிகளாயும், பச்சை நிறமாயும் இருக்கும்.
- அன்னபேதி என்ற தாது காசீசம் மலையில் உற்பத்தியாகிறதென்றும் கறுப்பு மஞ்சள், வெள்ளை ஆகிய மூன்று விதமாகும் என்றும் போகர் நூல் கூறும்.
- இது நீரில் கரையும்.
- சாராயத்தில் கரையாது.
- இதன்மேல் காற்றுப்பட்டால் வெண்மையான தூளாய்விடும்.

Vernacular Names:

- Eng - Green Vitroil
- Green - Copperas
- Sans - Kasosa
- Fr - Sulphate Ferreux
- Ger - Schwefel Saures
- Ben - Hirakas
- Can - Hirakasa
- Arab - Zaje Asfara
- Hind - Haratutia
- Guj - Harakasis
- Punj - Sangi-sabz10
- Malay - Madukalpa
- Tel - Tagramu

Organoleptic Character:

- Taste - துவர்ப்பு
- Bio transformation - வெப்பம்

பொதுக் குணம்:

‘‘முளைவிரணஞ் சூலைமந்த முட்டாமைக் கட்டி
விளையறன்ம கோதரநோய் வீட்டும் - வளைமலைபோற்
காட்டுமன்னந் தன்னைக் கணத்திற் சலமாக்கிக்
காட்டுமன்ன பேதியது காண்’’

Actions:

- Nutrient
- Astringent
- Deodorant
- Anthelmintic
- Antiperiodic

ii) LEMON:

- Botanical Name : *Citrus limon* Linn.
- English name : Lime
- Family : Rutaceae
- Part Used : Leaf, Fruit,Unripe fruit,Fruit juice, Oil.

Organoleptic characters:

- Suvai : Pulippu
- Thanmai : Veppam
- Pirivu : Karppu

பொது குணம்:

"மந்திரிக்கு மந்திரியாய் மன்னனுக்கு மன்னனெனத்
தந்திரிக்குமித்திரன்போற் சாருமே – முந்தவரு
கம்பீர மாய்ச்சிரக்கின் கெண்ணியமாய் வாகடர்க்குச்
சம்பீர மாமெலுமிச் சை."

Actions:

- Refridgerant
- Rubefacient
- Carminative

INGREDIENTS OF PARANGIPATTAI CHOORANAM

Fig 5(i):

Parangipattai (SMILAX CHINA)

Fig 5 (ii):

Karunthulasi (OCIMUM TENUIFLORUM)

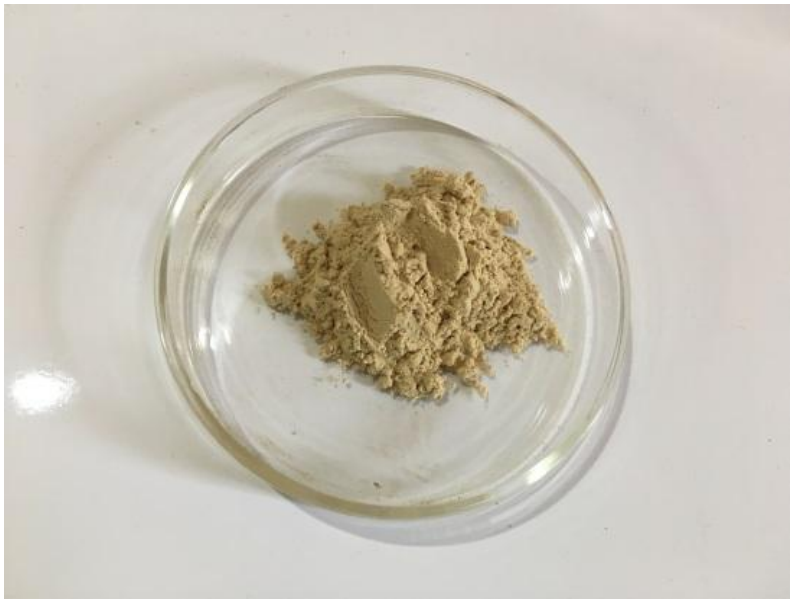


Fig 5 (iii)Parangipattai chooranam

INGREDIENTS OF ANNABEDHI CHENDURAM

Fig 6(i): Annabedhi

Fig 6 (ii): Lemon (CITRUS LIMON)

Fig 6 (iii): Annabedhi chenduram

MATERIALS AND METHODS

AProtocol was prepared and submittedbefore Institutional Ethical Committee (IEC)ofNationalInstituteofSiddha. Date of IEC approval & IEC number is NIS/IEC/2016/11-24/14.10.2016. The trial was registered in Clinical trial Registry of India with Reg.NoCTRI/2017/06/008755 [Registered on: 05/06/2017].Afterobtaining approval from thecommittee, the clinical studyon VENPULLI (Vitiligo) in children with the trialdrug PARANGIPATTAI CHOORANAM (internal) and ANNABEDHI CHENDURAM (external) wascarriedoutasperthe protocol.

The trial drug *"*PARANGIPATTAI CHOORANAM (internal) and ANNABEDHI CHENDURAM (external)*"* was given for 48 days. For OP patients before and after treatment the clinical assessment is done and prognosis was noted. After the end of the treatment, the patient was advised to visit the OPD for another 1 month for follow-up.

METHODOLOGY:

1. **INGREDIENTS AND PREPARATION OF THE TRIAL DRUG:**

A. INTERNAL MEDICINE:

NAME : *PARANGIPATTAI CHOORANAM.*

INGREDIENTS:

1. PARANGIPATTAI (SMILAX CHINA Linn.) - 1 PART
2. KARUNTHULASI (OCIMUM TENUIFLORUM Linn.) - 1 PART

SOURCE OF TRIAL MEDICINE:

The required drugs were purchased from a well reputed country shop and raw drugs were authenticated by the medicinal botanist of NIS. The medicine was prepared in Gunapadam lab of National Institute of Siddha after proper purification. The prepared medicine were also be authenticated by the concerned Head of the Dept for its completeness.All the ingredients mentioned in the formulation is purified as per the direction described in the Siddha literature.

PURIFICATION OF RAW DRUG:

Parangipattai: The drug was boiled in milk for 3 hours then dried well.

PREPARATION:

Parangipattai was soaked in equal amount of Karunthulasi juice and kept in sunlight until it was dried. Then it is grinded into fine powder and filtered by the process by vasthirakaayam.

B. EXTERNAL MEDICINE:

NAME : *ANNABEDHI CHENDURAM*.

INGREDIENTS:

1. ANNABEDHI
2. LEMON JUICE

PURIFICATION OF ANNABEDHI:

Anabedhi was grinded with Chunnaneer in Kalvam for 6 hours.

PREPARATION:

Purified Annabedhi was grinded with lemon juice in kalvam and kept in pudam to prepare it as a chenduram.

STUDY DESIGN:

Study Type : An open clinical trial

Study Place : Department of Kuzhanthai Maruthuvam,
Ayothidass Pandithar Hospital (Opd & Ipd),
National Institute of Siddha,
Tambaram Sanatorium
Chennai-47.

Study Period : 24 Months

Number of Patients : 30 Patients (Both male and female children)

Drug Formulation:

- ❖ INTERNAL MEDICINE - PARANGIPATTAI CHOORANAM (INTERNAL)
- ❖ EXTERNAL MEDICINE - ANNABEDHI CHENDURAM (EXTERNAL)

Internal Medicine:

NAME	:	PARANGIPATTAI CHOORANAM.
DOSAGE	:	½ - 1 gram (bd).
VEHICLE	:	Sakkarai (palm jaggery).
DURATION	:	1Mandalam (48 days).
DISPENSING	:	The prepared chooranam was dispensed in a pure container with required details and investigators contact number.
REFERENCE	:	SIDDHA VAITHIYA THIRATTU (Pg.no:221).

External Medicine:

NAME	:	ANNABEDHI CHENDURAM.
APPLICATION	:	With lemon juice
DURATION	:	1 Mandalam (48 days).
DISPENSING	:	The prepared chenduram was dispensed in a pure container with required details and investigators contact number.
REFERENCE	:	GUNAPAADAM THATHU JEEVA VAGUPU (Pg.no:528)

INCLUSION CRITERIA

- Age: 5 – 12 years
- Sex: Both male and female children.
- Hypo pigmented patches with hyper pigmented border without any structural changes in any part of the body**.**
- Patients who are willing to stay in IPD Ward for atleast 10 days or willing to attend OP Dept. as required.
- Patient's informant / Parent willing to sign the informed consent stating that he/she will consciously stick to the treatment during 48 days but can opt out of the trial of his / her own conscious discretion.
- Willing to cooperate for taking photographs whenever required with his\her consent.

EXCLUSION CRITERIA

- Albinism
- Dermatological aspect of Leprosy
- Tinea versicolor
- Burn scars
- Dermatological aspect of Addison's diseases
- Post inflammatory hypopigmentation
- Pityriasis alba
- Alopecia aerate
- Chemical leukoderma

WITHDRAWL CRITERIA

- Exacerbation of symptoms and signs
- If any adverse reactions and unwanted symptoms occurred during the drug trial.
- Intolerance to the drug.
- Patient turned unwilling to continue in the course of clinical trial.
- Occurrence of any serious illness.

STUDY ENROLMENT:

- In this study, patients reporting at the NIS OPD were examined clinically for enrolling in the study based on inclusion and exclusion criteria.
- The patients who are to be enrolled were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them.
- After ascertaining the patient's informant willingness, informed consent (Form II) was obtained in writing from their parents in the consent form.
- All these patients were given investigators phone number so as to report easily if any complications arise.
- Complete clinical history, complaints and duration, examination findings—all were recorded in the prescribed Proforma in the history and clinical assessment forms separately. Screening Form - I is filled up. Form III was used for recording the patient's history, laboratory investigations and clinical examination of signs and symptoms respectively.

- Patients were advised to take the trial drug and appropriate dietary advice (Form-V) is given according to the patient's perfect understanding.

CONDUCT OF THE STUDY:

- The trial drug "PARANGIPATTAI CHOORANAM (internal) and ANNABEDHI CHENDURAM (external)" was given for 48 days (twice a day),OP patients should visit the hospital once in 7 days.
- At each clinical visit clinical assessment was done and prognosis was noted.
- For IP patients who were not in a situation to stay in the hospital for a long time they were advised to attend the OPD for further follow up.
- Siddha investigations like Neerkuri and Neikuri were carried out.
- After the end of the treatment the patient were advised to visit the OPD for one week for follow up.
- If any trial patients who failed to collect the trial drug on the prescribed day but was willing to continue in the trial from the next day or two, he/she was allowed, but defaulters more than one week and more will not be allowed to continue and withdrawn from the study and a fresh case was included.

CLINICAL ASSESSMENT:

To assess the improvement by VASI Score (In annexure C).

SIDDHA ASSESSMENT:

- Nilam
- Kalam
- Uyirthathukkal
- Udal thathukkal
- Envagai thervugal
- Neerkuri
- Neikkuri

OUT COME:

Efficacy of the trial drug measured by VASI Score.

Data Management:

After enrolling the patient in the study, a separate file for each patient was opened and all forms were filed in the file. Study no, and Patient no, were entered on the top of file for easy identification.Whenever study patient visits OPD during the study period, the respective patient file was taken and necessary recordings were made at the assessment for or other suitable form.

The data recordings in all forms were monitored and scrutinized by HOD, Dept. of Kuzhanthai Maruthuvam.Data analysis was done with the help of senior research officer (statics) of NIS.

Adverse Effect/Serious Effect Management:

If the trial patient develops any adverse reaction such as continuous vomiting, diarrhoea, high fever, rashes, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National Institute of Siddha. The details of adverse reactions will be recorded in prescribed Pharmacovigilance form and the same will be reported to Regional Pharmacovigilance centre.

Ethical Issues:

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

DATA COLLECTION FORMS:

- FORM I - SCREENING & SELECTION PROFORMA
- FORM II - CONSENT FORM
- FORM II A - ASSENT FORM
- FORM III - CASE RECORD FORM
- FORM IV - INFORMATION SHEET.
- FORM V - DIETARY FORM
- FORM VI - DRUG COMPLAINCE
- FORM VII - ADVERSE EFFECT
- FORM VIII - WITHDRAWL FORM
- FORM IX - PHARMOCOVIGILENCE

ANALYTICAL SPECIFICATIONS FOR TRAIL DRUG

PHYSICOCHEMICAL ANALYSIS

Particle size

Particle size determination was carried out by optical microscopic method. In which the sample were dissolved in the sterile distilled water (app 1/100th dilution). Diluted sample were mounted on the slide and fixed with stage of appropriate location. Light microscopic image were drawn with scale micrometre to arrive at the average particle size. Minimum 30 observations were made to ascertain the mean average particle size of the sample.

Percentage Loss on Drying

10gm of test drug was accurately weighed in evaporating dish .The sample was dried at 105^{o}C for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

Determination of Total Ash

3 g of test drug was accurately weighed in silica dish and incinerated at the furnace at a temperature of 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Acid Insoluble Ash

The ash obtained by total ash test was boiled with 25 ml of dilute hydrochloric acid for 6mins. Then the insoluble matter is collected in crucible and will be washed with hot water and ignited to constant weight. Percentage of acid insoluble ash will be calculated with reference to the weight of air-dried ash.

Acid insoluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Water Soluble Ash

The ash obtained by total ash test was boiled with 25 ml of water for 5 mins. The insoluble matter is collected in crucible and will be washed with hot water, and ignite for 15mins at a temperature not exceeding 450ºC. Weight of the insoluble matter will be subtracted from the weight of the ash; the difference in weight represents the water soluble ash. Calculate the percentage of water-soluble ash with reference to the air-dried drug.

Water Soluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Alcohol Soluble Extractive

About 5 g of test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

Alcohol sol extract = Weight of Extract/ Wt of the Sample taken X 100

Determination of Water Soluble Extractive

About 5 g of the test sample was macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand and for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

Water soluble extract = Weight of Extract/ Wt of the Sample taken X 100

Determination of pH

About 5 g of test sample was dissolved in 25ml of distilled water and filtered the resultant solution is allowed to stand for 30 mins and the subjected to pH evaluation.

Thin Layer Chromatography and High Performance Thin Layer Chromatography:

1. TLC Analysis:

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

2. High Performance Thin Layer Chromatography Analysis:

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

(a) Chromatogram Development:

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

(b) Scanning:

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

Heavy/Toxic Metal Analysis by AAS:

Methodology:

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

Sample Digestion:

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

Standard reparation:

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

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

Microbial contamination by Pour Plate Method:

Objective:

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

Methodology:

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

Observation:

No growth was observed after incubation period reveals the absence of specific pathogen.

Test for Specific Pathogen:

Methodology:

One part of the test sample was dissolved in 9 mL of sterile distilled water and the test sample was directly inoculated in to the specific pathogen medium (EMB, DCC, Mannitol, Cetrimide) by pour plate method. The plates were incubated at 37^{o}C for 24 - 72h for observation. Presence of specific pathogen identified by their characteristic colour with respect to pattern of colony formation in each differential media.

Analysis of Pesticides Organochlorine, Organophosphorus and Pyrethroids:

Extraction:

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

Aflatoxin Assay by TLC (B1,B2,G1,G2):

Solvent:

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

Test solution: Concentration 1 µg per ml.

Procedure:

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

BIOCHEMICAL ANALYSIS

Biochemical Analysis of Parangipattai chooranamwas done at the Biochemistry lab at National Institute of Siddha, Chennai by the method of Kolkate.

Preparation of Extract:

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

PROCEDURE:

I. Test for Acid Radicals

Test for Sulphate:

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

Test for chloride:

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

Test for Phosphate:

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

Test for carbonate:

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

Test for Nitrate:

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

II.Test for Basic radicals

Test for lead:

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

Test for copper:

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

Test for Aluminium:

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

Test for Iron:

a. To the 2ml of extract add 2ml of dil.ammonium solution

b. To the 2ml of extract 2ml of thiocyanate solution and 2ml of con HNo3 is added.

Test for Zinc:

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

Test for Calcium:

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

Test for Magnesium:

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

Test for Ammonium:

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

Test for Potassium:

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

Test for Sodium:

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

Test for Mercury:

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

Test for Arsenic:

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

III. Test for Phytochemical:

Test for Starch:

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

Test For Reducing Sugar:

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

Test for the Alkaloids:

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

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

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

Test for Tannic Acid:

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

Test for AminoAcid:

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

Test for Coumarins:

To the test sample, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow colour.

Test for Saponins:

To the test sample, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

Test for glycosides- Borntrager's Test:

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

Test for flavonoids:

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for phenols:Lead acetate test:

To the test sample; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

Test for steroids:

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

Triterpenoids:

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentrated sulphuric acid was added from the sides of the test tube, appearance of red ring indicates the presence of triterpenoids.

Test for Cyanins:

Anthocyanin:

To the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100ºC. Formation of bluish green colour indicates the presence of anthocyanin.

OBSERVATION AND RESULT

PHYSICO-CHEMICAL ANALYSIS:

Organoleptic characters: *(Table 9)*

Sl.No	Specification	Character
1	Colour	Milky white
2	Odour	Mild
3	Taste	Bitter and sweet
4	Consistency	Very fine powder

Physicochemical characters of Parangipattai chooranam: *(Table 10)*

S.No	Parameter	Mean (n=3) SD
1	Loss on Drying at 105 °C (%)	8.5 ± 2.80
2	Total Ash (%)	0.55 ± 0.05
3	Acid insoluble Ash (%)	0.32 ± 0.15
4	Water Soluble Ash (%)	7.46 ± 0.72
5	Alcohol Soluble Extractive (%)	34.44 ± 2.12
6	Water soluble Extractive (%)	28.86 ± 0.81
7	pH	4.8

PARTICLE SIZE DETERMINATION:

Microscopic observation of the particle size analysis reveals that the average particle size of the sample PPC was found to be 121.9± 45.24 µm further the sample PPC has particle with the size range of lowest 41.1 µm to highest 211.341.1 µm.

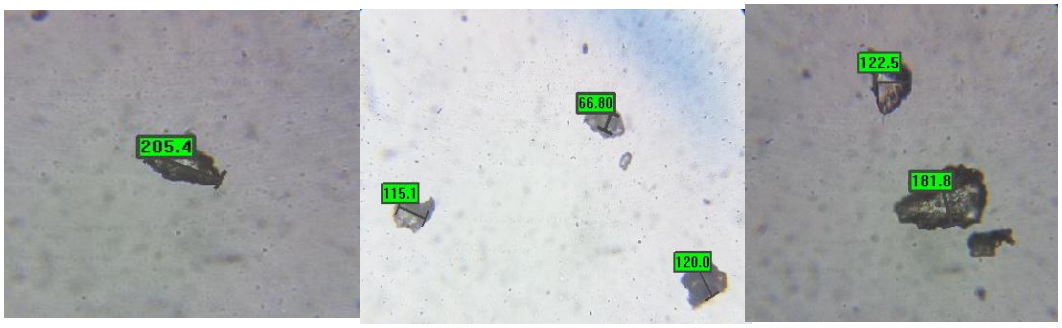


Fig 7: Particle size determination

HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY:

HPTLC finger printing analysis of the sample PPC reveals the presence of four prominent peaks corresponds to presence of four versatile phytocomponents present with in it. Rf value of the peaks ranges from 0.30 to 0.89. Further the peak 2 occupies the major percentage of area of 38.78 % which denotes the abundant existence of such compound. Followed by this peak 3 and 1 occupies the percentage area of 31.34 and 16.90%. Peak 4 occupies the percentage area of 13%

HPTLC peak table: ***(Table 11)***

Peak	Start Rf	Start height	Max Rf	Max height	Max %	End Rf	End height	Area	Area %
1	0.30	12.0	0.31	17.2	16.90	0.33	5.0	179.5	13.42
2	0.45	1.5	0.46	39.4	38.78	0.48	0.5	428.3	32.02
3	0.49	0.3	0.50	31.9	31.34	0.53	0.1	413.9	30.95
4	0.89	0.7	0.92	13.2	13.00	0.94	2.9	315.8	23.61

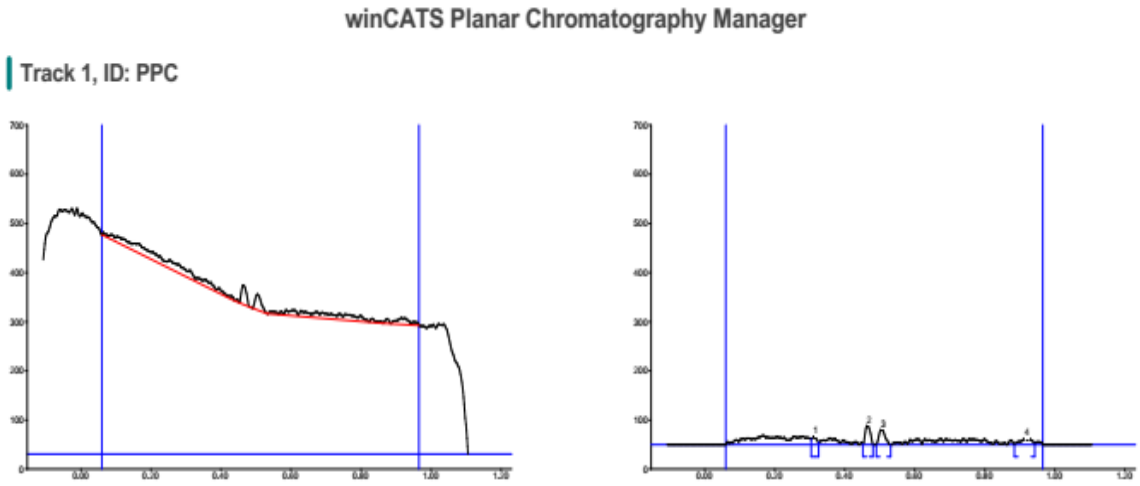


Fig 8: HPTLC finger printing

HEAVY/TOXIC METAL ANALYSIS BY AAS:

Results of the present investigation has clearly shows that the sample PPC has no traces of Mercury and hence it was considered that the heavy metals mercury was absent in the sample PPC. The level of arsenic, lead and cadmium was found to be 0.009 ppm, 0.150 ppm and 0.009 ppm respectively. It was observed that all three reported heavy metals (arsenic, lead and cadmium) seem very less when compare to the allowed recommended limit.

