AN OPEN CLINICAL STUDY ON "NEER KANA MAANTHAM" (ACUTE NASOPHARYNGITIS) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG *MANJANAATHI KUDINEER*

The Dissertation Submitted By

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CERTIFICATE

This is to certify that the dissertation entitled **"AN OPEN CLINICAL STUDY ON NEER KANA MAANTHAM"** is a bonafide work done by **Dr. M.HARIPRIYA**, Government Siddha Medical College, Chennai – 600 106 in partial fulfillment of the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supervision during the academic year 2016 – 2019.

Name & Signature of the Guide

Name & Signature of the Head of Department

Name & Signature of the Dean/ Principal

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CONTENTS

INTRODUCTION

INTRODUCTION

Siddha system of medicine which has been araised from South India is the traditional medicine. Among all the system of medicines in India it has uniqueness in diagnosing the disease and treating it.

Siddha system of medicine not only cures the disease but also plays a major role in increasing the immune system.

The herbal preparation of the Siddha medicine can be given right from birth to prevent the illness.

Thereby its plays a major role in pediatric age group by increasing their immune power. And moreover it is not harmful to their body and has no side effects. It also prevents them from further infections.

Children become ill easier since they aren't built with a proper immune system. And moreover they are prone to several pathogens from the surrounding environment.

Among these they are easily affected by Acute Naso-Pharyngitis (Common cold).

The symptoms of Acute Naso Pharyngitis are cold, running nose, fever, rumbling noise in stomach, diarrhea, fatigue which are compared to the symptoms of ***Neer Kana Maantham*** in the Siddha literature Bala Vagadam.

URIT's are extremely common in children on an average of 6-8 times a year.

Peak prevalence in Children aged between 2-10years.

The frequency of Acute Naso pharyngitis varies due to exposure, such as spending more time in indoors, near an infected person and specifically for children, they acquire at schools.

Acute Naso pharyngitis is the inflammation of nasal passage on the upper part of pharynx.

Cold last for 1week. Mild cold last for 2/3 days. Severe cold may last for upto

2 weeks.

Most common infectious agents include various viruses and bacteria.

Among this Rhino viruses are the most important viruses which cause at least one-half of the cold. They can multiple only inside the living cells.

Children have close contact with their parents and other adults and children. Young children are not able to practice good personal hygiene such as washing the hands properly etc. New born acquire temporary cold from their mother.

Common cold can lead to the development of other diseases like pneumonia, asthma, acute bronchitis. There is currently no cure for the common cold. Treatment involves in relieving the symptoms and to keep the body as healthy as possible.

In modern system of medicine, it is most commonly prescribed by medications such as antibiotics and anti-histamines with cough suppressants.

But, long term use of antibiotics is associated with many side effects like dizziness, headache, vomiting, drowsiness and skin rashes.

Doctors may prescribe a course of board-spectrum antibiotics for 3-5days, which fight a range of bacteria and also cause the loss of good flora of the gut.

In Siddha system of medicine, it is mostly treated by herbs which as no side effects and it prevent the body from getting affected by further infections.

Bala vagadam a literature in Siddha system deals with the children diseases. It is one of the books of Pediatric in Siddha system which describes from birth to late childhood. It also explains about the treatments of each pediatric disease under the herbal formulation which is safe for the child and also helps in increasing their immune power by preventing them from further infections.

Maantham one of the disease affecting the child from the age group of 3months to 12years is explained. It is classified into 21types in the text Bala vagadam.

As per the Siddha literature NEER KANA MAANTHAM is one of the types of Maantham which is caused due to the derangements of the three humours (Vatha, Pitha, and Kapha) in mother which affects the children also.

It affects the upper respiratory tract causing fever, irritation of throat, lack of appetite. It gives more trouble to the children under the age group of 2-12years.

In this condition mostly children are prone to antibiotics which become resistant on continuous consumption and need a higher dosage for recovery which affect the children in future.

So the author tries to evaluate a Siddha herbal formulation *Manjanaathi Kudineer Chooranam* mentioned in "***Bala Vagadam***" for the treatment of "**Neer Kana Maantham"(Acute Naso pharyngitis)**

AIM AND OBJECTIVE

AIM AND OBJECTIVE

AIM :

The aim of the study is the management of NEER KANA MAANTHAM (ACUTE NASOPHARYNGITIS) through the Siddha trial drug MANJANAATHI KUDINEER .

OBJECTIVE :

To review the literature of the disease Neer Kana Maantham in Siddha aspect and Modern aspect.

To compare the etiology, incidence, clinical features, treatment, prognosis and complications of Neer Kana Maantham with Acute Naso Pharyngitis (Common Cold) in Modern science.

To know the predominance of disease age, sex, climate, family history, diet and socio economic status are considered.

To study the Neer Kana Maantham based on Siddha parameters such as dearanged mukkuttram, poripulangal, ezhu udar kattukal and envagai thervugal.

To evaluate the Pharmacological activity- Anti microbial activity for the trial drug Manjanaathi Kudineer .

To evaluate the Bio chemical analysis, Physico chemical analysis, Phyto chemical analysis of the trial drug Manjanaathi Kudineer .

To evaluate the Toxicological analysis – Acute toxicity of the trial drug Manjanaathi Kudineer .

To have the clinical trial of Neer Kana Maantham with trial drug Manjanaathi Kudineer in Govt. Siddha Medical College & Hospital, Chennai-106.

REVIEW OF SIDDHA LITERATURE

SIDDHA ASPECT

SIDDHA LITERATURE REVIEW

மாந்தம்

வேறு பெயர்கள்

மாந்தம், அலசம், அலசகம் என பிள்ளைப் பிணி மருத்துவ நூலில் குறிப்பிடப்பட்டுள்ளது.

இயல்

- மந்த இயல்பு உடையது மாந்தம் எனப்படும்.
- மாந்தம் என்பது உருவ நிலையில் உடல் நிலையில் மந்தம்.
- அருவ நிலையில் அகக்கருவிகளாகிய மனம், புத்தி, சித்தம், அகங்காரம் ஆகிய அனைத்து அந்தக்கரணங் களிலும் மந்தம் என குழந்தை மருத்துவத்தில் கூறப்பட்டுள்ளது.
- உண்ட உணவு செரியாமல் வயிற்றில் புளித்து வயிறு உப்பி இரைந்து மந்தத்தை உண்டாக்கி வாந்தியையும், கழிச்சலையும் உண்டாக்கி துன்பத்தை ஏற்படுத்தும் நோய் என பிள்ளைப்பிணி மருத்துவத்தில் குறிப்பிடப்பட்டுள்ளது.

நோய் வரும் பருவம்:

- ✓ இந்நோய் தாலப்பருவம், சப்பாணிப்பருவம், முத்தப் பருவம், வருகைப்பருவங்களில் உண்டாகக் கூடிய நோய்களாகும்.
- ✓ குழந்தையின் முதலாண்டிலிருந்து மூன்று ஆண்டுகள் வரைத் தொடரும் என குழந்தை மருத்துவம் மற்றும் தன்வந்திரி குழந்தை வாகடத்தில் உள்ளது.
- ✓ இந்நோய் 3 மாதம் முதல் 12 வயது வரை வரக்கூடியது.
- ✓ பால் மட்டும் குடிக்கும் பருவம், பாலும் சோறும் உண்ணும் பருவம், சோறு மட்டும் உண்ணும் பருவம் ஆகிய மூன்று பருவங்களில் மாந்தம் ஏற்படும் என பிள்ளைப்பிணி மருத்துவத்தில் குறிப்பிடப்பட்டு உள்ளது.

நோய் வரும் வழி :

- குழந்தை பிறந்த ஒரு ஆண்டிற்குள் நீர் நிலைகளில் பழுத்து உதிர்ந்த சருகுகள் விழுந்து அழுகியிருக்கும் நீரைக்குடிப்பதாலும்.
- எருமைப்பால், புளித்த எருமை மோர், எருமை நெய், வாழைப்பழம், மாம்பழம், தேங்காய், இளநீர், கடலை, வெல்லம், காட்டுத்துவரை, மொச்சைக்கொட்டை,

புளியங்கொட்டை, பருப்புருண்டை, மாவினாற் செய்யப்பட்ட பொருள்கள், அதிரசம், வாயுப் பொருட்கள், சோறு இவைகளை அதிகமாக உண்பதாலும் மாந்த நோய் உண்டாம் என குழந்தை மருத்துவம் குறிப்பிடுகிறது.

- பாகற்காய்கள், ஊன், பெரிய உளுவைமீன், வாளைமீன், பன்றி, வரால் மீன், கெண்டைமீன் இவைகளை உண்பதாலும் மாந்த நோய் உண்டாகும் என பிள்ளைப்பிணி மருத்துவத்தில் குறிப்பிடுகிறது.
- மோதிபால், நெய், கதலிபழம், இளநீர், தேங்காய், புளித்த மோர், மாமிசம், கனிகள், உளுந்து, மொச்சை, புளியங்கொட்டை, உளுவை, கெண்டை மீன், பாகல், சுரை முதலான வாயுப்பண்டங்களை பால் கொடுக்கும் மாதர்கள் மிகுதியாக உண்டால் நோய் உண்டாகும் என ஆவி அளிக்கும் அமுத முறை சுருக்கத்தில் குறிப்பிடப்பட்டுள்ளது.
- உணவினால் மட்டுமின்றி செயலின் வேறு பாட்டாலும் மாந்த நோய் குழந்தையைத் தாக்கும். வறுமை, பசி, துயரம், மனக்கவலை, பயம், கோபம், இச்சை போன்ற உணர்வுகளால் குழந்தையானது தாக்குறும் போது உணவு செரிக்கும் தன்மையில்

மாறுபாடு நிகழ்ந்து மாந்தம் உண்டாகிறது என பிள்ளைப்பிணி மருத்துவம் நூல் கூறுகிறது.