Table 12: Heavy metal analysis:

Name of the Heavy Metal	Absorption Max Λ max	Result Analysis	Maximum Limit
Mercury	253.7nm	BDL	1 ppm
Lead	217.0 nm	0.150 ppm	10 ppm
Arsenic	193.7 nm	0.009 ppm	3 ppm
Cadmium	228.8 nm	0.009 ppm	0.3 ppm

MICROBIAL CONTAMINATION BY POUR PLATE METHOD: *(Table 13)*

No growth / colonies were observed in any of the plates inoculates with the test sample.

Test	Result	Specification	As per AYUSH/WHO
Total Bacterial Count	Absent	NMT 10^5CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^3CFU/g	

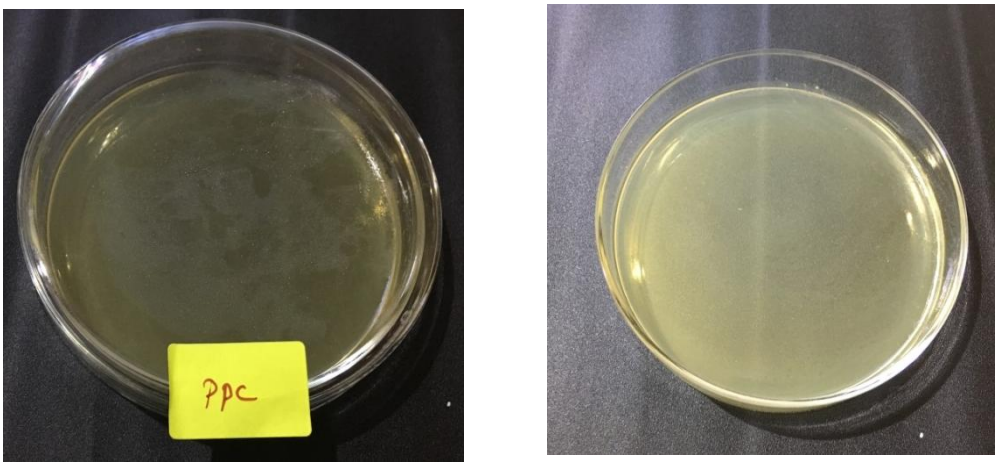


Fig 9: Microbial contamination by Pour plate method.

TEST FOR SPECIFIC PATHOGEN :*(Table 14)*

No growth / colonies were observed in any of the plates inoculated with the test sample.

Organism	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

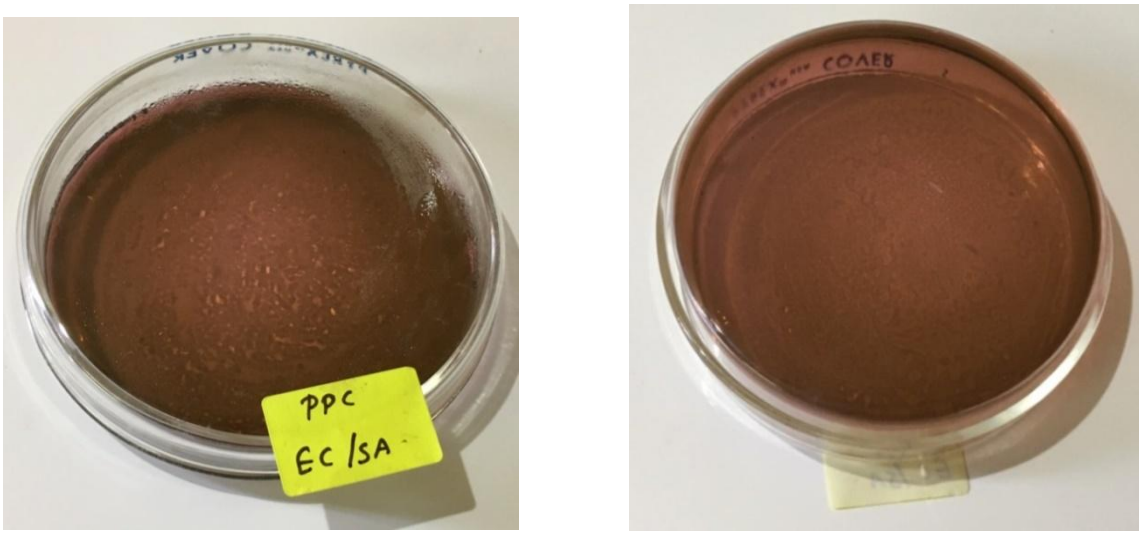


Fig 10(i): Culture plate with E-coli and Salmonella specific medium.

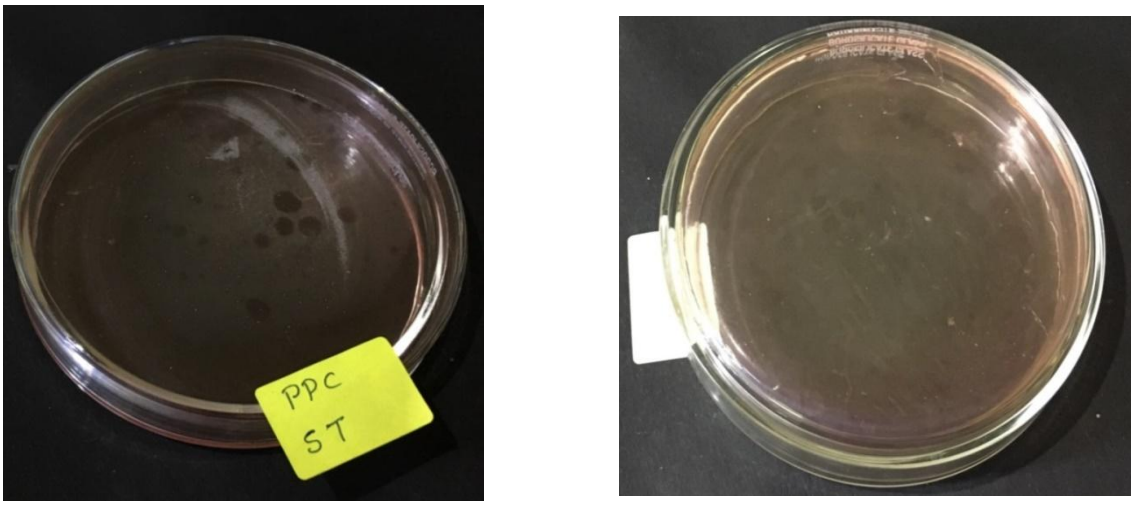


Fig 10 (ii): Culture plate with Staphylococcus Aureus specific medium

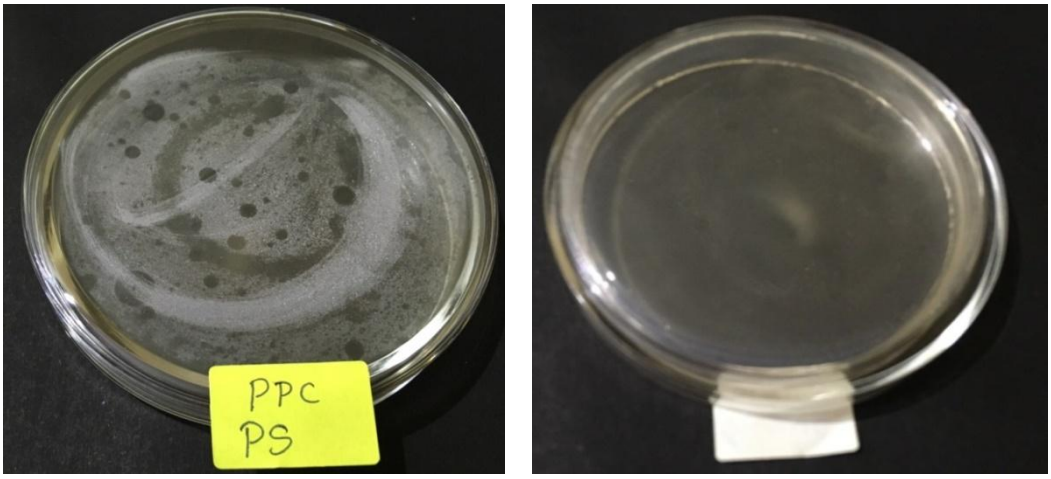


Fig 10 (iii): Culture plate with Pseudomonas Aeruginosa specific medium

ANALYSIS OF PESTICIDES ORGANOCHLORINE, ORGANOPHOSPHORUS AND PYRETHROIDS:

The results showed that there were no traces of pesticides residues such as Organo chlorine and Organo phosphorus Pesticides in the sample PPC. Further sample shows the presence of Cypermethrin belongs to pyrethroid type of pesticide at the concentration of 0.1 mg/kg which was low when compare the AYUSH prescribed limit of 1mg/kg.

Table 15: Pesticide residue:

Pesticide Residue	**Sample PPC**	**AYUSH Limit (mg/kg)**
I.Organo Chlorine Pesticides:		
Alpha BHC	BQL	0.1
Beta BHC	BQL	0.1
Gamma BHC	BQL	0.1
Delta BHC	BQL	0.1
DDT	BQL	1
Endosulphan	BQL	3
II.Organo Phosphorus Pesticides:		
Malathion	BQL	1
Chlorpyriphos	BQL	0.2
Dichlorovos	BQL	1
III.Pyrethroid:		
Cypermethrin	0.1 mg/kg	1

BQL – Below quantification limit

AFLOTOXIN ASSAY BY TLC (B1,B2,G1,G2):

The results shown that there is a presence of aflatoxins B1 in the sample PPC and further there is no detection other aflatoxins like aflatoxins B2, G1 and G2 when compare to that of the respective standards.

Table 16: Aflatoxin assay:

Aflatoxin	Sample PPC	AYUSH Specification limit
B1	Present – 0.01 ppm level	0.5 ppm
B2	Not Detected - Absent	0.1 ppm
G1	Not Detected - Absent	0.5 ppm
G2	Not Detected - Absent	0.1 ppm

BIOCHEMICAL ANALYSIS OF PARANGIPATTAI CHOORANAM:

I Results of Acid radicals studies: *[Table 17 (i)]*

S.NO	Parameter	Observation	Result
1	Test for Sulphate	Cloudy appearancePresent	Positive
2	Test for Chloride	-	Negative
3	Test For Phosphate	-	Negative
4	Test For Carbonate	Cloudy appearancePresent	Positive
5	Test For Nitrate	-	Negative
6	Test for Sulphide	-	Negative
7	Test For Fluoride &oxalate	-	Negative
8	Test For Nitrite	-	Negative
9	Test For Borax	-	Negative

Interpretation

The acidic radicals test shows the presence of **Sulphate** and **Carbonate.**

II Results of basic radicals studies:*[Table 17 (ii)]*

S.NO	Parameter	Observation	Result
1	Test for Lead	-	Negative
2	Test for Copper	-	Negative
3	Test For Aluminium	-	Negative
4	Test For Iron	Mild red colour appear	Positive
5	Test For Zinc	White precipitate is formed	Positive
6	Test for Calcium	Cloudy appearance and white precipitate present	Positive
7	Test For Magnesium	-	Negative
8	Test For Ammonium	Brown colour appear	Positive
9	Test For Potassium	Yellow precipitate is obtained	Positive
10	Test For Sodium	-	Negative
11	Test For Mercury	-	Negative
12	Test For Arsenic	-	Negative

Interpretation

The basic radical test shows the presence of**Iron, Zinc,Calcium,Ammonium**, **Potassium**and absence of heavy metals such as lead, arsenic and mercury.

III Test for Phytochemical:*[Table 17 (iii)]*

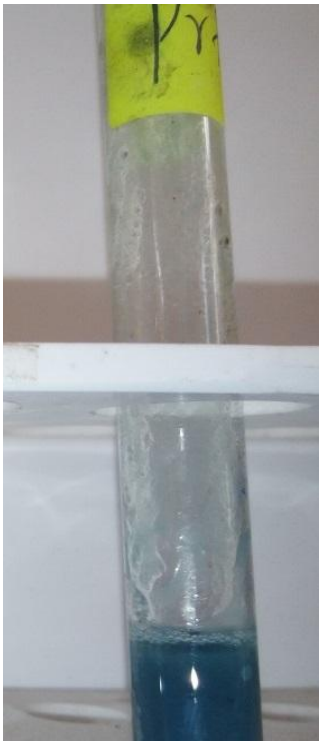
S.NO	Parameter	Observation	Result
1	Test for Starch	Blue colour developed *[Fig 11 (i)]*	Positive
2	Test for Reducing sugars	Characteristic coloured precipitate present *[(Fig 11 (ii)]*	Positive
3	Test For Alkaloids	Yellow colour developed*[Fig 11 (iii)]*	Positive
4	Test For Tannic acid.	Blue-black precipitate obtained*[Fig 11 (iv)]*	Positive
6	Test for Amino acid	-	Negative
7	Test for Flavonoids	Yellow colour appear *[Fig 11 (v)]*	Positive
8	Test for Glycosides (Borntrager's test)	Pink colour appear *[Fig 11 (vi)]*	Negative

9	Test for Steroids	Yellow with green fluorescence present *[Fig 11 (vii)]*	Positive
10	Test for Triterpenoids (Liebermann–Burchard test)	Red ring appear *[Fig 11 (viii)]*	Positive
11	Test for Coumarin	Yellow colour formed *[Fig 11 (ix)]*	Positive
12	Test for Saponins	Copious lather formed *[Fig 11 (x)]*	Positive
13	Test for Anthrocyanin	Bluish green colour formed *[Fig 11 (xi)]*	Negative
14	Test for phenol	Bulky white precipitate formed *[Fig 11 (xii)]*	Positive

Interpretation

The phytochemical test shows the presence of **Starch, Sugar, Alkaloids, Tannic acid, Flavonoids, Steroids, Triterpenoids, Coumarin, Saponin and Phenol.**