- மேலும் சோறு மட்டும் உண்ணும் பருவத்தில் குழந்தையின் உணவு குற்றத்தினாலும் உணவின் வேறுபாட்டாலும் மாந்தம் ஏற்படும்.
- குழந்தையின் தூய்மையற்ற தன்மை, சரியான நேரத்தில் சாப்பிடாது நேரந்தவறி சாப்பிடல், சுத்தமற்ற உணவுப் பொருட்களைச் சாப்பிடல், உணவில் போதிய ஊட்டச்சத்து இல்லாத நிலை ஆகிய காரணங்களினாலும் இந்நோய் வரும்.

உணவுப்பழக்கத்தால் மாந்தம் தோன்றுதல் :

வாதம் :

சமானன் – உண்ணும் உணவின் செரிமானத்திற்கு உதவுகிறது.

பித்தம் :

அனற்பித்தம் –உணவுப்பொருள்களின் செரிமானத்திற்கு முதன்மை பங்கு வகிக்கிறது.

கபம் :

கிலேதகம் – உண்ணும் உணவினை மெத்தென செய்யும்.

இக்குற்றங்களின் பாதிப்பால் மாந்தம் ஏற்படுகிறது.

நோய் வகைகள் :

குழந்தை மருத்துவத்தில் மாந்த நோய் 21 வகைகளாகப் பிரிக்கப்பட்டுள்ளது.

1. வளி மாந்தம்
2. அழல் மாந்தம்
3. ஐய மாந்தம்
4. விட மாந்தம்
5. போர் மாந்தம்
6. வாலை மாந்தம்
7. சுர மாந்தம்
8. நீர் மாந்தம்
9. செரியா மாந்தம்
10. கட்டு மாந்தம்
11. பால் மாந்தம்
12. எரி மாந்தம்
13. துலை மாந்தம்
14. தலை மாந்தம்
15. கண மாந்தம்
16. வலிப்பு (இழுப்பு) மாந்தம்
17. சுழி மாந்தம்
18. முக்கு மாந்தம்

19. சந்நி மாந்தம்
20. ஊதல் மாந்தம்
21. வீக்க மாந்தம்

இத்துடன் இன்னும் 10 வகை குறிப்பிடப்பட்டுள்ளது

1. உப்பன் மாந்தம்
2. வாந்தி மாந்தம்
3. வறட்சி மாந்தம்
4. திட்டு மாந்தம்
5. உளை மாந்தம்
6. அக்கர மாந்தம்
7. பேய் மாந்தம்
8. நீர்க்கண மாந்தம்
9. தோட மாந்தம்
10. கருப்ப மாந்தம்

மற்றொரு வகைப்பாட்டின் படி 8 வகைப்படும்.

1. பொது மாந்தம்
2. செரியா மாந்தம்
3. தலை மாந்தம்
4. போர் மாந்தம்
5. கட்டு மாந்தம்

6. விட மாந்தம்
7. நீர் மாந்தம்
8. சுழி மாந்தம்

தன்வந்திரி பாலவாகடத்தில் மாந்த நோய் 21 வகையாக பிரிக்கப்பட்டுள்ளது.

1. அழல் மாந்தம்
2. ஊதல் மாந்தம்
3. எரி மாந்தம்
4. ஐய மாந்தம்
5. கண மாந்தம்
6. சந்நி மாந்தம்
7. சுர மாந்தம்
8. கரி மாந்தம்
9. செரியா மாந்தம்
10. தலை மாந்தம்
11. துலை மாந்தம்
12. நீர் மாந்தம்
13. பால் மாந்தம்
14. போர் மாந்தம்
15. முக்கு மாந்தம்
16. வலிப்பு மாந்தம்

17.வளி மாந்தம்

18.வாலை மாந்தம்

19.விட மாந்தம்

20.வீக்க மாந்தம்

அனுபவ வைத்திய தேவரட்சியத்தில் 8 வகைகள்

1. செரியா மாந்தம்
2. பீர் மாந்தம்
3. சுர மாந்தம்
4. விஷ மாந்தம்
5. சுழி மாந்தம்
6. ஊது மாந்தம்
7. நீர் மாந்தம்
8. தலை மாந்தம்

மதலை நூலில் மாந்தம் 13 வகைகளாகப் பிரிக்கப் பட்டு உள்ளது

(கும்ப முனி பாலவாகடம்)

“தோன்றி வாத பித்தம் சொல்லிய சிலெற்ப மாந்தம்
ஊன்றியதடுக்கு மாந்தம்விச மாந்தம் போர்மாந்தம் தான்
கன்றியபால் மாந்தம் வன்கப மாந்தம் பொது மாந்தம் பின்
வந்திடும் வினையாம் சன்னி வலி சாத்தி பதிமூன்றாதாமே”.

அவை :

1. வாத மாந்தம்
2. பித்தமாந்தம்
3. சிலேற்பன மாந்தம்
4. நடுக்கு மாந்தம்
5. விஷ மாந்தம்
6. போர் மாந்தம்
7. பால் மாந்தம்
8. வங்கப மாந்தம்
9. பொது மாந்தம்
10. வினை மாந்தம்
11. சன்னி மாந்தம்
12. வலி மாந்தம்
13. சாத்தி மாந்தம்

பிள்ளைப்பிணி மருத்துவம் பாகம் 2-ல் மாந்தத்தின் வகைகள் – 53

43 வகை மாந்தங்கள் குறி குண விளக்கங்களுடன் காணப்படுகின்றன.

மீதமுள்ள 10 மாந்தங்கள் பெயரளவில் மட்டும் வகைப்படுத்தப் பட்டுள்ளத்து.

பொது குறிகுணங்கள் :

- குழந்தையின் உடம்பு கனத்தல், நோதல்.
- விடா சுரம்
- மிகுதியான வியர்வை உண்டாதல்
- கண் குழி விழுந்து, விழி சிவந்து காணும்.
- முகம் வெளுத்து ஒரு வகை மங்கிய ஒளி காணும்.
- குரல் தாழ்ந்து காணப்படும்.
- தாயினிடம் பால் உண்ணாது.
- சீதமும் மலமுமாகவும், கெட்டுபோனபால் போலவும், தண்ணீர் போலவும் நிறமாக பேதியாதல்.
- கை கால்கள் சூடு இல்லாமல் குளிர்ந்து காணல்
- குழந்தை கையில் தங்காமல் அழுவதோடு துள்ளும்.
- அடிக்கடி வாந்தி, பசியின்மை ஏற்படும்.
- உடம்பில் ஒருவித வெப்பு நாற்றம் உண்டாகும்.

ஆகிய குறிகுணங்கள் குழந்தை மருத்துவத்தில் குறிப்பிடப் பட்டு உள்ளது.

நீர்க்கண மாந்தம் குறிகுணம்

“இருமு மூக்கில் நீர்வடியும்
இடையில் இடையில் சுரங்காயும்
பொருமி வயிறு இரைச்சலுண்டாம்
போதப் பலவித மாய்க்கழியும்
சொருகுங் கண்ணும் உடம்புமுகம்
சோர்ந்து தலையும் புரட்டலுண்டாம்
மருவி மயக்கம் உண்டாக்கும்
வருகு நீர்க்கண மாந்தமுமே”.

- குழந்தை மருத்துவம் (பாலவாகடம்-பக்கம்-179)

குறிகுணங்கள் :

1. இருமல்
2. மூக்கில் நீர் வடிதல்
3. சுரம்
4. கழிச்சல்
5. உடல், முகம் சோர்வடைதல்
6. வயிறு இரைச்சல்
7. மயக்கம் உண்டாகும்.

ஆத்மரட்சாமிர்தத்தில் :

1. இருமல்
2. மூக்கில் நீர் வடிதல்
3. இடையில் சுரங்காயும்
4. பொருமி வயிறு இறைச்சலுண்டாம்
5. பலவிதமாய்க் கழியும்
6. மயக்கம்
7. கண், முகம், உடம்பு சோர்ந்து போகும்.

சித்த மருத்துவ நோய் கணிப்பு

- பிணியறிமுறைமை
- உயிர் தாதுக்கள் (முக்குற்றம்)
- உடல் தாதுக்கள் (ஏழு உடற்கட்டுகள்)
- பருவ காலங்கள்
- ஐவகை நிலங்கள்
- எண்வகைத் தேர்வு
- நீர்க்குறி
- நெய்க்குறி
- நாடி

மேற்குறிய காரணிகளின் மாறுபாடுகளை ஒன்றுடன் ஒன்று ஒப்பிட்டு நோய் கணிக்கப்படுகிறது.

பிணியறிமுறைமை:

- பொறியால் அறிதல்
- புலனால் அறிதல்
- வினாவுதல்

நீர்க்கண மாந்தத்தில் நோயாளிக்கு காணும் குறிகுணங்கள்:

1. **பொறியால் அறிதல்**

   மூக்கு – மூக்கு நீர் பாய்தல்

   நா – இயல்பு

   கண் – சிலவேளை கண் சிவத்தல்

   காது – இயல்பு

   தோல் – இயல்பு

2. **புலனால் அறிதல்**

   ஊறு – இயல்பு

   ஓசை – இயல்பு

   ஒளி – இயல்பு

   சுவை – இயல்பு

   நாற்றம் – மூக்கில் சளி சவ்வு தடித்தல்

3. வினாவுதல்

மருத்துவர் நோயாளியிடம் வினாவுதல் மூலம் நோயைக் கணிக்க முடியும். நோயாளியால் பேச முடியாத நேரத்தில் அவன் சுற்றத்தாரிடம் வினாவுதல் மூலம் நோயைக் கணிக்க முடியும்.

உயிர் தாதுக்கள் :

“மந்தமலாது வாயுவராது”

- தேரன் சேகரப்பா

இதில் மந்தத்தினால் வாயு உண்டாகும் என அறியலாம்.