Fig 11(i): Test for Proteins *Fig 11(ii): Test for carbohydrate*



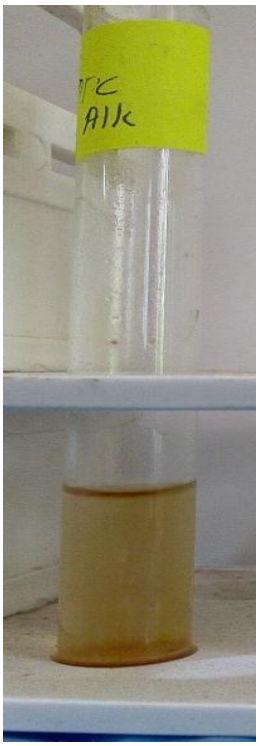


Fig 11(iii): Test for Alkaloids

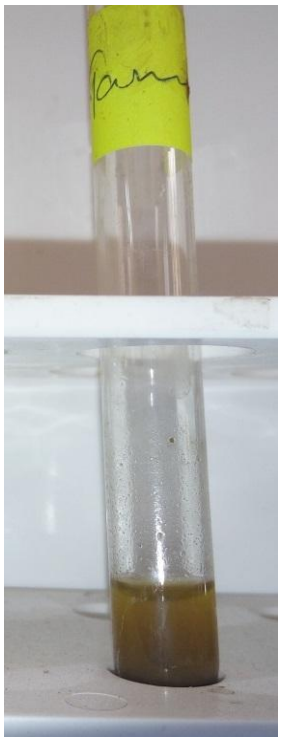


Fig 11(iv): Test for Tanins

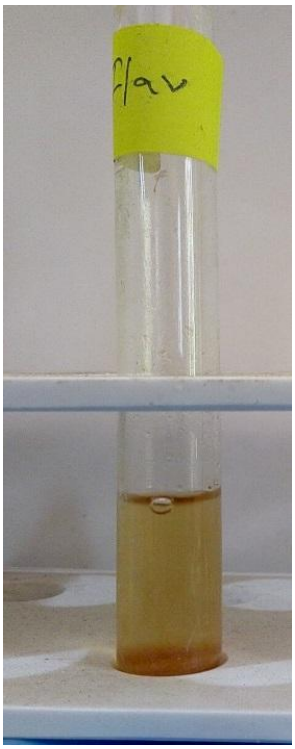


Fig 11(v): Test for Flavinoids

Fig 11(vi): Test for Glycosides

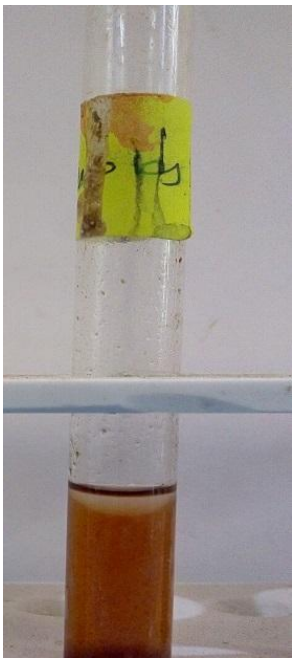


Fig 11(vii): Test for Steroids

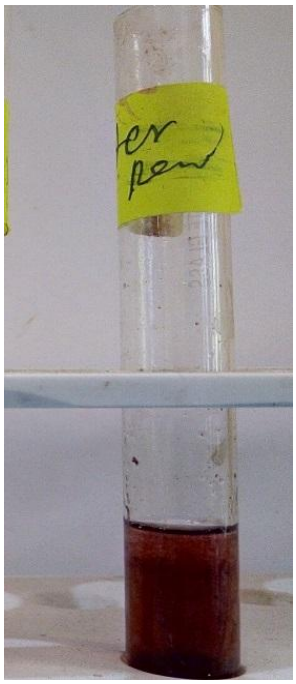


Fig 11(viii): Test for Triterpenoids

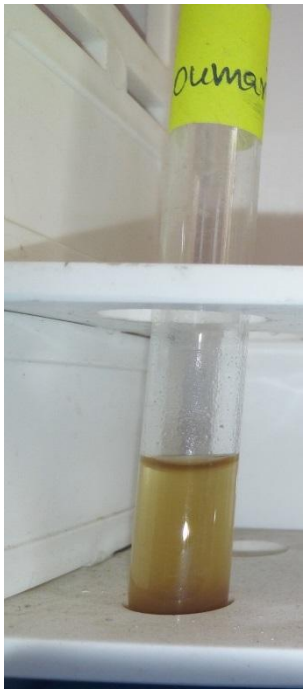


Fig 11(ix):Test for Coumarin

Fig 11(x): Test for Saponin

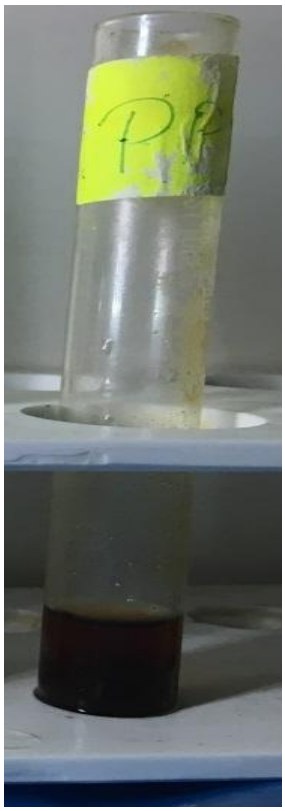


Fig 11(xi): Test for Anthrocyanin

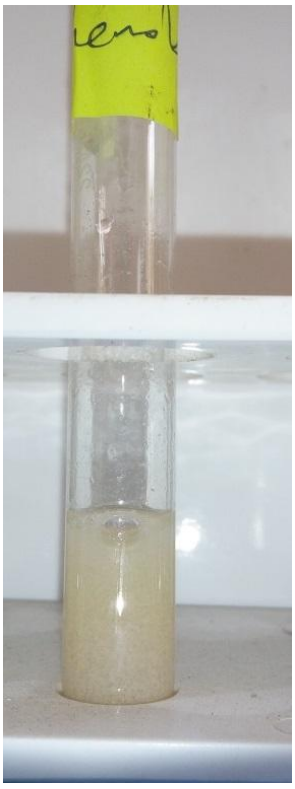


Fig 11(xii): Test for Phenol

CLINICAL STUDIES

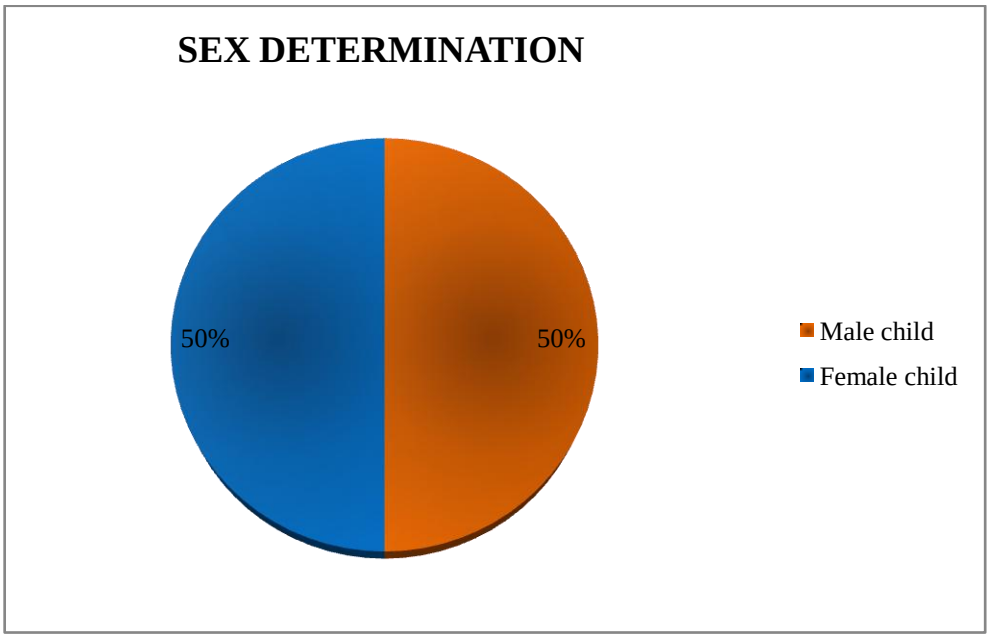
30 children with the complaints of Venpulli (Vitiligo) were treated in Kuzhanthai Maruthuvam department of Ayothidas Pandithar hospital, National Institute of Siddha, Chennai with the trail drug Parangipattai chooranam and Annabedhi chenduram twice a day for 48 days. Results were observed under the following criteria.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO SEX:

Table 18(i):

S.No	Sex	No. of cases	Percentage (%)
1	Male child	15	50
2	Female child	15	50

Fig 12(i):



Inference:

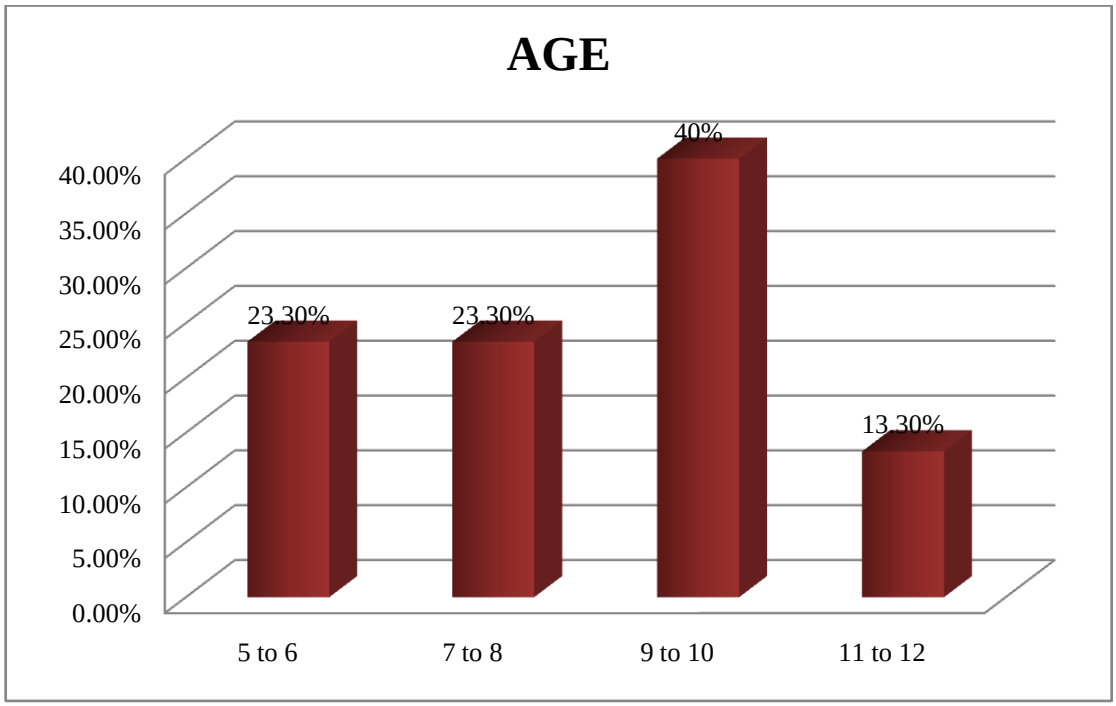
Out of 30 children 16 (53.3%) were female children and 14 (46.7%) were male children.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO AGE:

Table 18(ii):

S.No	Age	No. of cases	Percentage (%)
1	5-6	7	23.3
2	7-8	7	23.3
3	9-10	12	40
4	11-12	4	13.3

Fig 12(ii):



Inference:

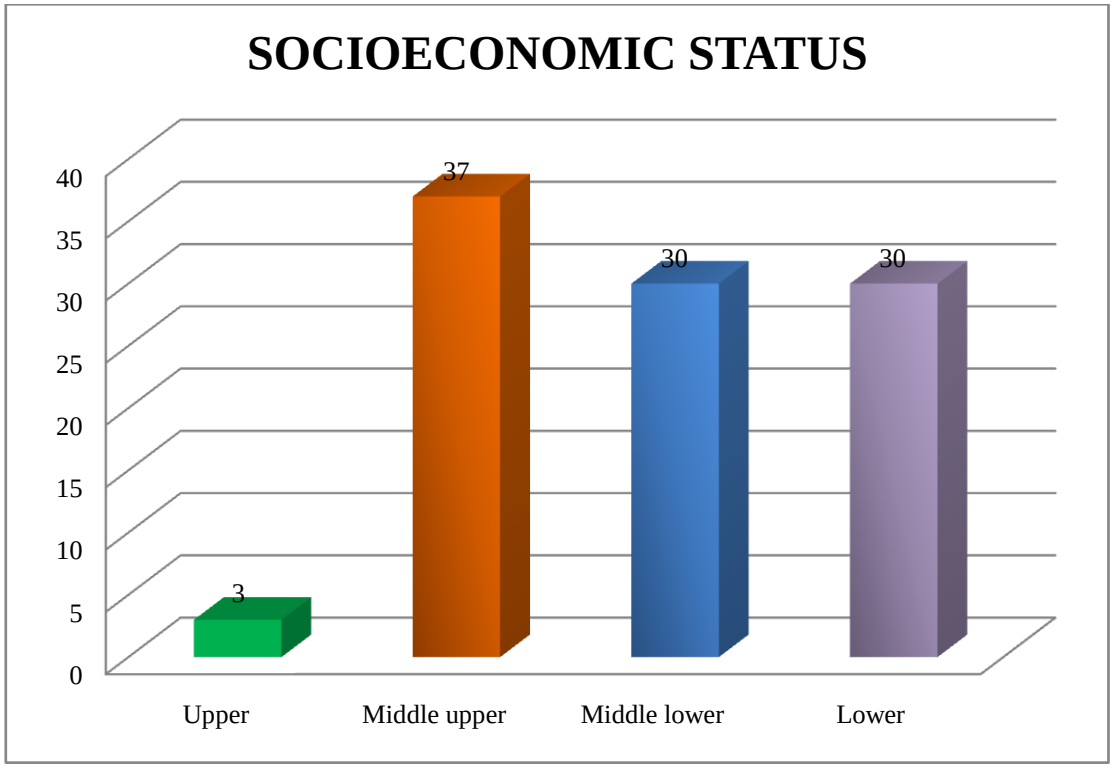
40% of the children were between 9 to 10 years of age, 23.3% of children were between 5 to 6 and 7 to 8 years of age and 13.30% of children were between 11 to 12 years of age.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO SOCIO ECONOMIC STATUS:

Table 18(iii):

S.No	Socio economic status	No. of cases	Percentage (%)
1	Upper	1	3
2	Middle upper	11	37
3	Middle lower	9	30
4	Lower	9	30

Fig 12(iii):



Inference:

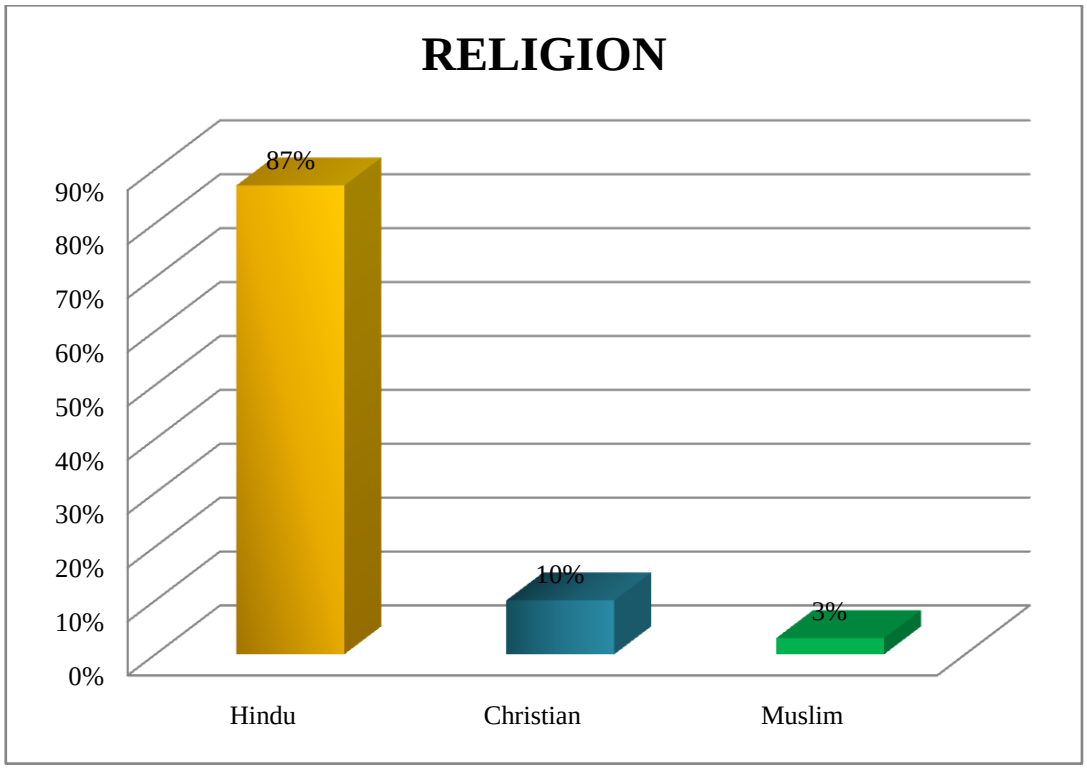
According to parent's socio economic status, about 3% were under upper economic group, 37% were under middle upper economic status group, 30% were under middle lower economic status group and 30% were lower economic group status.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO RELIGION:

Table 18(iv):

S.No	Religion	No. of cases	Percentage (%)
1	Hindu	26	87
2	Christian	3	10
3	Muslim	1	3

Fig 12(iv):



Inference:

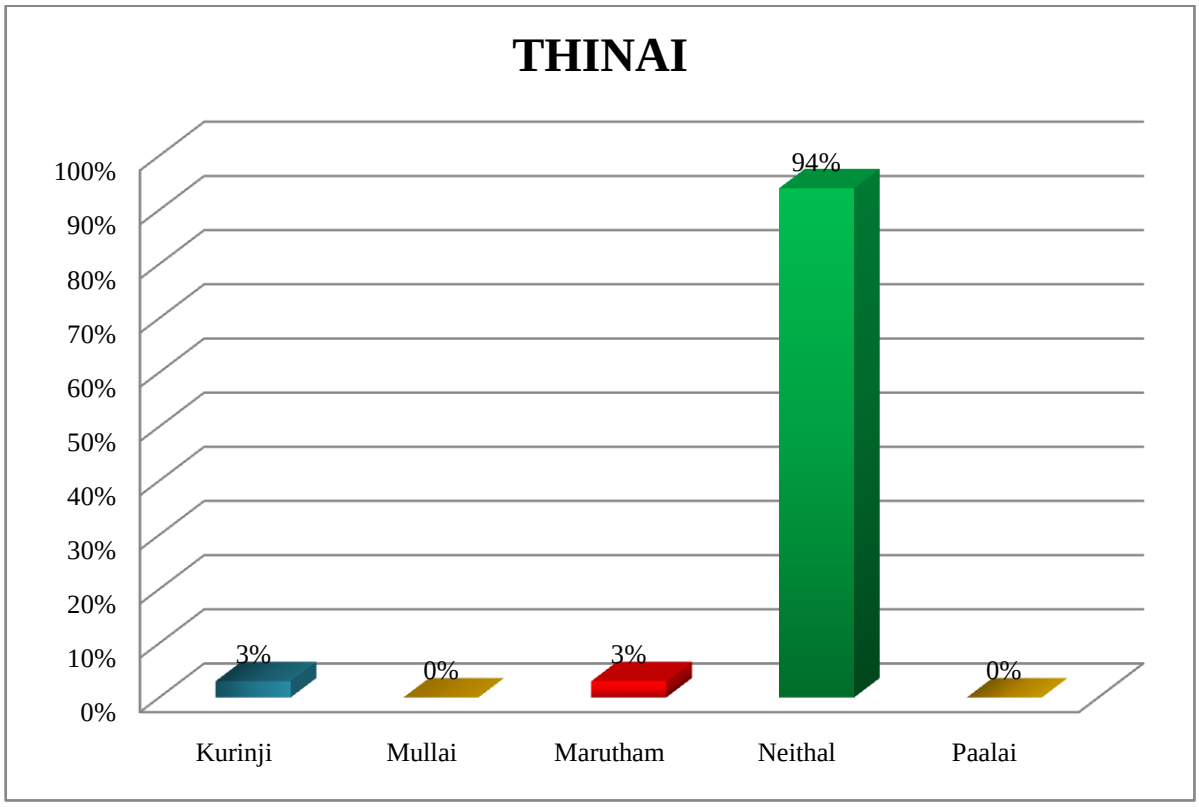
About 87% were Hindu, 10% were Christian and 3% were muslim.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO THINAI:

Table 18(v):

S.No	Nilam	No of cases	Percentage (%)
1	Kurinji	1	3
2	Mullai	-	-
3	Marutham	1	3
4	Neithal	28	94
5	Paalai	-	-

Fig 12(v):



Inference:

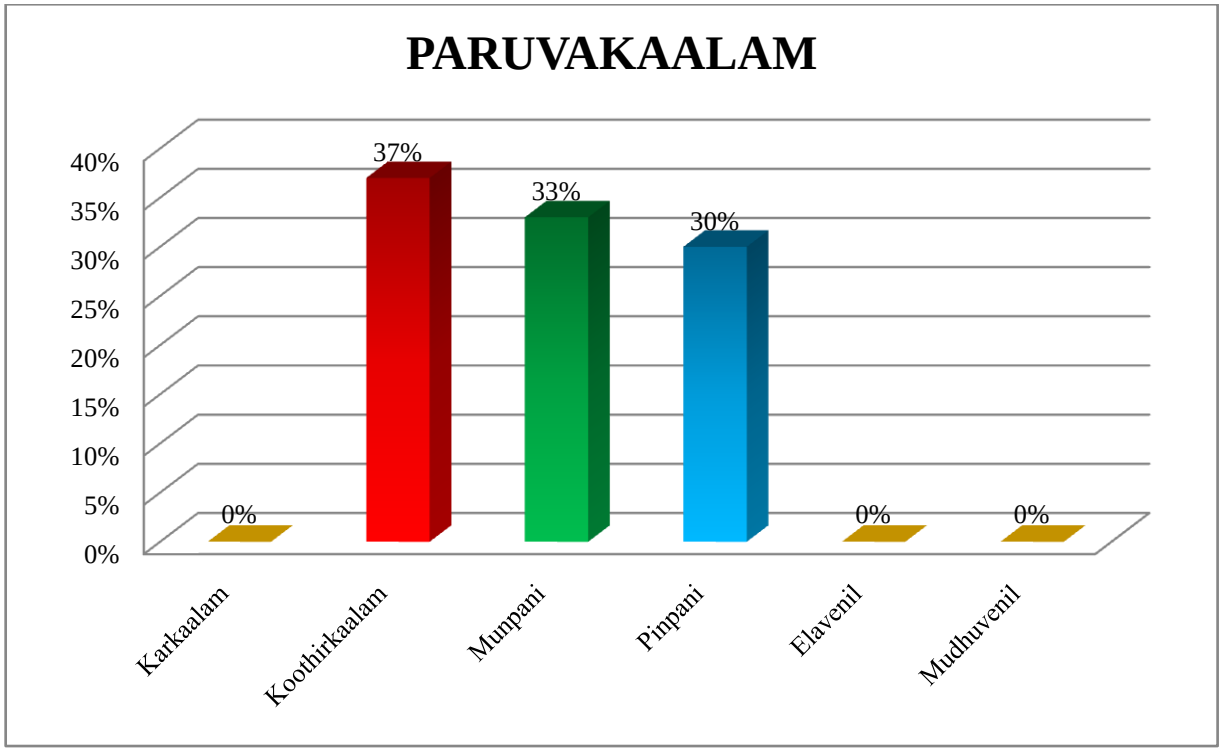
About 94% of affected children were from Neithal nilam, 3% were from Marutham nilam and 3% were from Kurinji nilam.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO PARUVAKAALAM:

Table 18(vi):

S.No	Paruvakaalam	No. of cases	Percentage (%)
1.	Karkaalam (Avani – puratasi)	-	-
2.	Koothirkaalam (Iyppasi – karthikai)	11	37
3.	Munpani (Markazhi – Thai)	10	33
4.	Pinpani (Masi – Panguni)	9	30
5.	Elavenil (Chitirai, Vaigasi)	-	-
6.	Mudhuvenil (Aani, Aadi)	-	-

Fig 12(vi):



Inference:

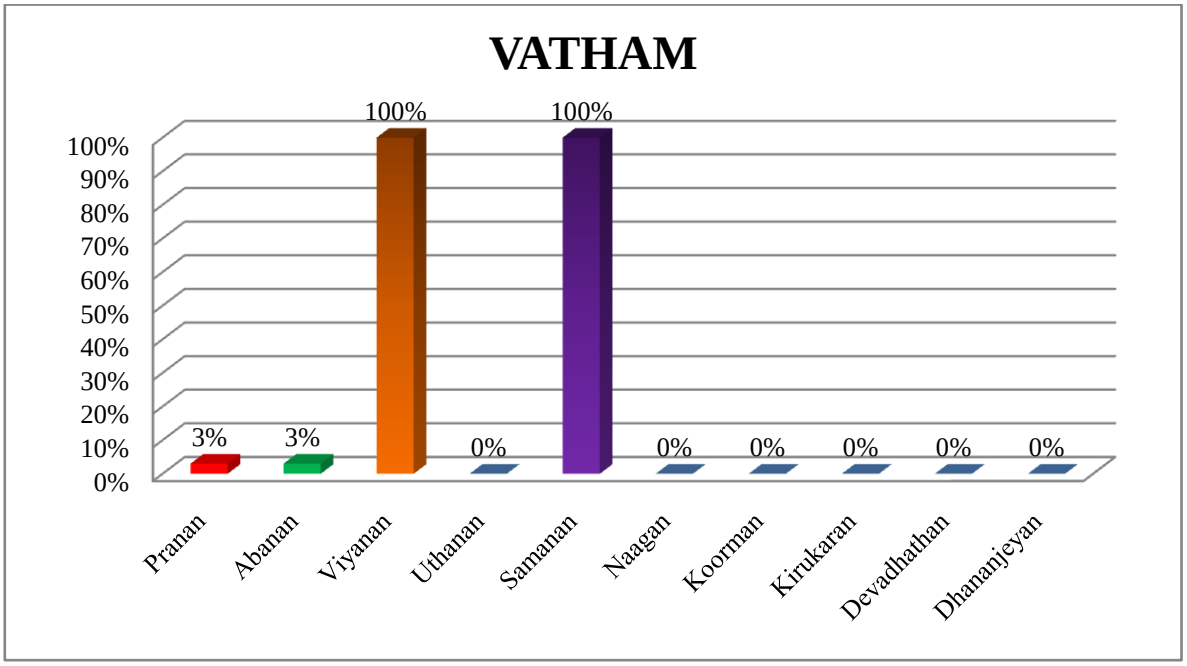
According to paruvakaalam highest incident of 11 cases (37%) were noted in Koothirkaalam, 10 cases (33%) were noted in Munpanikaalam, 9 cases (30%) were noted in Pinpanikaalam.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO DERANGEMENT OF VATHAM:

Table 18(vii):

S.No	Classification of Vatham	No. of Cases	Percentage (%)
1.	Pranan	1	3
2.	Abanan	1	3
3.	Viyanan	30	100
4.	Uthanan	-	-
5.	Samanan	30	100
6.	Naagan	-	-
7.	Koorman	-	-
8.	Kirukaran	-	-
9.	Devadhathan	-	-
10.	Dhananjeyan	-	-

Fig 12(vii):



Inference:

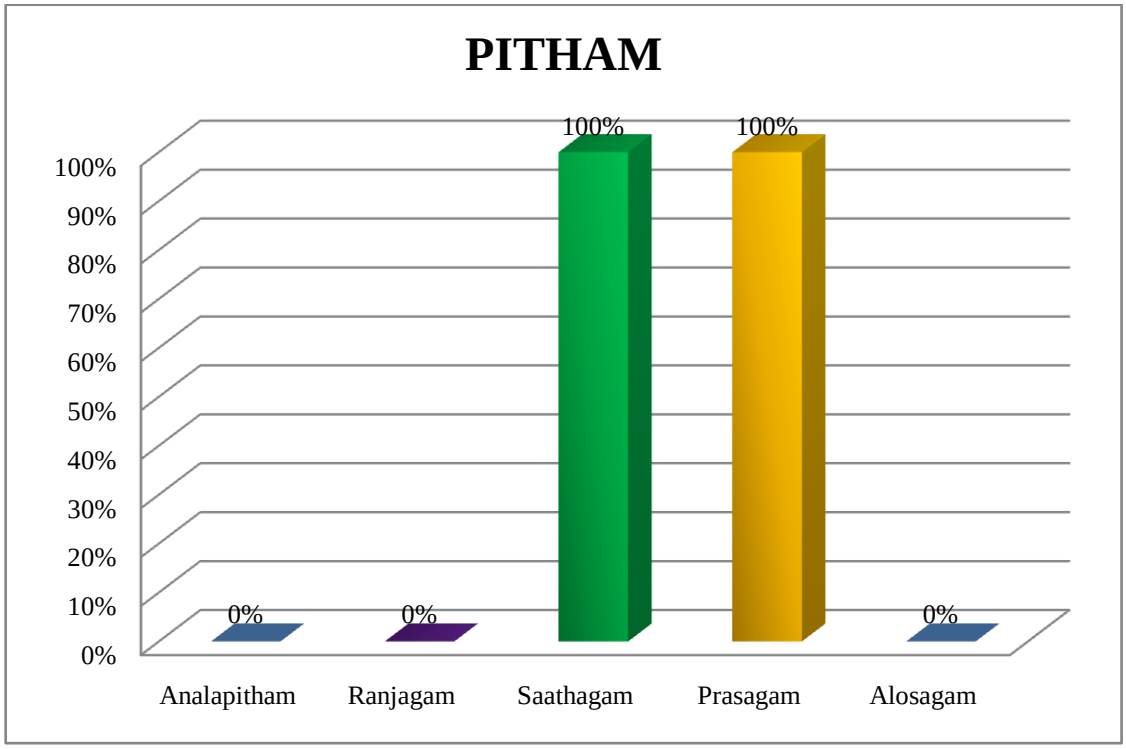
According to Vatham, derangement of Viyanan and Samanan was noted in 30 children (100%), derangement of Pranan in 1 child (3%), and derangement of Abanan in 1 child (3%).

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO DERANGEMENT OF PITHAM:

Table 18(viii):

S.No	Types of Pitham	No.of Cases	Percentage (%)
1.	Analapitham	-	-
2.	Ranjagam	-	-
3.	Saathagam	30	100
4.	Prasagam	30	100
5.	Alosagam	-	-

Fig 12(viii):



Inference:

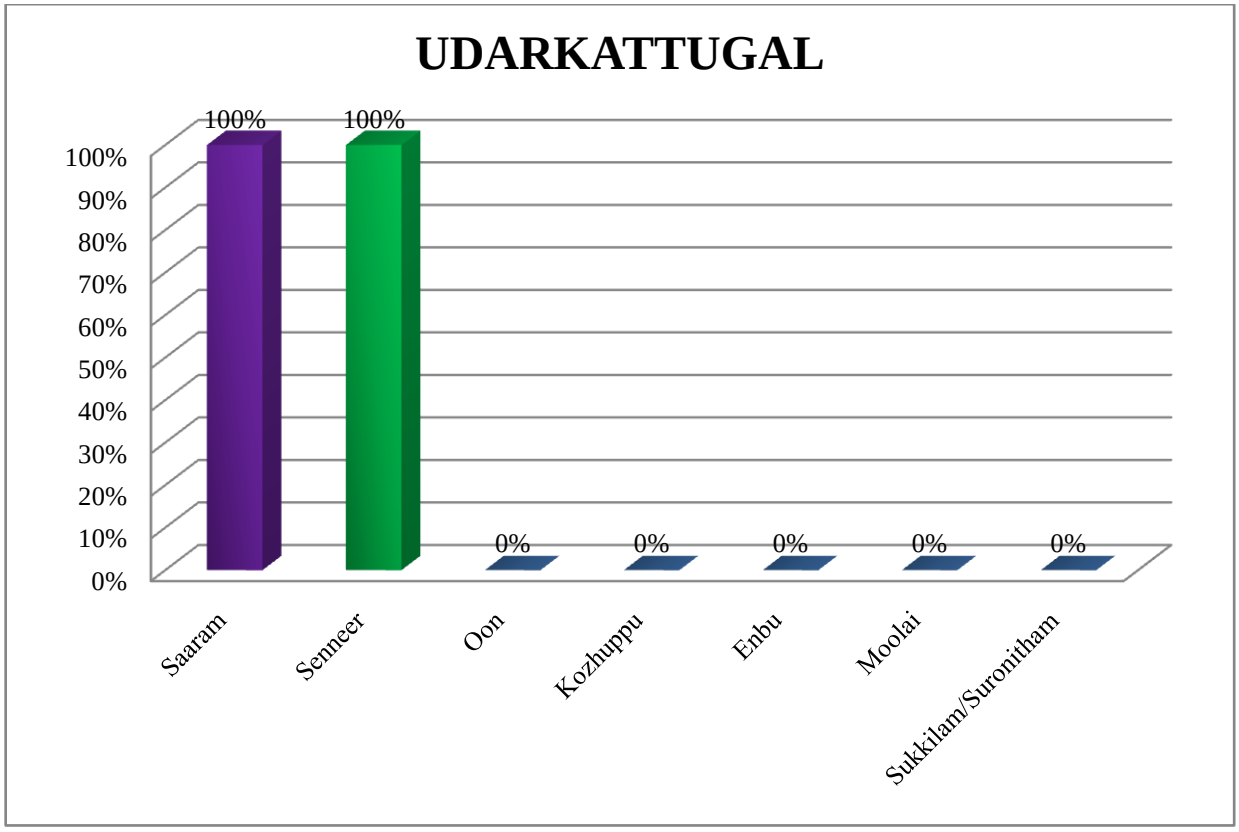
According to Pitham, derangement of Prasagam and Saathagam was seen in 30 children (100%).

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO DERANGEMENT OF EZHU UDARKATTUGAL:

Table 18(ix):

S.No	Udarkattugal	No.of Cases	Percentage (%)
1.	Saaram	30	100
2.	Senneer	30	100
3.	Oon	-	-
4.	Kozhuppu	-	-
5.	Enbu	-	-
6.	Moolai	-	-
7.	Sukkilam/Suronitham	-	-

Fig 12(ix):



Inference:

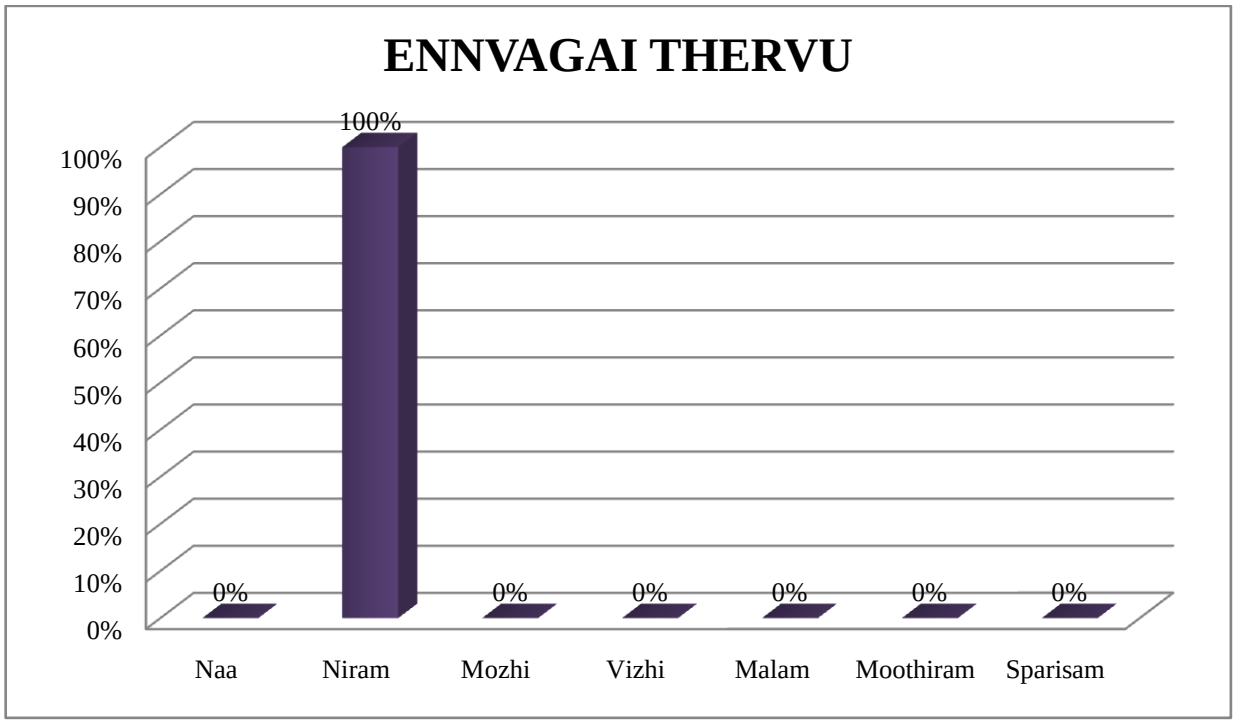
According to Udarkattgal, derangement of Saaram and Senneer was seen in 100% of children.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO DERANGEMENT OF ENN VAGAI THERVUGAL:

Table 18(x):

S.No	Enn Vagai Thervugal	No.of Cases	Percentage (%)
1	Naa	-	-
2	Niram	30	100
3	Mozhi	-	-
4	Vizhi	-	-
5	Malam	-	-
6	Moothiram	-	-
7	Sparisam	-	-
8	Naadi	Described below	

Fig 12(x):



Inference:

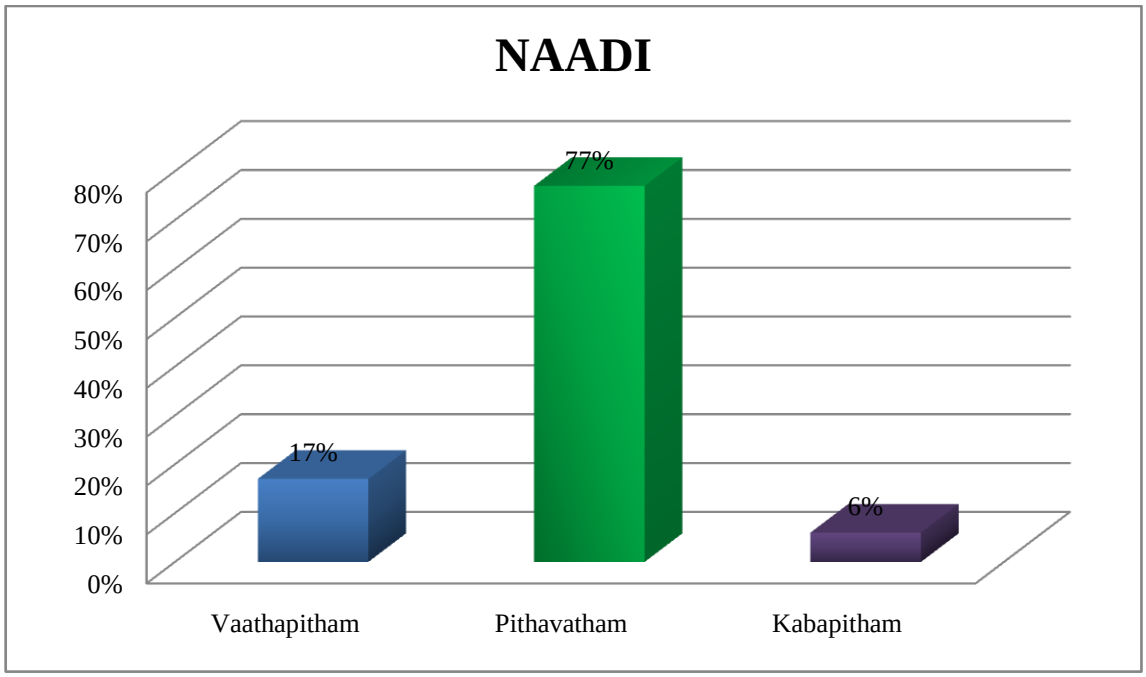
According to Envagai thervu, Niram is affected in all children.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO OBSERVATION OF NAADI:

Table 18(xi):

S.No	Naadi	No. of cases	Percentage (%)
1	Vaathapitham	5	17
2	Pithavatham	23	77
3	Kabapitham	2	6

Fig 12(xi):



Inference:

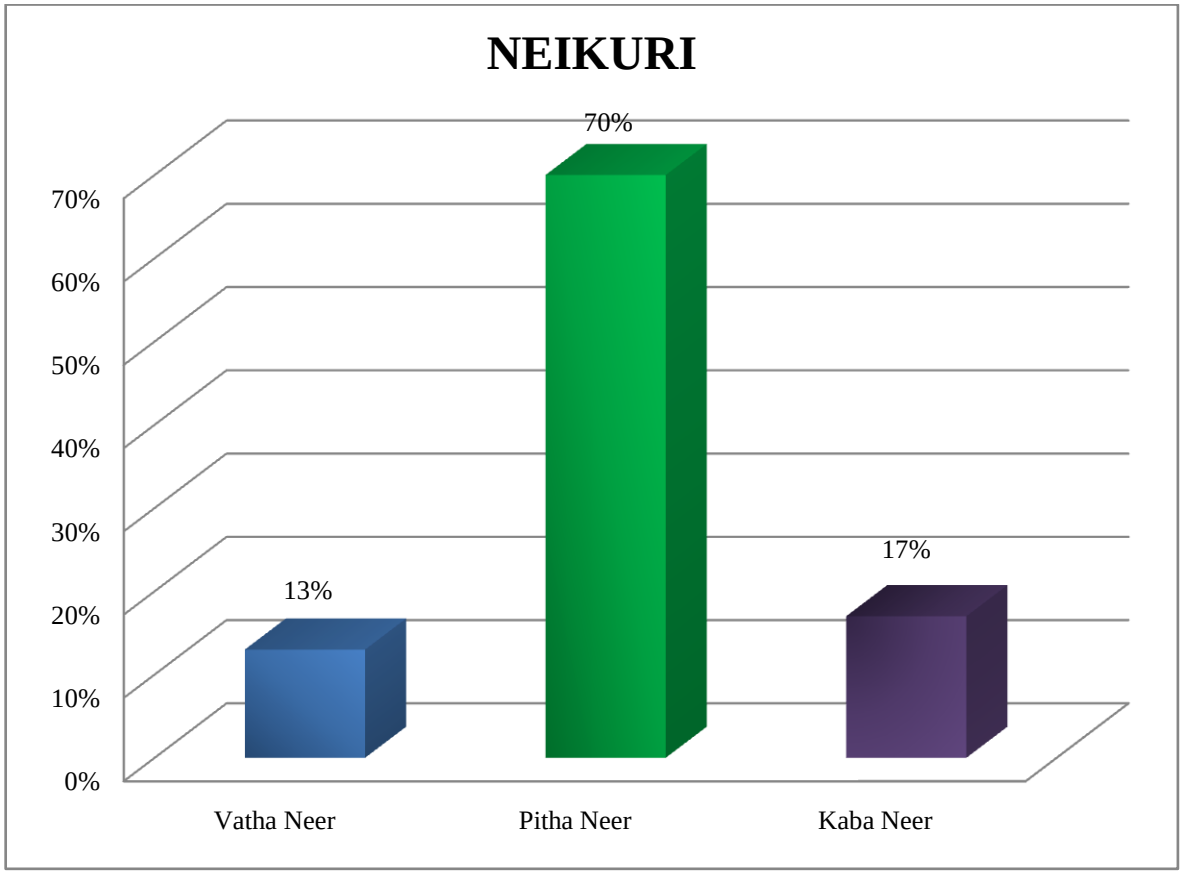
According to Naadi most of the children had Pithavatha naadi (77%), 17 % had Vaathapitha naadi and 6% had Kabapitha naadi.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO OBSERVATION OF NEIKURI ANALYSIS:

Table 18(xii):