மேலும்

“நடுங்கியதோர் பித்தமது கோபங் கொண்டு

நல்லவாயுவை பற்றி யழுத்திக் கொள்ளும்”

- பால வாகடம்

முதலில் பித்ததோடம் பாதிப்படைந்து (தன்னிலை வளர்ச்சி அடைந்து) பின்பு வளிகுற்றத்தின் தொழிலையும் (வேற்றுநிலை வளர்ச்சி அடைந்து) பாதிக்கும்.

I. வாதம்

நீர்க்கண மாந்தத்தில்

1. பிராணன் – இயல்பு
2. அபானன் – பாதிப்பு (சில வேளை கழிச்சல் காணல்)
3. வியானன் – பாதிப்பு (உடல் குன்றுதல்)
4. உதானன் – பாதிப்பு (இருமல் காணுதல்)
5. சமானன் – பாதிப்பு (பசியின்மை காணல்)
6. நாகன் – இயல்பு
7. கூர்மன் – இயல்பு
8. கிருகரன் – பாதிப்பு (இருமல், மூக்கில் நீர் வடிதல்)
9. தேவதத்தன் – இயல்பு
10. தனஞ்செயன்- --

II. பித்தம்

நீர்க்கண மாந்தத்தில்

1. அனற்பித்தம் – பாதிப்பு (பசியின்மை காணல்)
2. இரசக பித்தம் – பாதிப்பு (முகம் வெளுத்து காணல்)
3. சாதக பித்தம் – பாதிப்பு (உடல் சோர்வு காணல்)
4. பிராசகம் – இயல்பு
5. ஆலோசகம் – இயல்பு

III. கபம்

நீர்க்கண மாந்தத்தில்

1. அவலம்பகம் – பாதிப்பு (இருமல் காணல்)
2. கிலேதகம் – பாதிப்பு (செரியாமை)
3. போதகம் – இயல்பு
4. தற்பகம் – பாதிப்பு (சிலவேளை கண் சிவத்தல்)
5. சந்திகம் – இயல்பு

உடற்தாதுக்கள்

உண்ட உணவின் அன்னசாரமானது குடலில் உறிஞ்சப்பட்டு உடற் தாதுக்களான சாரம், செந்நீர், ஊன், கொழுப்பு, என்பு, மூளை, சுக்கிலம் / சுரோனிதம் போன்றவற்றை போடணிக்கிண்றது.

நீர்க்கண மாந்தத்தில் உடற்கட்டுகளின் நிலை

1. சாரம் – பாதிப்பு (உடற்சோர்வு காணல்)
2. செந்நீர் – பாதிப்பு (முகம் வெளுத்துக் காணல்)
3. ஊன் – இயல்பு
4. கொழுப்பு – இயல்பு
5. என்பு – இயல்பு
6. மூளை – இயல்பு
7. சுக்கிலம் / சுரோனிதம் ---

ஐவகை நிலங்கள்

1. குறிஞ்சி
2. முல்லை
3. நெய்தல்
4. மருதம்
5. பாலை

நெய்தல் மற்றும் **குறிஞ்சி** நிலப்பகுதிகளில் நீர்க்கண மாந்த நோய் தாக்கம் அதிகமாக காணப்படுகிறது.

முக்குற்றங்களும், பருவகாலங்களும்

1. கார்க்காலம்
2. கூதிர்க்காலம்
3. முன்பனிக்காலம்
4. பின்பனிக்காலம்
5. இளவேனிற்காலம்
6. முதுவேனிற்காலம்

கார்க்காலம் மற்றும் **கூதிர்க்காலம்**- நீர்க்கண மாந்த நோய் தாக்கம் அதிகமாக காணப்படுகிறது.

கபக்குற்றம் அதிகரித்து தனக்கு துணையாக வாத, பித்தக் குற்றத்தை அதிகரித்து இந்நோய் உண்டாகிறது.

எண்வகை தேர்வு

“நாடி பரிசம் நாநிறம் மொழிவிழி

மலம் மூத்திரமிவை மருத்துவராயுதம்”.

- நோய் நாடல் முதல் பாகம்.

நீர்க்கண மாந்தத்தில்

1. நா- இயல்பு
2. நிறம் – முகம் வெளுத்துக்காணல்
3. மொழி –குரல் ஒலி தாழ்தல்
4. விழி – சிலவேளை கண் சிவத்தல்
5. மலம் – சிலவேளை கழிச்சல் காணல்
6. மூத்திரம் – இயல்பு
7. பரிசம் – மித வெப்பம்
8. நாடி – வாதபித்தம், வாதகபம், பித்தகபம்

நீர்க்குறி

“அருந்துமாறி ரதமும் அவிரோதமாய்

அ஼஼கல் அலர்தல் அகாலவூன் தவிர்த்தழற்

குற்றளவருந்தி உறங்கி வைகறை

ஆடிக் கலசத் தாவியே காதுபெய்

தொரு முகூர்த்தக் கலைக்குட்படு நீரின்

நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே”.