S.No	Character of urine	Neikuri Reference	No.of Cases	Percentage (%)
1.	Spreads like snake	Vatha Neer	4	13
2.	Spreads like ring	Pitha Neer	21	70
3.	Static as pearl	Kaba Neer	5	17

Fig 12(xii):



Inference:

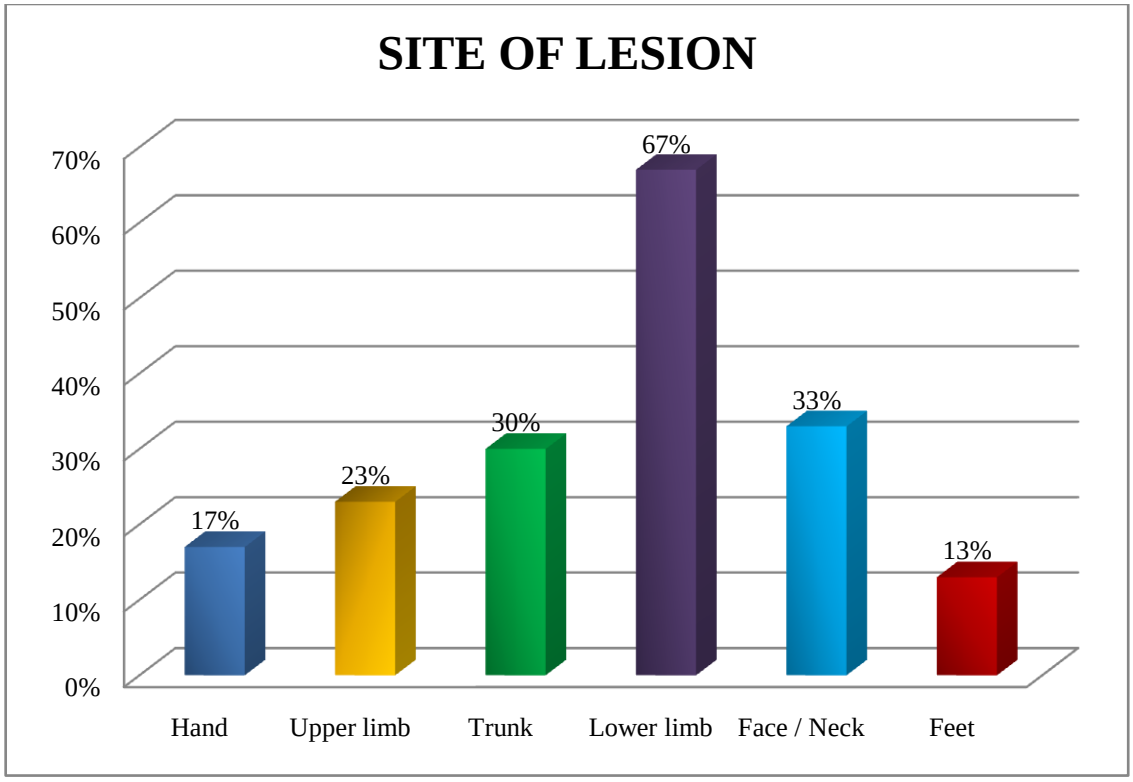
According to Neikuri, Vatha neer was observed in 13% of cases, pitha neer was observed in 70% of cases, Kaba neer was observed in 17% of cases.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO OBSERVATION OF SITE OF LESION:

Table 18(xiii):

S.No	Site of lesion	No of cases	Percentage (%)
1	Hand	5	17
2	Upper limb	7	23
3	Trunk	9	30
4	Lower limb	20	67
5	Face / Neck	10	33
6	Feet	4	13

Fig 12(xiii):



Inference:

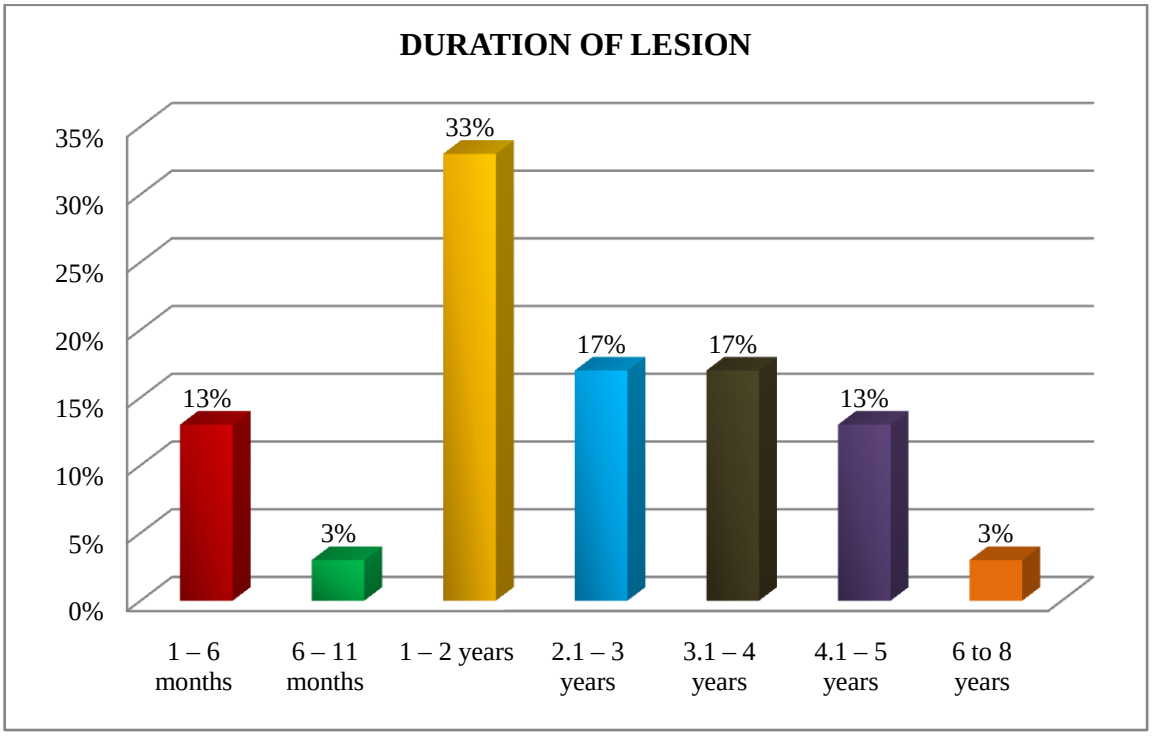
According to site of lesion, Out of 30, 5 children (17%) had lesion in hand region, 7 children (23%) had lesion in upper limb, 9 children (30%) had lesion in trunk, 20 children (67%) had lesion in lower limb, 10 children (33%) had lesion in face / neck and 4 children (13%) had lesion in feet region. Out of 30 children some of them are affected in multiple sites.

DISTRIBUTION OF CHILDREN WITH VENPULLI ACCORDING TO OBSERVATION OF DURATION:

Table 18(xiv):

S.No	Duration of disease	No. of cases	Percentage (%)
1	1 – 6 months	4	13
2	6 – 11 months	1	3
3	1 – 2 years	10	33
4	2.1 – 3 years	5	17
5	3.1 – 4 years	5	17
6	4.1 – 5 years	4	13
7	6 to 8 years	1	3

Fig 12(xiv):



Inference:

According to duration of lesion, 13% of children had symptoms for a period of 1 – 6 months, 3% had symptoms for 6 – 11 months, 33% had symptoms for 1 – 2 years, 17% had symptoms for 2.1 – 3 years, 17% had symptoms for 3.1 – 4 years, 13% had symptoms for 4.1 – 5 years, 3% had symptoms for 6 – 8 years.

CASE REPORT OF CHILDREN BASED ON VASI SCORE:

Table 18(xv):

S.No	OP No	Age/sex	` VASI SCORE		Clinical improvement
			Before treatment	**After treatment**	
1	J53023	5/MC	2	2	Pigmented spots present
2	J67723	11/MC	4	4	Pigmented spots present
3	I95743	8/MC	8	8	Pigmented spots present
4	J18389	9/FC	12	12	Pigmented spots present
5	J53927	5/FC	6.75	6.75	Pigmented spots present
6	I13367	12/MC	3.75	3	Good improvement
7	I92679	9/FC	25.75	25.75	Pigmented spots present
8	H79034	9/FC	4.5	4.5	Pigmented spots present
9	J78338	9/MC	7	3	Good improvement
10	J83578	10/FC	8.50	6.25	Pigmented spots present
11	G06709	8/MC	1	0.75	Good improvement
12	G38277	9/FC	5.25	5.25	Pigmented spots present
13	J53478	5/MC	10	10	Pigmented spots present
14	J79539	8/FC	1.75	1	Good improvement
15	G14179	7/MC	5.25	5.25	Pigmented spots present
16	I5508	6/FC	9	9	Pigmented spots present
17	J69491	12/MC	2	2	Pigmented spots present
18	I93488	10/FC	2.25	1.75	Good improvement
19	H26903	8/MC	1.75	1.50	Good improvement
20	I2673	9/MC	8	6.75	Good improvement
21	I56568	9/MC	1.75	1.25	Good improvement
22	I33170	5.6/FC	4.50	3	Good improvement
23	J82400	9/FC	0.50	0.25	Good improvement
24	K01039	12/MC	17.75	14.50	Good improvement
25	K5516	6/FC	5	3.75	Good improvement
26	H62701	9/FC	1.50	1	Good improvement
27	I16607	6/FC	2	0.50	Good improvement
28	J69637	8/MC	1	0.375	Good improvement
29	H51422	10/FC	1	0.75	Good improvement
30	K16822	8/MC	4	3	Good improvement

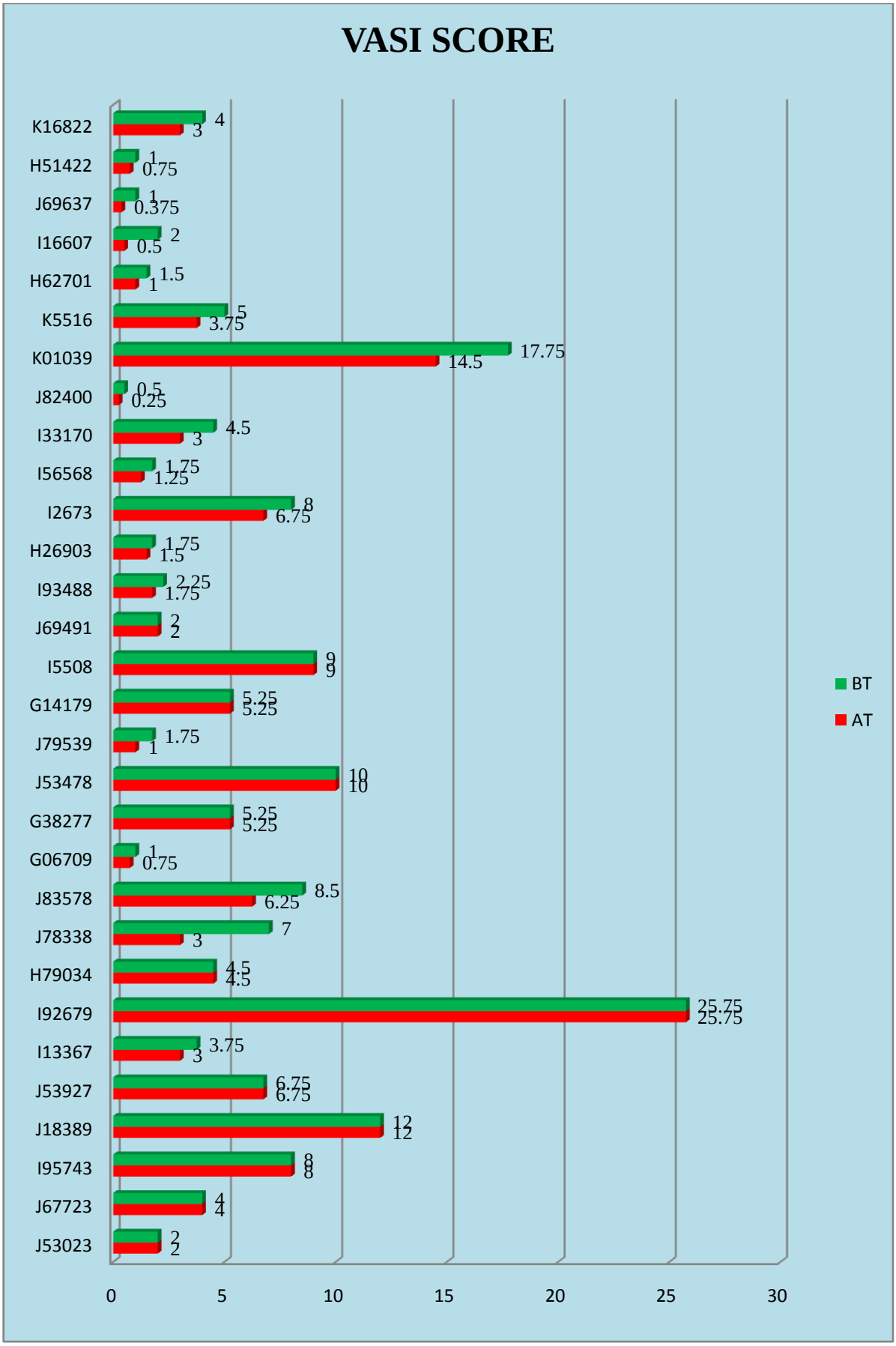

VASI SCORE
K16822
H51422
J69637
I16607
H62701
K5516
K01039
J82400
I33170
I56568
I2673
H26903
I93488
J69491
I5508
G14179
J79539
J53478
G38277
G06709
J83578
J78338
H79034
I92679
I13367
J53927
J18389
I95743
J67723
J53023
4
3
1
0.75
1
0.375
2
0.5
1.5
1
5
3.75
17.75
14.5
0.5
0.25
4.5
3
1.75
1.25
8
6.75
1.75
1.5
2.25
1.75
2
2
9
9
5.25
5.25
1.75
1
10
10
5.25
5.25
1
0.75
8.5
6.25
7
3
4.5
4.5
25.75
25.75
3.75
3
6.75
6.75
12
12
8
8
4
4
2
2
0
5
10
15
20
25
30
BT
AT

Fig 12(xv):

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. In my study statistical analysis was done for VASI score.

Paired Sample Statistics:

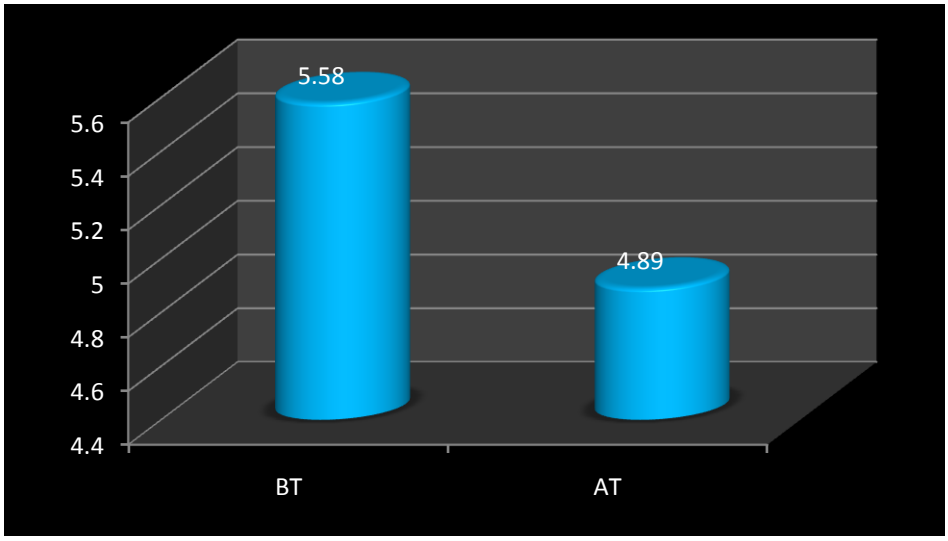
VASI Score:

Table 19: Distribution of Mean and Standard Deviation of VASI Score before and after treatment is as follows.

VASI Score	Mean ± Standard Deviation	t Value	p Value
Before treatment	5.58 ± 5.4	3.79	P < 0.001
After treatment	4.89 ± 5.36		

The Mean Standard Deviation of VASI Score before and after treatment was 5.58 ± 5.4 and 4.89 ± 5.36 respectively which is **statistically significant (p < 0.001)**.

The analysis reveals that there is 12% reduction in depigmentation when compared to before treatment.



PHOTOGRAPHS OF PATIENTS BEFORE AND AFTER TREATMENT:

Fig 13 (i): Before treatment

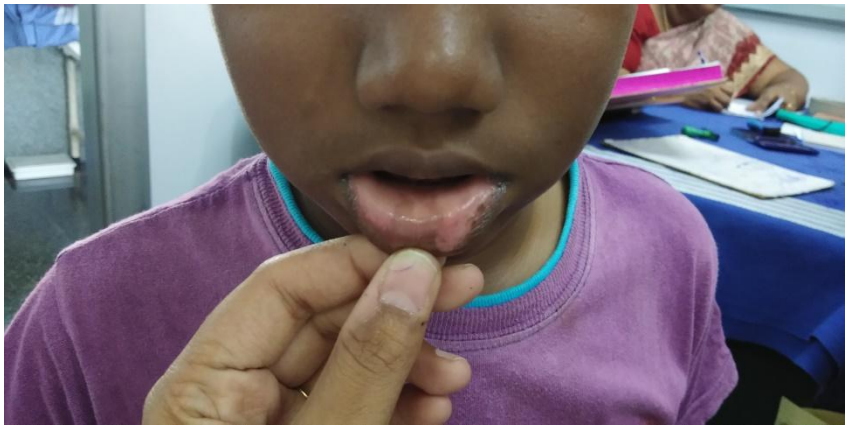


Fig 13 (ii): After treatment

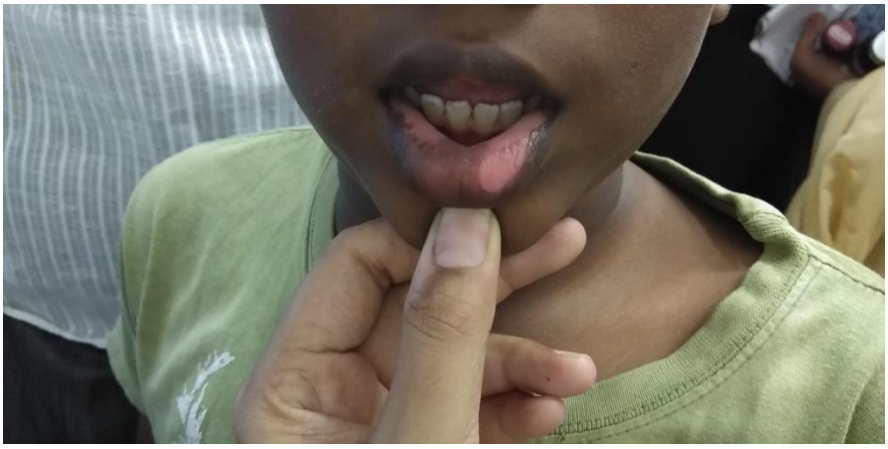


Fig 14 (i): Before treatment

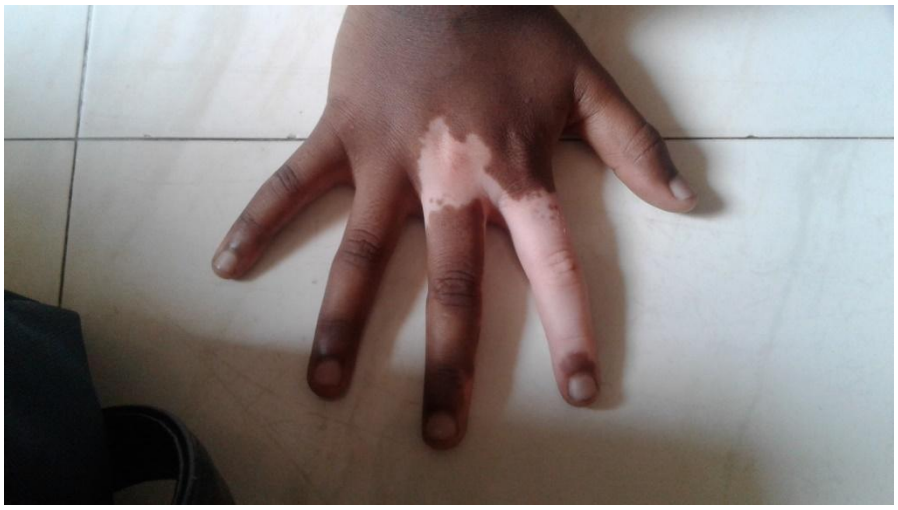


Fig 14 (ii): After treatment

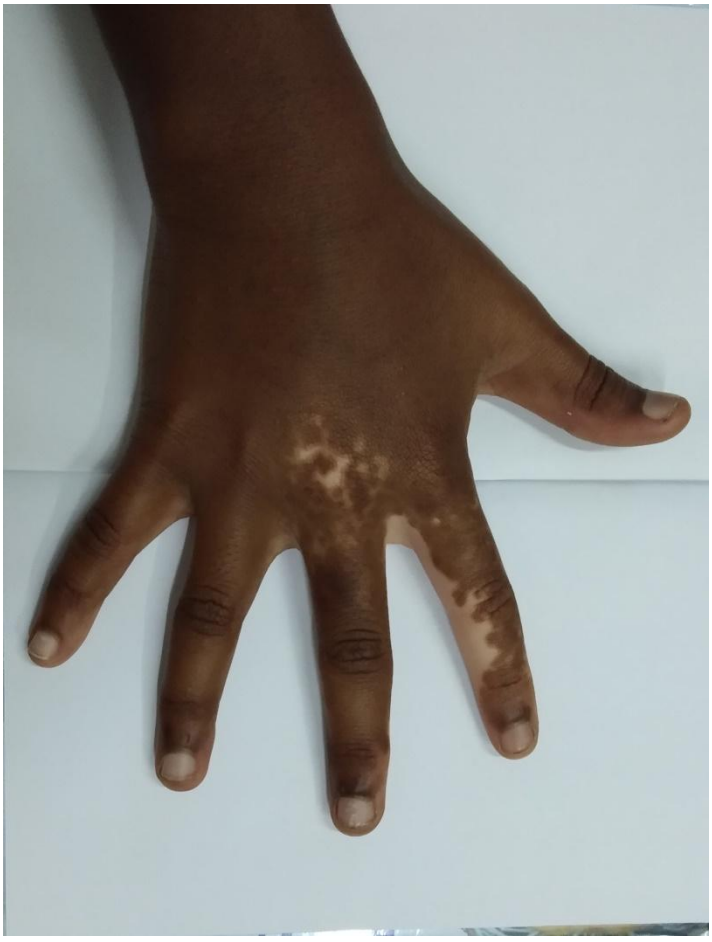


Fig 15 (i): Before treatment

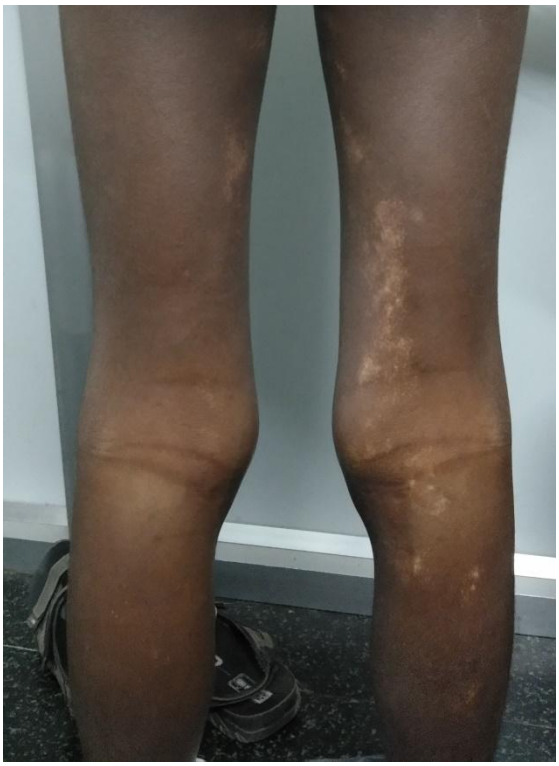


Fig 15 (ii): After treatment

Fig 16 (i): Before treatment

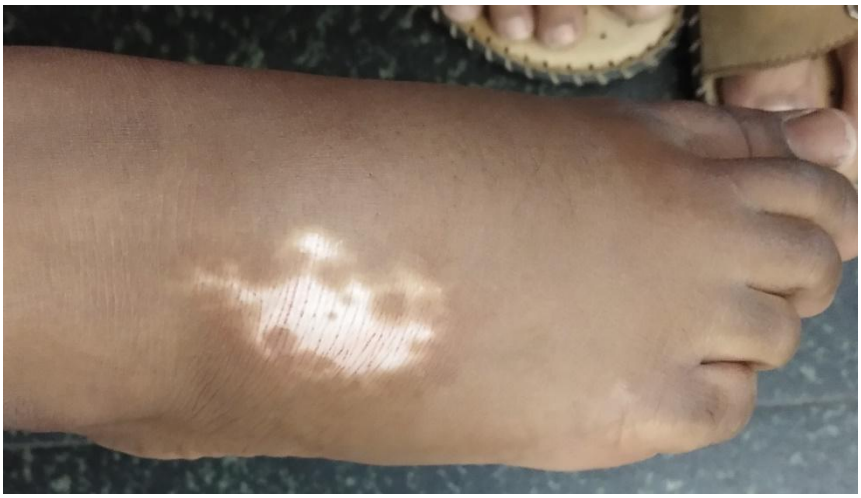
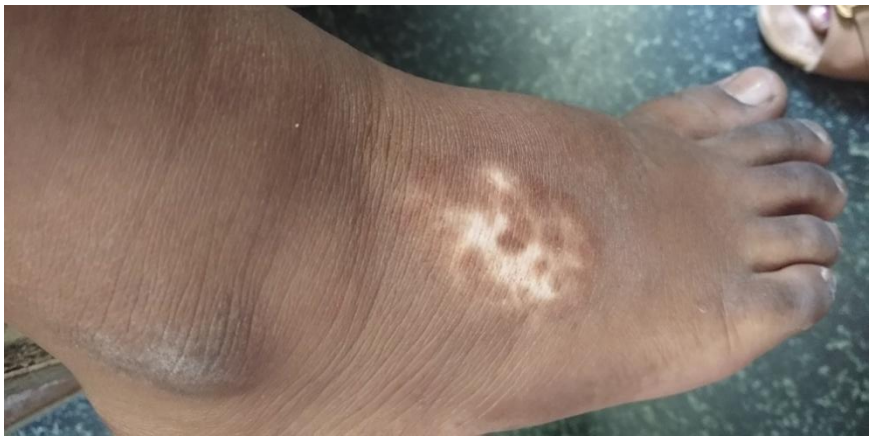


Fig 16 (ii): After treatment



DISCUSSION

- AProtocol was prepared and submitted before Institutional Ethical Committee (IEC)ofNationalInstituteofSiddha.
- The trial was registered in Clinical trial Registry of India
- The trial drug *"*PARANGIPATTAI CHOORANAM (internal) and ANNABEDHI CHENDURAM (external)*"* was given for 48 days. For OP patients before and after treatment the clinical assessment is done and prognosis was noted.

PRECLINICAL STUDIES

- **Physicochemical analysis:**

The drug Parangipattai choornam was in the consistency of fine powder with pale milky white in colour with mild odour, bitter and slightly sweet in taste.Microscopic observation of the particle size analysis reveals that the average particle size of the sample PPC was found to be 121.9± 45.24 µm further the sample PPC has particle with the size range of lowest 41.1 µm to highest 211.341.1 µm.

Physico-chemical analysis was done as preliminary evalution of Parangipattai chooranam. The method of measuring the moisture content in solid materials is loss on drying (LOD). Low moisture content is always desirable for higher stability of drugs. In Parangipattai chooranam loss of drying at $105C^0$ was found to be 8.5%, it falls in between the limit range (1-20%). So the less moisture content shows the good stability of the drug Parangipattai chooranam.

The ash value represents the purity of the drugs.The total ash includes both physiological ash, which is derived from the organic matter, and non-physiological ash which is the residue of the extraneous matters like sand/soil, inorganic materials. The non-physiologic ash is represented by acid soluble ash .The total ash in Parangipattai chooranam found to be 0.55% and the acid insoluble ash to be 0.32%. The both ash value were within the normal range. The minimal level of acid insoluble ash shows the less inorganic residue and purity of the Parangipattai chooranam.

The extractive values help to indicate the nature of chemical constituents present in the drug. The water soluble substance is polar in nature and the alcohol has the ability to dissolve non-polar substance.The water soluble extract value of Parangipattai chooranam is 28.55% and the Alcohol soluble extractive is 34.44%. Itshows the possibility of water soluble constituents such as sugars, plant acids, mucilageand alcohol soluble substance such as tannins, resinsand alkaloids to be present in the drug.

Strongly acidic nature of the drug can cause harmful effects to the body. So the screening for the pH is important for the drug.It represents the chemical nature of the drug. The pH of Parangipattai chooranam is found to be 4.8 that is weakly acidic and safe in pH. The weakly acidic drugs are rapidly absorbed from stomach. So the trial drug Parangipattai chooranam can act rapidly on oral administration.

Rf value of the peaks ranges from 0.30 to 0.89. Further the peak 2 occupies the major percentage of area of 38.78 % which denotes the abundant existence of such compound. Followed by this peak 3 and 1 occupies the percentage area of 31.34 and 16.90%. Peak 4 occupies the percentage area of 13%.

The drug is free of microbial contamination and pesticide residues. In heavy metals analysis mercury was not detected and lead, arsenic, cadmium were present within the permissible limit.Aflatoxin like B2, G1, G2 were not detected except B1 which was within the permissible limit.

- **Biochemical analysis**

The Bio chemical analysis of trial medicines showed shows presence ofSulphate, Carbonate, Iron, Zinc, Calcium, Ammonium and Potassium.

Phytochemicals such as Starch, Sugar, Alkaloids, Tannic acid, flavonoids, steroids, triterpenoids, coumarin, saponins and phenol are present in the trial drug

CLINICAL STUDIES:

- SEX:

  In the present study, Out of 30 cases 50% were male child and 50% were female child.

- AGE:

  In this study most of them were under 9 – 10 year of age (40%).

- SOCIOECONOMIC STATUS:

  Middle economic status (67%) group of peoples are mostly affected.

- THINAI:

  According to this study high incidence in Neithal nilam (94%) may be due to the location of study centre (i.e,) Neithal.

- PARUVAKAALAM:

  According to Paruvakalam high incidence of cases 37% were reported in Koothir kaalam and 33% were reported in Munpani kaalam and 30% were reported in Pinpani kaalam.

- VATHAM:

  100% of cases were affected from Viyanan and Samanan. Viyanan is affected due to change in skin colour and Samanan is affected because it doesn't control the other vadhas.

- PITHAM:

  According to Pitham, Prasagam and Saathagam were affected in 100% of cases.

  - Prasagam is important for pigmentation of skin and it was affected due to hypopigmention of the skin.
  - Saathagam was affected as Venpulli was a cosmetic issue that make the children to deny the exposure to the environment.

- UDARKATTUGAL:

  Among the treated childrenSaaram and Senneer was affected in 100% of cases.

  - Saaram strengthens the body and mind. It was affected in Venpulli due to mental disturbances and depression caused by hypopigmentation.
  - Senner is responsible for boldness and complexion in a person which was affected in Venpulli, due to hypopigmentation of skin causing inferiority that affects self-confidence of the child.

- ENN VAGAI THERVU:

  Niram is affected in 100% of cases which shows depigmented skin in all chidren.

- NAADI:

  On examination of naadi, 77% of cases had Pithavatha naadi, 13% of cases had Vaathapitha naadi and 6% of cases had Kabapitha naadi.

- NEIKURI:

  On Neikuri examination 13% were having vatha neer, 70% were having pitha neer and 17% were having kabha neer.

- SITE OF LESION:

  According to site of lesion, 17% had lesion in hand region,23% had lesion in upper limb, 30%had lesion in trunk, 67% had lesion in lower limb, 33%had lesion in face / neck and 13% had lesion in feet region. Out of 30 children some of them were affected from multiple sites.

CLINICAL IMPROVEMENT:

- 100% of children had pigmentation spots in depigmented area and in 57% of cases had good improvement as per VASI score.
- The Mean Standard Deviation of VASI Score before and after treatment was 5.58 ± 5.4 and 4.89 ± 5.36 respectively which is **statistically significant ($p < 0.001$)**.
- The analysis reveals that there is 12% reduction in depigmentation when compared to before treatment.

SUMMARY

- Evaluation of Parangipattai chooranam (Internal) and Annabedhi chenduram (External) was done after getting approved by IEC of National Institute of Siddha. [IEC No: NIS/IEC/2016/11-24/14.10.2016] and the trial is registered in Clinical trial Registry of India with Reg.NoCTRI/2017/06/008755 [Registered on: 05/06/2017].
- The raw drugs of Parangipattai chooranam and Annabedhi chenduram were identified and authentication certificate was obtained.
- The drug Parangipattai choornam was a fine powder pale milky white in colour with mild odour, bitter and slightly sweet in taste.
- The drug size has a particlesize with the range of lowest 41.1 µm to highest 211.341.1 µm. The loss on drying indicates the moisture content of the drug was determined as 8.5 ± 2.8%. The total ash was found to be 0.55 ± 0.05% which indicates the inorganic content of the drug. The water soluble ash was calculated as 7.46 ± 0.72% and the value of acid insoluble ash was found to be 0.32 ± 0.15% which indicates that the drug contains negligible amount of siliceous matter. The water soluble extractive value and alcohol soluble extractive value were found to be 25.86 ± 0.81% and 34.44 ± 2.12%. The pH value is measured as 4.8 which indicate that the drug is acidic.
- HPTLC was done to identify phyto- chemicals and their Rf values were calculated.
- The drug is free of microbial contamination and pesticide residues.
- In heavy metals analysis mercury was not detected and lead, arsenic, cadmium were present within the permissible limit.
- Aflatoxin like B2, G1, G2 were not detected except B1 which was within the permissible limit.
- The disease Venpulli was taken for the clinical study with Parangipattai chooranam (Internal) and Annabedhi chenduram (External) as a trial medicine and 30 cases were selected based on the approved protocol.
- The detailed study of Venpulli with reference to its etiology, pathogenesis, investigations, clinical features, diagnosis and treatment with trial drug was done.
- The results were observed by VASI score. Among the 30 cases treated 57% of the cases had moderate improvement and 43% had pigmented spots in depigmented area.

- Statistical analysis: The Mean Standard Deviation of VASI Score before and after treatment was 5.58 ± 5.4 and 4.89 ± 5.36 respectively which is **statistically significant ($p < 0.001$)**.
- The analysis reveals that there is 12% reduction in depigmentation when compared to before treatment.

CONCLUSION

- The poly herbal formulation Parangipattai chooranam (Internal) and Annabedhi chenduram (External)exhibited no toxicity on short term administration in children.
- The present clinical study confirms the efficacy and safety of the trial drug "Parangipattai chooranam (Internal) and Annabedhi chenduram (External)" which is Siddha poly herbal and herbomineral formulation respectively.
- It was found to be having good result on Venpulli patients in reducing clinical symptoms like depigmention of skin.
- The Mean Standard Deviation of VASI Score before and after treatment was 5.58 ± 5.4 and 4.89 ± 5.36 respectively which is **statistically significant ($p < 0.001$)**. The analysis reveals that there is 12% reduction in depigmentation when compared to before treatment.
- The qualitative outcome shows that 100% of the cases had pigmentation in depigmented area and good improvement in 57%.
- From the above results, the trial drug "Parangipattai chooranam (Internal) and Annabedhi chenduram (External)" provides moderate improvement in the treatment of Venpulli.
- The open clinical trial conducted on Venpulli with the trial drug Parangipattai chooranam (Internal) and Annabedhi chenduram (External) creates a very good impact on the pigmentation of the affected area. Hence the author recommends by increasing the trial period for about 90 days will bring out the tremendous effect of the drug in future which will reduce the stress of the affected children and enable to lead a healthy life.
- As a conclusion it can be stated that the Siddha Herbal formulation Parangipattai chooranam (Internal) and Annabedhi chenduram (External) can be used as a safe and extremely efficacious drug towards the management of Venpulli in children which takes a huge toll of inducing psychological stress and impact on the cosmetic purposes.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORM 1- SCREENING PROFOMA

1. Sl no: 2. OP/ IP No: 3.Name:

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

7. Date of completion: 8.Informant:

INCLUSION CRETERIA:	YES	NO
• Age: Between 5 to 12 years	☐	☐
• Sex: Both male and female children	☐	☐
• Hypo pigmented patches withHyper pigmented border without any structural changes in any part of the body	☐	☐
• Patient's informant / Parent willing to sign the informed consent stating that he/she will consciously stick to the treatment during 48 days	☐	☐
• Willing to cooperate for taking photographs whenever required with his\her consent	☐	☐

EXCLUSION CRITERIA	YES	NO
• Albinism	☐	☐
• Dermatogical manifestations of Leprosy	☐	☐
• Tinea versicolor	☐	☐
• Burn scars	☐	☐
• Dermatological aspect of Addisons diseases	☐	☐
• Post inflammatory hypopigmentation	☐	☐
• Pityriasis alba	☐	☐

- Alopecia aerate ☐ ☐
- Fungal infestation ☐ ☐

PATIENT SELECTED FOR TRIAL ☐ ☐

IF YES ADMITTED IN IP ☐ ☐

Signature of Investigator : Signature ofGuide:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORM II - CONSENT FORM

CERTIFICATE BY INVESTIGATOR

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

Signature _____

Date _____

Name _____ _____

CONSENT BY PARENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up to monitor and safeguard my son/daughter's body functions.

I am aware of my right to opt my son/daughter out of the trail at any time during the course of the trail without having to give the reasons for doing so. I agree to take photograph when and wherever required.

I, exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial entitled CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO).

Date : Signature _____

Name _____

Place : Signature of witness _____

Name _____

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை-47

பட்டமேற்படிப்பு குழந்தை மருத்துவத்துறை

வெண்படை நோய்க்கான பறங்கிப் பட்டை சூரணம் (உள்ளாட்சி) மற்றும் அன்னபேதி செந்தூரம் (வெளியாட்சி) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு

<u>ஒப்புதல் படிவம்</u>

<u>ஆய்வாளரால் சான்றளிக்கப்பட்டது</u>

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

தேதி: **கையொப்பம்:**

இடம்: **பெயர்:**

நோயாளியின் பெற்றோர் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறைப் பற்றியும், இந்த மருத்துவத்தை தொடர்ந்து எனது குழந்தையின் உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனைப் பாதுகாக்க பயன்படும் மருத்துவ ஆய்வுகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்பொழுது வேண்டுமானலும் என் குழந்தையை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு வெண்படை நோய்க்கான பறங்கிப் பட்டைசூரணம் (உள்ளாட்சி) மற்றும்அன்னபேதி செந்தூரம் (வெளியாட்சி) பரிகரிப்புத்திறனை கண்டறியும் மருத்துவ ஆய்வுக்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **பெற்றொர் கையொப்பம்:**

இடம்: **பெயர்:**

சாட்சிக்காரர் கையொப்பம்:

பெயர்:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORM II A - ASSENT FORM (By Patient)

1. Sl.no: 2. OP/IP No: 3.Name:
4. Age : 5. Gender : 6. Date of Enrollment:
7. Informant:

I, _____ understand that my parents (mom and dad)/ guardian have/ has given permission (said it's okay) for me to take part in the clinical trial about VENPULLI done by Dr.R.Vinodini.

I am taking part because I want to take part. I have been told that I can stop at any time if I want to do so and nothing will happen to me if I want to stop. I agree to take photograph when and wherever required.

Date: Signature of the patient:

Place: Signature of parent / guardian:

தேசிய சித்த மருந்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை-47

பட்டமேற்படிப்பு குழந்தை மருத்துவத்துறை

வெண்படை நோய்க்கான பறங்கிப் பட்டை சூரணம் (உள்ளாட்சி) மற்றும் அன்னபேதி செந்தூரம் (வெளியாட்சி) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவஆய்வு

<u>ஒப்புதல் படிவம் குழந்தைக்கானது</u>

---------- ஆகியநான் தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்டமேற்படிப்பு குழந்தை மருத்துவத் துறையில் பயிலும் மரு.இரா.வினோதினி அவர்களால் நடத்தப்படும் வெண்படை நோய்க்கான பறங்கிப் பட்டை சூரணம் (உள்ளாட்சி) மற்றும் அன்னபேதி செந்தூரம் (வெளியாட்சி)பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வில் பங்கேற்பதற்கு எனது பெற்றோர்\காப்பாளர் திரு\திருமதி----------சம்மதம் தெரிவித்திருப்பதை நன்கு அறிவேன்.

எனக்கு இந்த ஆராய்ச்சி பற்றி புரியும் வகையில் எடுத்துரைக்கப்பட்டுள்ளது. இவ்வாராய்ச்சியில் இருந்து எப்போது வேண்டுமானாலும் விலக எனக்கு உரிமை இருக்கின்றது என்பதை பற்றியும் நன்கு தெரிந்துகொண்டு இந்த ஆராய்ச்சியில் பங்கேற்க சம்மதிக்கிறேன்.

தேதி: **குழந்தையின் கையொப்பம்**

இடம்: **பெயர்**

பெற்றொர் கையொப்பம்

பெயர்

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORM III- CASE REPORT FORM

Demographic data

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

1. **COMPLAINTS AND DURATION**

---

2. **HISTORY OF PRESENT ILLNESS**

---

3. **HISTORY OF PAST ILLNESS**

FAMILY HISTORY

Any Hereditary/ Familial Disease Yes ☐ No ☐

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

Family H/O similar condition ----------

IMMUNIZATION HISTORY:

Immunization : Complete ☐ Incomplete ☐ Complete but time lag ☐

FOOD HABITS:

1. Veg ☐ 2. Non-Veg ☐ 3. Mixed ☐

General Examination

1. Pallor Yes ☐ No ☐
2. Jaundice Yes ☐ No ☐
3. Cyanosis Yes ☐ No ☐

4. Clubbing Yes ☐ No ☐
5. Pedal Edema Yes ☐ No ☐
6. Lymphadenopathy Yes ☐ No ☐
7. Jugular venous pulse _____

Vital signs:-

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

Anthropometry:-

Height - cm

Weight - kg

EXAMINATION OF THE AFFECTED AREA:

Site of the lesion ----------

Color of the lesion ----------

Size of the lesions ----------

Shape of the lesions ----------

Margin of the lesion ----------

Other systems:

Respiratory system : Normal ☐ Affected ☐

Cardio vascular system: Normal ☐ Affected ☐

Gastro intestinal system: Normal ☐ Affected ☐

Musculoskeletal system: Normal ☐ Affected ☐

Central nervous system: Normal ☐ Affected ☐

Endocrine system : Normal ☐ Affected ☐

SIDDHA ASSESSMENT:

Nilam:-

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Paalai ☐

Kaala Iyalbu:-

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

Yaakai:-

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

Gunam:-

Sathuvam ☐ Rasatham ☐ Thamasam ☐

Pori / Pulangal:-

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

Kanmendhirium / Kanmavidayam

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

UYIR THATHUKKAL:

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

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

Kabam:

	Normal	Affected	Remarks
Avalambagam	☐	☐	
Kilethagam	☐	☐	
Pothagam	☐	☐	
Tharpagam	☐	☐	
Santhigam	☐	☐	

UDALTHATHUKKAL:

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

ENVAGAI THERVUGAL:

	Normal	Affected	Remarks
Naa			
Niram	☐	☐	
Thanmai	☐	☐	
Suvai	☐	☐	
Niram	☐	☐	
Mozhi	☐	☐	
Vizhi	☐	☐	

Niram ☐ ☐

Thanmai ☐ ☐

Paarvai ☐ ☐

Sparisam ☐ ☐

Malam

Niram ☐ ☐

Nurai ☐ ☐

Elagal ☐ ☐

Erugal ☐ ☐

Moothiram	Normal	Affected	Remarks

Neerkuri:

Niram ☐ ☐

Edai ☐ ☐

Nurai ☐ ☐

Manam ☐ ☐

Enjal ☐ ☐

Neikuri:

Vatham ☐

Pitham ☐

Kabam ☐

Others ☐

Naadi:

Diagnosis:

Date: Signature of Investigator:

Place: Signature of Guide:

CLINICAL ASSESSMENT BY VITILIGO AREA SEVERITY INDEXES (VASI) SCORE:

Sl.no	**Location**	**Hand units**		**Depigmentation**		**Total hand units**	
		BT	**AT**	**BT**	**AT**	**BT**	**AT**
1.	Hands						
2.	Upper Extremities						
3.	Trunk						
4.	Lower Extremities						
5.	Face/Neck						
6.	Feet						
	Total						

TOTAL BODY VASI SCORE:

Date: Signature of Investigator:

Place: Signature of Guide:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORM VI -DRUG COMPLIANCE FORM

S. NO: --------- OPD/IPD NO: ---------- NAME: ----------

NAME OF THE DRUG: Parangipattai Chooranam (Internal) & Annabedhi Chenduram (External)

DOSAGE AND DURATION:

INTERNAL: ½ - 1 gram (bd) with Sakkarai for 48 days.

EXTERNAL: Apply with lemon juice in the affected area for 48 days

DAY	DATE	MORNING	NIGHT	DAY	DATE	MORNING	NIGHT
1				25			
2				26			
3				27			
4				28			
5				29			
6				30			
7				31			
8				32			
9				33			
10				34			
11				35			
12				36			
13				37			

14				38			
15				39			
16				40			
17				41			
18				42			
19				43			
20				44			
21				45			
22				46			
23				47			
24				48			

Date: Signature of the Investigator:

Station: Signature of the Guide:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORM V- DIETARY ADVICE FORM

The following diet to be taken:

- Drink adequate water
- Green vegetables/spinach
- Carrot
- Watermelon
- Coriander
- Beetroot
- Soya beans
- Walnuts
- Pumpkin
- Apple
- Fig fruit
- Honey
- Banana flower
- Pomegranate
- Black dates

The following food should be avoided:

- Bitter gourd
- Brinjal
- Sea foods
- Pickles
- Chicken

- Papaya
- Chocolate
- Green chilli
- Tamarind
- Citrus fruits (Grapes, Orange, Lemon)
- Packaged food
- Tinned foods or drinks
- Curd
- Raw tomato
- Coffee
- Raw garlic
- Raw onion

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORM IV – PATIENT INFORMATION SHEET

Name of Principal Investigator:- Dr.R.VINODINI

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, Dr.R.VINODINI Studying as PG Scholar in department of Kuzhandhai Maruthuvam at National Institute of Siddha, Tambaram Sanatorium doing a trial on the study VENPULLI (Vitiligo). Vitiligo is a disease, which is characterized by depigmentation of skin due to disappearance of melanocytes and melanin. In this regard, I am in a need to ask you few questions about your child illness. 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. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree your child to be a participant in this study, he/she will be included in the study primarily by signing the consent form and then you will be given the internal medicine PARANGIPATTAI CHOORANAM ½-1gm twice a day with palm jaggery and ANNABEDHI CHENDURAM as external medicine for 48 days.

The information I am collecting in this study will remain between you and me.

If you wish to find out more about this study before taking part, you can ask all the questions you want to principle investigator Dr.R.VINODINI (9791979749). You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel no: 91-44-22380789, for rights and participation in the study.

தேசிய சித்த மருந்துவ நிறுவனம்

அயோத்திதாச பண்டிதர் மருத்துவமனை, சென்னை-47

பட்டமேற்படிப்பு குழந்தை மருத்துவத்துறை

வெண்படை நோய்க்கான பறங்கிப் பட்டை சூரணம் (உள்ளாட்சி) மற்றும் அன்னபேதி செந்தூரம் (வெளியாட்சி) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவஆய்வு

ஆராய்ச்சியாளர் பெயர்: மரு.இரா.வினோதினி

மருத்துவ ஆய்விற்கான தகவல் படிவம்

தேசிய சித்த மருத்துவ நிறுவனத்தில் குழந்தை மருத்துவத் துறையில் பட்ட மேற்படிப்பு பயின்று வரும் மரு.இரா.வினோதினிஆகிய நான் வெண்படை நோய்க்கான பறங்கிப் பட்டை சூரணம் (உள்ளாட்சி) மற்றும் அன்னபேதி செந்தூரம் (வெளியாட்சி)பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன். வெண்படைஎன்னும் நோயில் உடலில் மங்கிய வெண்மையான நிறமுள்ள பல அளவான புள்ளிகளும், படைகளும் விகாரமாகக் காணுவதோடு சிலவேளை அவ்விடத்திலுள்ள மயிரும் வெளுத்துக் காணும். .சித்த மருந்துவ பட்டமேற்படிப்பில் ஆய்வின் ஒரு பகுதியாக வெண்படை நோய்க்கான பறங்கிப் பட்டை சூரணம் (உள்ளாட்சி) மற்றும் அன்னபேதி செந்தூரம் (வெளியாட்சி)பரிகரிப்புத் திறனை கண்டறியும் ஆய்வினை மேற்கொண்டுள்ளேன்.

இது சம்பந்தமான குழந்தையின் அனைத்து விவரங்களும் இரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன். இது போன்ற விவரங்களை தெரிவிப்பதால் தங்களுக்கோ தங்களது குழந்தைக்கோ தங்களின் வேலை தளத்திலோ எந்த ஒரு பாதிப்பும் ஏற்படாது. இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப்பட மாட்டாது.இந்த ஆராய்ச்சிக்கு நோயினராக சேர்ந்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் தங்களது குழந்தையை விலக்கிக் கொள்ளலாம். இருந்தாலும் இந்த மருத்துவ ஆய்வில் சேர்வதன் மூலமாக தங்களது குழந்தையின் நோய் குறைவது மட்டுமல்லாமல் மருத்துவத்துறை சார்ந்த வல்லுநர்களுக்கு இந்த நோய்க்கான தீர்வுகளை கண்டறிவதற்கு மிகவும் உதவியாக இருக்கும்.

இந்த ஆராய்ச்சிக்கு தங்களது விருப்பத்தின் பேரில் தங்களது குழந்தையை உட்படுத்தும் பட்சத்தில் முதன்மையாக ஒப்புதல் படிவத்தில் கையெழுத்திட்ட பின்பு தாங்கள் பறங்கிப் பட்டை சூரணம் ½ - 1கி அளவு 2 வேளை பனைவெல்லத்தில் 48 நாட்கள் உள்மருந்தாக தர வேண்டும் மற்றும் அன்னபேதி செந்தூரம் ஒரு வேளை எலுமிச்சை சாற்றில் கலந்து பாதிக்கப்பட்ட இடத்தில் பூச வேண்டும்.

இந்த மருத்துவ ஆய்வின் தொடர்பாக உங்களிடமிருந்து சேகரிக்கப்படும் அனைத்து விவரங்களும் உங்களுக்கும் ஆராய்ச்சியாளரான எனக்கும் மட்டுமே அறிந்திருக்கக் கூடியதாக இருக்கும்.இந்த ஆராய்ச்சி சம்மந்தமாக மற்ற விபரங்களையும் நோயின் தன்மை பற்றியும் அறிவதற்கு ஆராய்ச்சியாளரான மரு.இரா.வினோதினி கைபேசி எண் 9791979749 தொடர்பு கொள்ளலாம். மேலும் இந்த ஆராய்ச்சி தொடர்பாக நிறுவன நீதி நெறி குழு தேசிய சித்த மருந்துவ நிறுவனம் தொலைபேசி எண் 91-44-22380789 தொடர்பு கொள்ளலாம்.

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

Form VII – ADVERSE REACTION FORM

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

Name :

Age :

Gender :

OPD/ IPD No :

Date of trial commencement :

Date of withdrawal from trial :

Description of adverse reaction :

Date: Signature of Investigator:

Place:

Signature of Guide:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

POST GRADUATE DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF PARANGIPATTAI CHOORANAM (INTERNAL) AND ANNABEDHI CHENDURAM (EXTERNAL) FOR VENPULLI (VITILIGO) IN CHILDREN.

FORMVIII - WITHDRAWL FORM

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

Date of trial commencement	:
Date of withdrawal from trial	:
Reason(s) for withdrawal	: Yes/ No
Long absence at reporting	: Yes/ No
Irregular treatment	: Yes/ No
Shift of locality	: Yes/ No
Complication / adverse reactions if any	: Yes/ No
Exacerbation of symptoms	: Yes/ No
Patient not willing to continue	: Yes/ No

Date: Signature of Investigator:

Place: Signature of Guide:

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Reporting Form for Suspected Adverse Reactions to Siddha Drugs

Please note: i.Allconsumers / 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.

PeripheralCenter code: State:

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

<table>
<tr><td>Name</td><td>Father name</td><td rowspan="2">Patient / Record No.</td></tr>
<tr><td>Ethnicity</td><td>Occupation</td></tr>
<tr><td colspan="2" rowspan="2">Address
Village / Town
Post / Via
District / State</td><td>Date of Birth / Age:</td></tr>
<tr><td>Sex: Male / Female
Weight :
Degam:</td></tr>
</table>

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,
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

Station:

Signature of the Investigator:

Signature of the Guide:

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

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

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr. R.Vinodini – I year, Dept.of Kuzhanthai Maruthuvam	
Protocol Title:- Clinical Evaluation of Parangipattai Chooranam (Internal) and Annabedhi Chenduram (External) for Venpulli (Vitiligo) in Children.	
Documents filed	1) Protocol, 2) Data Collection forms
Clinical trial Protocol (others – Specify)	**Yes-(M.D-Dissertation)**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/2016/11-24/ 14.10.2016**

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

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

(Dr.V.Subramanian)
Chairman

NATIONAL INSTITUTE OF SIDDHA ★ CHENNAI 600 047

V. Banumathi 14/10/16

(Prof.Dr.V.Banumathi)
Member Secretary

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

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

Smilax china Linn. (Liliaceae), Root

Ocimum tenuiflorum Linn. (Lamiaceae), Leaf

Citrus limon (Linn.) Burm. f. (Rutaceae), Fruit

DEPARTMENT OF MEDICINAL BOTANY CHENNAI 600 047 National Institute of Siddha

Certificate No: NISMB2922017

Date: 23-3-17

Authorizd Signatory

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

NATIONAL INSTITUTE OF SIDDHA
MINISTRY OF AYUSH
GOVERNMENT OF INDIA
TAMBARAM SANATORIUM, CHENNAI - 600 047
Tele : 044-22411611 Fax : 22381314
nischennaisiddha@yahoo.co.in www.nischennai.org

F.No:NIS/Gunapadam/Au/2017/7 13.07.17

AUTHENTIFICATION CERTIFICATE

Certified that the sample submitted for identification by **Dr. R. Vinodini**, II year PG scholar, Dept. of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai - 47, is identified as **Anna bethi- Sulphate of Iron** on the basis of macroscopic character.

This certificate is issued for the purpose of preparing her dissertation medicine in Gunapadam laboratory, NIS.

Dr. S. Visweswaran, M.D (s)

Head of Department
Department of Gunapadam
National Institute of Siddha
Tambaram Sanatorium, Chennai-47.

Noble research solutions
We Trust in Quality and Ethics

Noble Research Solutions

We Trust in Quality and ethics

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

Date: 20.03.2018

To,

Dr.R.Vinodini
National Institute of Siddha,
Tambaram Sanatorium, Chennai 600047, Tamil Nadu, India.

Project Id: **NRS/AS/0086/01/2018**

This is to certify that Dr.R.Vinodini from Govt Siddha Medical College, Arumbakkam, Chennai, has carried out the following activity at our facility for the trial drug *Parangipattai Chooranam (PPC)*

S.No	Study Description	Annexure no
1.	Standardization and Physicochemical Evaluation of study drug *Parangipattai Chooranam (PPC)*	1

Note:

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

NOBLE RESEARCH SOLUTIONS TAMIL NADU INDIA CHENNAI

For NOBLE RESEARCH SOLUTIONS

Services offered : Standardization and Characterization of ASU formulations
In-vitro and In-silico Evaluations / Instrumental analysis / Histopathological Analysis
Blood & Serum Estimations
Thesis Writing / Research Article Preparation and Publication Services

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

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

This Certificate is awarded to Dr/~~Mr/Mrs~~.....R. VINODINI.....

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

"RESEARCH METHODOLOGY & BIOSTATISTICS"

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

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 06th to 10th June 2016.

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

Prof.**Dr.S.PUSHKALA,** M.D.,
REGISTRAR (FAC)

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

FRONTIER MEDIVILLE

(A Unit of FRONTIER LIFELINE HOSPITAL & Dr.K.M.CHERIAN HEART FOUNDATION)

Elavur/Edoor Village, Gummidipoondi Taluk, Thiruvallur District, Tamilnadu, India - 601 201. Tel : +91 44 27940001/ 15

V CME - A V CANAL & E C DEFECTS

This is to certify that Dr. R. VINOTHINI . NLS

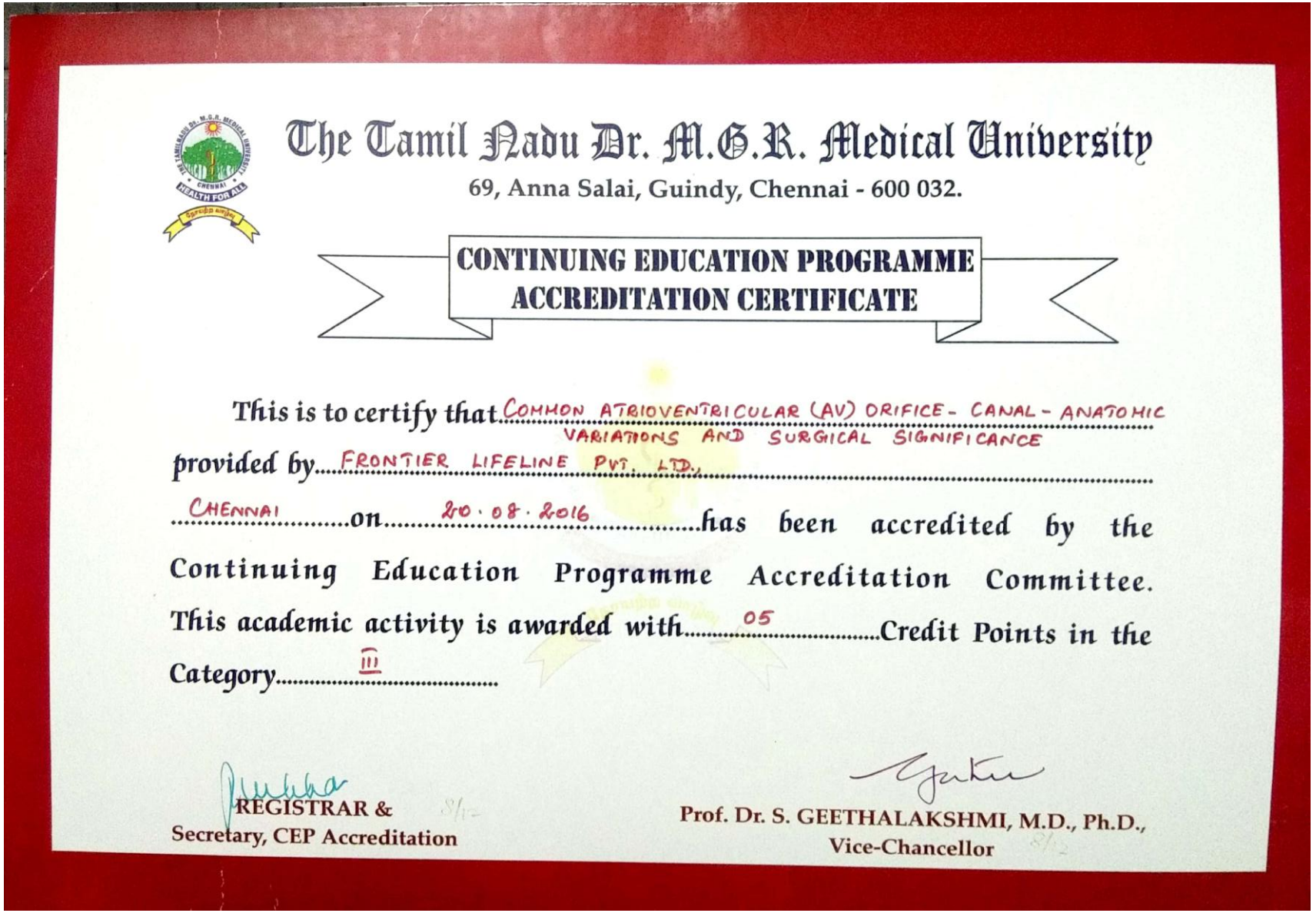
has participated in the V C M E and Work Shop Programme conducted under the auspices of the Maurice Lew & Saroja Bharati International Centre of Excellence in Cardiac Pathology held at Frontier Mediville on 20th August 2016 on 'Common Atrioventricular (AV) Orfice - Canal, Anatomic variations and surgical significance'

Dr. K.M.Cherian
Chairman & CEO
Frontier Lifeline Hospital

Dr.Saroja Bharati
Prof. Pathology Rush Medical University
Chicago, USA

Dr. Sarasa Bharati
HOD Pathology & Advisor - Academics
Frontier Lifeline Hospital

Reg. Office : R 30 C, Ambattur Industrial Estate Road, Chennai - 600 101. India. Tel.: +91 44 42017575, 2656422 / 6252 Web : www.frontierlifeline.com / www.frontiermediville.com



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

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

CONTINUING EDUCATION PROGRAMME ACCREDITATION CERTIFICATE

This is to certify that COMMON ATRIOVENTRICULAR (AV) ORIFICE - CANAL - ANATOMIC VARIATIONS AND SURGICAL SIGNIFICANCE provided by FRONTIER LIFELINE PVT. LTD., CHENNAI on 20.08.2016 has been accredited by the Continuing Education Programme Accreditation Committee. This academic activity is awarded with 05 Credit Points in the Category III

REGISTRAR &
Secretary, CEP Accreditation

Prof. Dr. S. GEETHALAKSHMI, M.D., Ph.D.,
Vice-Chancellor

SASTRA UNIVERSITY
ENGINEERING · MANAGEMENT · LAW · SCIENCES · HUMANITIES · EDUCATION
(A UNIVERSITY U/S 3 OF THE UGC ACT, 1956)

Centre For Advanced Research In Indian System Of Medicine (CARISM)

Certificate of Participation

This is to certify that Dr. **R.VINODINI** of **National Institute of Siddha, Chennai** participated in Ministry of AYUSH supported training programme on **"Characterization Techniques in the Standardization of Ayurvedha & Siddha Herbo-Metallic Preparations"** held during 28 to 30 march 2016.