-நோய் நாடல் நோய் முதல்நாடல் பகுதி - 1

விளக்கம்

நீர்க்குறி பார்க்கும் முதல் நாள் இரவு நன்கு உணவு உண்டு உறங்க வேண்டும். பின் விடியற்காலை படிக பாத்திரத்தில் நீரினைப் பிடித்து அதன் நீர்க்குறி மற்றும் நிறக்குறியினை கண்டறிதல் வேண்டும்.

"வந்த நீர் கரியெடை மணம் நுரை எஞ்சலென்

றைந்தியலுளவை யறைகுது முறையே."

- நோய் நாடல் முதல் பாகம்.

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

நெய்க்குறி

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

"நிறக்குறிக் குரைத்த நிருமாண நீரிற்
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடுவிடுத்
தென்றுறத் திறந்தொலி யோகா தமைந்ததி
னின்ற திவலை போம் நெறிவிழியறியும்
சிறுநீரில் நல்லெண்ணெய் விட்டு பார்ப்பது."

-நோய் நாடல் நோய் முதல்நாடல் பகுதி - 1

நோயாளியின் சிறுநீரை சோதனை வட்டில் ஊற்றி சூரிய ஒளி மிகுந்த இடத்தில் நீரின் அலையில்லாத போது நல்லெண்ணெய்த் துளி விட்டு பார்ப்பது.

“அரவென நீண்டினஃதே வாதம்

ஆழி போற் பரவின் பித்தம்

முத்தொத்து நிற்கின் கபம்”.

விளக்கம் :

வாத நீர் – பாம்பு போல் பரவும்

பித்த நீர் - மோதிரம் போல் பரவும்

கப நீர் – முத்து போல் பரவும்

நாடி நடை

நீர்க்கண மாந்தத்தில்

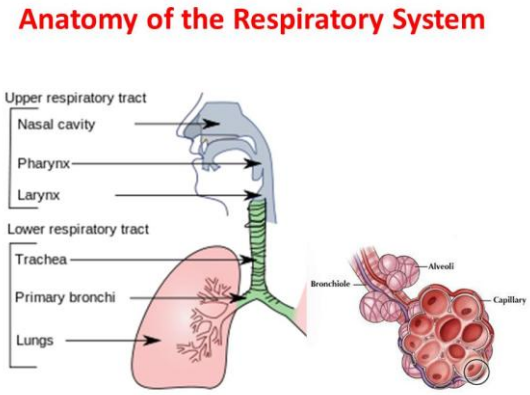
- வாதபித்தம்
- வாதகபம்
- பித்தகபம்

MODERN ASPECT

MODERN ASPECT

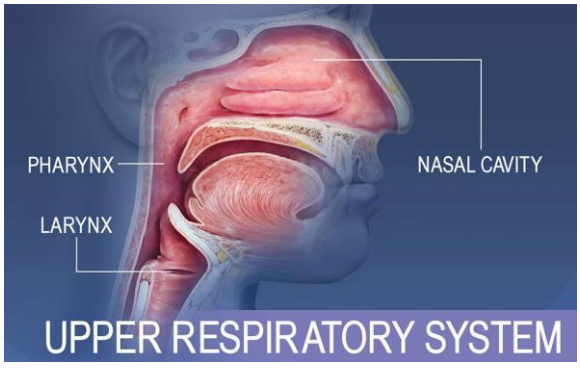
RESPIRATORY SYSTEM

Respiratory system is one of the important system in our body, which plays major role in respiration. It is divided into upper and lower airways. The upper respiratory tract includes nose, para nasal sinus, pharynx, larynx. Lower respiratory tract includes trachea, bronchi, bronchioles and alveoli.



UPPER RESPIRATORY TRACT

Upper Respiratory Tract refers to the parts of respiratory system lying above the sternal angle, above the glottis. It includes the nose, nasopharynx and oropharynx. It plays main role in fighting with the infection which affects the human being through oral and mucosal route.



ANATOMY AND PHYSIOLOGY OF UPPER RESPIRATORY TRACT

NOSE

The nose is the visible part of the respiratory system.

Protruding prominently from the face, the nose serves as a vent for air exchange and also as the organ of smell.

The structures of the nose are divided into two main parts,

External nose and

Internal nasal cavity

External nose has a skeletal frame work that is

- Partly bone
- Partly cartilaginous

The bones are the nasal bones which form the bridge of the nose and the frontal process of the maxillae.

The cartilages are the superior and inferior nasal cartilages, the septal cartilages and some small cartilages.

The nasal cavity extends from the external nares to the posterior nasal apertures. It is sub divided into right and left halves by a midline nasal septum.

Each half has a :

Floor – separates it from oral cavity, formed by the hard palate

Roof - narrow and formed by the

Body of sphenoid

Cribriform plate of ethmoid bone

Frontal bone

Nasal bone and cartilage

Lateral wall – shows three horizontal bony projections, covered by mucous membrane, the superior, middle and inferior conchae.

Medial wall (septum)- Osteocartilagenous partition, covered by the mucoperiosteum.