P. Brindha
Convener
Prof. **P. Brindha**

Registrar
SASTRA University

SIDDHI CHARITABLE TRUST

15/1, Ramanujar Street, Pollachi. Tamil Nadu

PRISM

(PLATFORM FOR RESEARCHERS IN INDIAN SYSTEMS OF MEDICINE)

Certificate of Participation / Presentation

This is certify that

Dr/~~Mr./Ms~~.....R. VINODINI.....

has participated / Presented a Poster / Oral in the..PRISM-4.....

held at MADURAI on 17-07-2016

AN APPRAISAL OF NUTRITIONAL DIET PANCHAMUDICHI KANCHI

FOR CEREBRAL PALSY CHILDREN

"WON THIRD PRIZE"

Dr. Ramasamy

Trustee, Siddhi Charitable Trust

உலகத் தமிழாராய்ச்சி நிறுவனம்
தரமணி, சென்னை - 600 113
மற்றும்
Dr. ஜெ. நினைவு அறக்கட்டளை
இணைந்து நடத்தும்
திருமந்திரம் மற்றும் வர்மஅறிவியல் பன்னாட்டுப் பயிலரங்கம்
IWTV2016 INTERNATIONAL WORKSHOP ON TIRUMANDIRAM & VARMAN SCIENCE

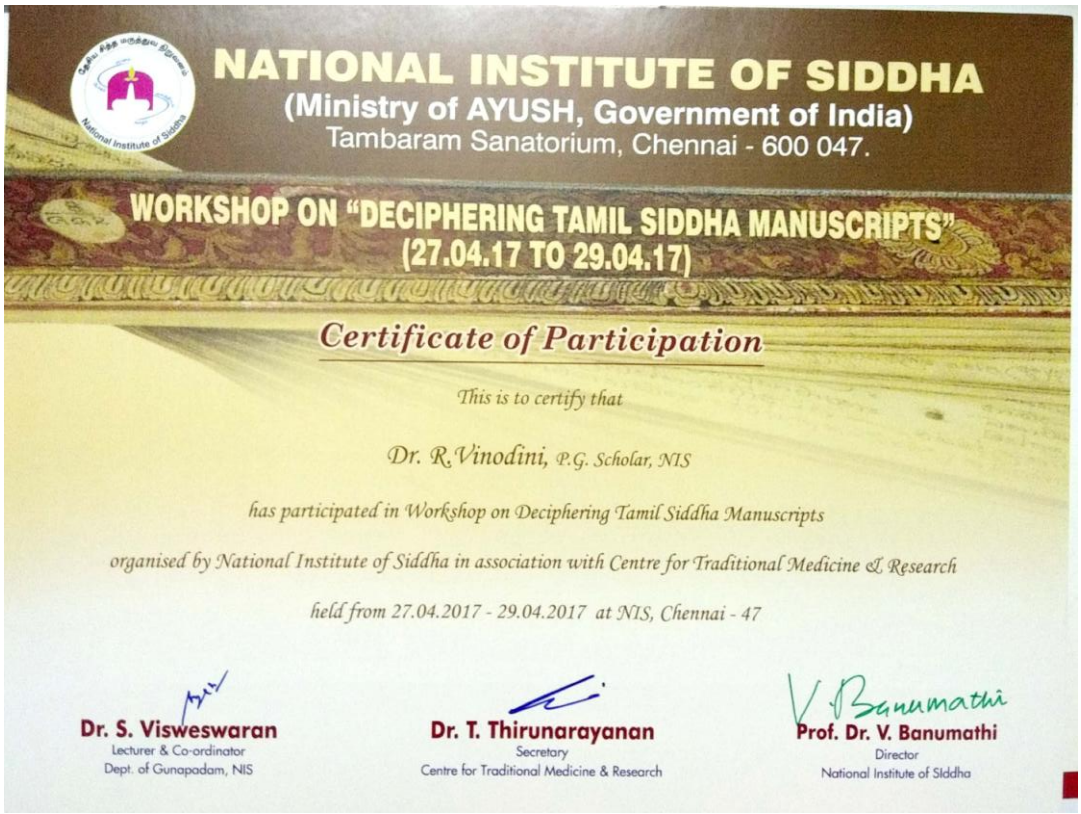
சான்றிதழ்

திரு / திருமதி / செல்வி ..... அவர்கள்
16 மற்றும் 17 ஏப்ரல் 2016, ஆகிய இரண்டு நாள் நடைபெற்ற பன்னாட்டுப் பயிலரங்க பயிற்சி பட்டறையில் பங்கேற்றுப் பயிற்சி பெற்றமைக்காக இச்சான்றிதழ் வழங்கப்படுகிறது.

Dr.ம.பா.அகத்தியர்
பயிலரங்கக்குழு தலைவர்,
Dr. ஜெ. நினைவு அறக்கட்டளை,
வடபழனி, சென்னை - 600 026

முனைவர். தி.மகாலட்சுமி
திருமூலர் இருக்கை, நிறுவன்
உலகத் தமிழாராய்ச்சி நிறுவனம்
தரமணி, சென்னை - 600 113

முனைவர். கோ.விசயராகவன்
இயக்குநர்
உலகத் தமிழாராய்ச்சி நிறுவனம்
தரமணி, சென்னை - 600 113



NATIONAL INSTITUTE OF SIDDHA
(Ministry of AYUSH, Government of India)
Tambaram Sanatorium, Chennai - 600 047.

WORKSHOP ON "DECIPHERING TAMIL SIDDHA MANUSCRIPTS"
(27.04.17 TO 29.04.17)

Certificate of Participation

This is to certify that

Dr. R.Vinodini, P.G. Scholar, NIS

has participated in Workshop on Deciphering Tamil Siddha Manuscripts

organised by National Institute of Siddha in association with Centre for Traditional Medicine & Research

held from 27.04.2017 - 29.04.2017 at NIS, Chennai - 47

Dr. S. Visweswaran
Lecturer & Co-ordinator
Dept. of Gunapadam, NIS

Dr. T. Thirunarayanan
Secretary
Centre for Traditional Medicine & Research

Prof. Dr. V. Banumathi
Director
National Institute of Siddha

Government of India
Ministry of AYUSH

Siddhar Agathiyar
Father of Siddha Medicine

Certificate of Achievement

This Certificate is proudly presented to

Dr. Vinodini R
NIS Chennai

for making oral presentation/poster presentation titled

EFFICACY of Madhumega Kudineeer A Siddha Herbal Formulation in The Management OF Sirai Pai Neerkatti (POLYCYSTIC Ovarian Syndrome)- An open PILOT STUDY.

in the National Conference on "Prevention and Management of Lifestyle Disorders through Siddha system of Medicine" on **the first Siddha Day** held on **04.01.2018** – organised by Central Council for Research in Siddha (CCRS) jointly with Directorate of Indian Medicine and Homoeopathy, Govt. of Tamil Nadu, The Tamil Nadu Dr. M.G.R. Medical University and National Institute of Siddha.

மார்கழி
ஆயில்யம்
சித்த மருத்துவத்
திருநாள்

Prof. Dr. R. S. Ramaswamy
(Director General
Central Council for Research in Siddha)
Chairman

Prof. Dr. P. Parthiban
(Joint Director, DIM&H
Govt. of Tamil Nadu)
Organising Secretary

Certificate. No: FSD/Pres/ 137

IN COLLABORATION WITH

MINISTRY OF AYUSH Govt OF INDIA

सत्यमेव जयते

NORTHERN PROVINCIAL COUNCIL

1ST INTERNATIONAL CONFERENCE & EXHIBITION ON SIDDHA MEDICINE -2018

23RD - 27TH AT UNIT OF SIDDHA MEDICINE
UNIVERSITY OF JAFFNA.
SRI LANKA

CERTIFICATE

THIS IS TO CERTIFY THAT Prof / Dr. / Mr. / Ms. .....R.VINODINI.....(ORAL PRESENTATION)..... PARTICIPATED / PRESENTED A PAPER ON EFFICACY OF HADHUMEGIA KUDINEER A SIDDHA HERBAL FORMULATION IN THE..... IN THE ABOVE CONFERENCE HELD ON 26TH & 27TH FEBRUARY 2018. MANAGEMENT OF SINAIPAINEERKATTI-AN OPEN PILOT STUDY

.....

Prof . R. VIGNESWARAN
VICE CHANCELLOR
UNIVERSITY OF JAFFNA

.....

Shri. A. NATRAJAN
CONSULATE GENERAL,
HIGH COMMISSION OF INDIA
JAFFNA

BIBILIOGRAPHY

1) Kliegman, Behrman, Jenson/ Nelson textbook of pediatrics Vol II/ 18th Edition/ Pg.no: 2685

2) Dr.R.Thiagarajan/ Siddha Sirappu Maruthuvam/ Indian System of Medicine and Homeopathy/ 1994/ Pg.no: 267,268

3) Dr.K.N.Kuppusamy Mudhaliar and Dr.K.K.Uthamarayen/ Siddha Vaithiya Thirattu/ Published by Indian System of Medicine and Homeopathy/ 2009/ Pg.no 221,222

4) Dr.R.Thiyagarajan/Gunapadam thaadhu seeva vaguppu/ published by Indian system of medicine and Homeopathy/ 2009/ Pg.no:528

5) The Siddha formulary of India part, Pg.no 155

6) S.B.Ramachandiran /Yugi mamunivar vaithiya chinthamani/ Second edition/ Thamarai noolagam/ 2005

7) Nelson 2002, Nelson textbook of paediatric vol III/Pg.no:2685

8) Dr. K.S Uththamarayan H.B.I.M/ Siddhar Aaruvai Maruthuvam/ Indian System of Medicine and Homeopathy/ sixth edition/ 2013

9) K.S.Murugesa Mudhaliyar/ Gunapadam Mooligai part 1/ Indian System of Medicine and Homeopathy.

10) Kandasamy mudhaliyar, Rathina naayakar & sons/ Thirumagal publication/ 1910.

11) Muthu karuppu pillai/ Sri vasi villa publication/ Thanvanthiri vaithiyam part -1

12) Sabapathy/ Vaithiya saarasangiraham/ Anbuselvi publisher/ first edition

13) I.Poniayyan/ Pararasasekaram/ Thirugnanasambadar printers/ 1935/ 4th part.

14) Dr.K.Radhakrishnan L.I.M PART -2/ Anubhava vaithiya deva ragasiyam/ AB Rathna naayakar and sons.

15) Dr.Deva Aasirvatham Saamuvel/ Marunthu Sei Eyalum Kalaiyum/ Published by Indian Medicine and Homeopathy/ 2014/ Pg.no:283

16) Dr. M. Shanmugavelu, H.B.I.M, Noi Nadal Noi Mudhal Nadal Thirattu, Part – I, Indian Medicine and Homeopathy, Fourth Edition 2006

17) N. Madhavi, E. Anil Kumar, T. Maheswar, Neha Arya, Standardization of Swasari vati with reference To gas chromatography, scanning electron microscopy And EDAX. Int. J. Res. Ayurveda Pharm. 2014; 5(2):126-131 http://dx.doi.org/ 10.7897/2277-4343.05226.

18) K.N.Kuppusamy, K.S.Uthamaraayan. Siddha Vaithiya Thirattu. Published by Indian System of Medicine and Homeopathy. 2009. Pg no 221,222.

19) Deva aasirvatham saamuvel. Marunthu Sei Iyalum Kalaiyum. Published by Indian System of Medicine and Homeopathy. 2014. Pg.no:283.

20) Practice of Dermatology, P.N. Behl, A.Agarwal, Govind srivastara 16. Dermatology lecture notes, Debabrata bandy opabhay, Professor & Head Dept. of Dermatology, R.G.Kar medical college, Calcutta, India.

21) Andrew's diseases of the skin, Harry L.Arnold, Clinical Professor of Dermatology, Pg no-120.

22) Dr.U.Satya Narayanan, Biochemistry, 2nd edition, revised & reprint 2005, Book&Allied (P) ltd, Kolkatta, India.

23) Dr.M.N.Chatterjee & Dr.Rana Text book of Medical Biochemistry, 2nd edition 1995, Shinde, Jeypee Brothers.

24) JS Pasricha, Ramji Gupta,textbook of Dermatology, fourth edition 2013 ,page no 234

25) Premanshu Bhushan,Dermatology in week,first edition,2006,pg no-321.

26) Sanjay Ghosh,Skin cases diagnosis and treatment,second edition,2014,pg no-436

27) Brain KR, Turner TD. The Practical Evaluation of Phytopharmaceuticals. Bristol: Wright Scientechnica; 1975:36-45

28) Takashi Hiroi. Measurement of Particle Size Distribution in Turbid Solutions by Dynamic Light Scattering Microscopy. J Vis Exp. 2017; (119): 54885.

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

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

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

32) Protocol for testing of Ayurvedic, Siddha and Unani Medicines, Dr D.R. Lohar published by Pharmacopoeial Laboratory for Indian Medicine, AYUSH, Ministry of Health and Family Welfare, Government of India, Ghaziabad, 2011.

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

34) www.ncbi.nlm.nih.gov>PMC4230268

35) www.ncbi.nlm.nih.gov/pmc/article/PMC3900367/

36) http://newsletter.vitiligosupport.org/newsletter/fall2011/fall.html.

Clinical Trial Details (PDF Generation Date :- Tue, 04 Jul 2017 08:05:38 GMT)

CTRI Number	CTRI/2017/06/008755 [Registered on: 05/06/2017] - **Trial Registered Prospectively**
Last Modified On	25/05/2017
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Single Arm Trial
Public Title of Study	Clinical evaluation of Venpulli (Vitiligo) in children
Scientific Title of Study	Clinical Evaluation of PARANGIPATTAI CHOORANAM (Internal medicine) and ANNABEDHI CHENDURAM (External medicine) for VENPULLI (Vitiligo) in children

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 R Vinodini
Designation	MD siddha
Affiliation	National institute of siddha
Address	Department of Kuzhanthai maruthuvam, Ayothidass pandithar hospital, National institute of siddha, Tambaram sanatorium, Chennai Department of Kuzhanthai maruthuvam, Ayothidass pandithar hospital, National institute of siddha, Tambaram sanatorium, Chennai Kancheepuram TAMIL NADU 600047 India
Phone	9791979749
Fax	
Email	vinodini02@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr M Meenakshi sundaram
Designation	Head of the department
Affiliation	National institute of siddha
Address	Department of Kuzhanthai maruthuvam, Ayothidass pandithar hospital, National institute of siddha, Tambaram sanatorium, Chennai Department of Kuzhanthai maruthuvam, Ayothidass pandithar hospital, National institute of siddha, Tambaram sanatorium, Chennai Kancheepuram TAMIL NADU 600047 India
Phone	9444214582
Fax	
Email	mmssiddha@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr A M Amala Hazel
Designation	Lecturer
Affiliation	National institute of siddha
Address	Department of Kuzhanthai maruthuvam, Ayothidass pandithar hospital, National institute of siddha, Tambaram sanatorium,

	Chennai Department of Kuzhanthai maruthuvam, Ayothidass pandithar hospital, National institute of siddha, Tambaram sanatorium, Chennai Kancheepuram TAMIL NADU 600047 India
Phone	9486909809
Fax	
Email	dramalaaruldhas@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Self

Primary Sponsor

Primary Sponsor Details	
Name	Self
Address	National institute of siddha, Tambaram sanatorium, chennai
Type of Sponsor	Other [Research student]

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 R Vinodini	National institute of siddha	Department of Kuzhanthai maruthuvam, Ayothidass pandithar hospital, National institute of siddha, Tambaram sanatorium, Chennaittt Kancheepuram TAMIL NADU	9791979749 vinodini02@gmail.com

Details of Ethics Committee

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

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Babies with symptom of hypopigmented patches with hyperpigmented border without any structural changes in any part of the body

Intervention / Comparator Agent

Type	Name	Details
Intervention	PARANGIPATTAI CHOORANAM (Internal)and ANNABEDHI CHENDURAM (External)	PARANGIPATTAI CHOORANAM is a single herb formulation in a dosage of 1/2 - 1 g (b.d) for 48 days. ANNABEDHI CHENDURAM mixed with lime juice and applied externally in the affected areas
Comparator Agent	NA	NA

Inclusion Criteria

Inclusion Criteria	
Age From	5.00 Year(s)
Age To	12.00 Year(s)
Gender	Both
Details	1.Hypo pigmented patches with hyper pigmented border without any structural changes in any part of the body. 2.Patients who are willing to stay in IPD Ward for atleast 10 days or willing to attend OP Dept. as required. 3.Patient's informant / Parent willing to sign the informed consent stating that he/she will consciously stick to the treatment during 48 days but can opt out of the trial of his / her own conscious discretion. 4.Willing to cooperate for taking photographs whenever required with hisher consent.

Exclusion Criteria

Exclusion Criteria	
Details	1.Albinism 2.Dermatological aspect of Leprosy 3.Tinea versicolor 4.Burn scars 5.Dermatological aspect of Addisons diseases 6.Post inflammatory hypopigmentation 7.Pityriasis alba 8.Alopecia aerate 9.Chemical leucoderma

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

Primary Outcome

Outcome	Timepoints
Efficacy of the trial drug measured by VASI Score.	1-48 days

Secondary Outcome

Outcome	Timepoints
Occurrence of new lesion, anywhere else in the body after intake of trial medicine	3 months

Target Sample Size	**Total Sample Size=**30 **Sample Size from India=**30
Phase of Trial	Phase 2
Date of First Enrollment (India)	20/06/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	Clinical evaluation of PARANGIPATTAI CHOORANAM (Internal) and ANNABEDHI CHENDURAM (External) for VENPULLI (Venpulli) in children.