Formed by Superiorly – the vertical plate of ethmoid bone

Posteriorly – the vomer bone

Anteriorly – the septal cartilage

ARTERIAL SUPPLY

Anterior ethmoidal artery

Posterior ethmoidal artery

Sphenopalatine artery

Greater palatine artery

Superior labial artery

VENOUS SUPPLY

Lateral Nasal veins from alae

NERVE SUPPLY

Trigeminal nerve

Anterior superior ophthalmic nerve

Anterior inferior maxillary nerve

Post superior maxillary nerve.

PHARYNX

The pharynx is a wide muscular tube, situated behind the nose, the mouth and the larynx.

Length : About 12cm

Width : Upper part is widest and collapsible (3.5cm)

Middle part is narrow

Lower end is the narrowest of the gastro intestinal tract

Clinically it is a part of the upper respiratory tract where the infections are common.

It is divided into 3 parts

Nasopharynx

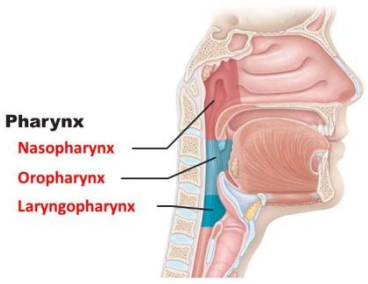
It is the upper part which is situated behind the nose and above the lower border of soft palate and it transmits only air.

Oropharynx

It is the middle part of the pharynx situated behind the oral cavity and it transmits both air and food.

Laryngopharynx

It is the lower part which extends from the upper border of epiglottis to the lower border of cricoid cartilage and it transmit only food.



BOUNDARIES

Superiorly – Base of the skull

Posterior part of the body of sphenoid

Basilar part of the occipital bone

In front of the pharyngeal tubercle

Inferiorly – Continuous with oesophagus

Lower border of cricoid cartilage

Posteriorly – Prevertebral fossa

Anteriorly – It communicates with the nasal cavity, oral cavity and larynx. The anterior wall of pharynx is incomplete.

Laterally – It communicates with Middle ear cavity

- Mandible
- Tongue
- Pterigoid plate
- Hyoid bone
- Thyroid

MUSCLES

The muscular basis of the wall of the pharynx is formed by 3 pairs of constrictors namely,

Superior constrictor

Middle constrictor

Inferior constrictor

NERVE SUPPLY

Pharyngeal branch of the vagus

Pharyngeal branch of the glosso pharyngeal nerve'

Pharyngeal branch of the superior cervical sympathetic ganglion

Cranial accessory nerve

Maxillary nerve

ARTERIAL SUPPLY

Ascending pharyngeal branch of the external carotid artery.

Ascending palatine and tonsilar branches of the facial artery.

Dorsal lingual branches of the lingual artery.

The greater palatine pharyngeal and pterigoid branches of maxillary artery.

VENOUS SUPPLY

Internal jugular vein

Facial vein

LYMPHATICS

Retropharyngeal , deep cervical lymph nodes.

PHYSIOLOGY :

The functions of nose are

Provides an airway for respiration

Moistens and warms entering air

Filters inspired air and cleanses it of foreign matter

Serves as a resonating chamber for speech

Houses the olfactory (smell) receptors

The functions of pharynx are

Respiration

Swallowing

Language formation

Protective function

ACUTE NASOPHARYNGITIS

(COMMON COLD)

Acute naso pharyngitis is commonly known as cold. It is an inflammation of the mucous membranes of the upper pharynx, the naso pharynx or the naso pharyngeal duct which extends between the oral and nasal palate. It is also referred as upper respiratory infection or rhinitis. It is very common pathology among children and adolescent.

ETIOLOGY :

It may be due to infective and non-infective cause. Non infective cause like allergic to food, low socio economic status, dust allergy, environmental changes like pollution, climate change and family history can cause naso pharyngitis. A virus or bacteria causes infective naso pharyngitis. Although viruses causes most acute nasopharyngitis episodes, group A streptococcus causes 37% of infection in children older than 5years, other bacterial cause of infection are group C streptococcus (5%), anaerobic species (1%). Between viruses Rhino virus, Corona virus and Adeno virus account for the 30% of total case. It can spread through tiny air droplets that are expelled when a person infected with sneezes.

EPIDEMOLOGY :

Common cold(Acute Naso pharyngitis) which comes under Acute Respiratory Tract Infections is very common and constitutes major cause of childhood morbidity.

Colds are frequent and recurring problem. Children in preschool and elementary school can have 6-12 colds per year. The common cold occurs most frequently during the rain fall, winter and spring season.

On an average, a child in urban area during first five years of life may suffer from 5-8episodes of ARI per year. In rural areas the reported incidence per child is lower (1episodes per year).

The infection is transmitted either by direct contact with infected secretions or by inhaling the airborne virus after individuals sneeze or cough.

The incubation period of the organism is 2-5days.

Among this RVs are the most common occurring in 25-80%of cases and Coronavirus 10-20%, Influenza virus 10-15% of cases, 5%of cases occur by adenovirus.

PATHOLOGY :

The symptoms of common cold are believed to be primarily related to the immune response to the virus. The mechanism of this immune response is virus specific. For example, the rhinovirus is typically acquired by direct contact; it binds to human ICAM-I receptors through unknown mechanism to trigger the release of inflammatory mediators. These inflammatory mediators then produce the symptoms. It does not generally cause damage to the nasal epithelium. The respiratory syncytial virus (RSV) on the other hand, is contracted by direct contact and airborne droplets. It then replicates in the nose and throat before frequently spreading to the lower respiratory tract. Respiratory syncytial virus cause epithelium damage. Human Para influenza virus typically results in inflammation of the nose, throat and bronchi. In young children when it affects the trachea it may produce the symptoms of croup due to the small size of their airways.

CLINICAL MANIFESTATION:

IN YOUNG CHILDREN:

In general children 3months-3years have fevers in the early course of infection.

Few hours before onset of fever, sneezing, irritability and restlessness present.

Nasal discharge begins within few hours quickly leading to nasal obstruction.

A few infant may vomit and some have diarrhea.

IN OLDER CHILDREN:

The initial symptoms are dryness and irritation in the nose, these symptoms follow with in few hours.

Watery nasal discharge.

Sneezing

Coughing

Muscular aches

Head aches

Malaise

Anorexia

Low grade fever may be present.

COMPLICATIONS:

Sinus infection (acute sinusitis). It is characterized by inflammation and swelling of the mucous membranes that line sinus cavities

Asthma

Acute bronchitis (Chest cold)

Sore throat and tonsillitis

Acute suppurative otitis media

Pneumonia

TRIAL DRUG

TRAIL DRUG – MANJANAATHI KUDINEER

TRIAL DRUG - INGREDIENTS

Thippili (*Piper Longum)*

Milagu (*Piper Nigrum)*

Chukku (*Zingiber Officinale)*

Notchi ilia (*Vitex Negundo)*

Vasambu (*Acorus Calamus)*

Nuna ilai *(Morinda Tinctoria)*

Poduthalai kai (*Phyla Nodiflora)*

Omam (*Carum Copticum)*

Uthamani ilia (*Pergularia Daemia)*

Kalarchi ilai (*Caesalpinia Bonduc)*

நுணா

Botanical Name - *Morinda Tinctoria*

English Name – Indian Mulberry

Family – Rubiaceae

Used part - Leaves

சுவை – கார்ப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

"பட்டை காப்பனொடு பாரச்சி லேஷ்மசுரம்

ஒட்டிநின்ற புண்கிரந்தி ஒட்டுங்காண் – மட்டலரை

ஏந்து **நுணாவின் இலைமந்தம் தீர்த்து** நல்ல

காந்திதரு மேகமடுங் காண்".

CHEMICAL CONSTITUTENTS : morindin, morindone

ACTIONS : Tonic, Febrifuge, Emmenagogue

PHARMACOLOGICAL ACTIVITES : Anti microbial, Anti inflammatory, Anti oxidant

நொச்சி

Botanical Name - *Vitex Negundo*

English Name – Five leaved chaste tree

Family – Laminaceae

Used part - Leaves

சுவை – கைப்பு, துவர்ப்பு, கார்ப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

"நோயா கலியை நொடிக்கு ளருந்த வெல்லம்

யோயா மணாளு முயர்த்துதலுக் – காய

வந்தமுதல் நண்பாகி வாதத்தை யேயுறவாற்

சிந்துவா ரங்கனலுந் தீ".

CHEMICAL CONSTITUTENTS : Viridiflorol, p-caryophylene, 4-terpineol

ACTIONS : Expectorant, Aletrnative, Vermifuge

PHARMACOLOGICAL ACTIVITES : Anti microbial, Anti inflammatory

உத்தாமணி

Botanical Name - *Pergularia Daemia*

English Name – Dog's bane whitelow plant

Family – Asclepiadaceae

Used part - Leaves

சுவை – கைப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

"ஆலித் தெழுந்தநோய் அத்தனை யுந்தீருமே
வேலிப் பருத்தியதின் மெல்இலையால் – வேலொத்துக்
கண்டிக்கும் வாதங் கடுஞ்சன்னி தோடமும்போம்
உண்டிக்கும் வாசனையாம் ஓது.
உத்தா மணியிலையால் உள்வயிற்றுக் குன்மமொடு
குத்தாம் வலியுங் குளிரும்போம் – பற்றி
இசிக்கும் வலியிரைப்பும் எத்தடிப்பும் ஏகும்
பசிக்குமதி மாந்தமும்போம் பார்".

CHEMICAL CONSTITUTENTS : pergularin

ACTIONS : Expectorant, Anthelmintic, Emetic

PHARMACOLOGICAL ACTIVITES : Anti inflammatory, Antipyretic, Analgesic

கழற்சி

Botanical Name - *Caesalpinia Bonduc*

English Name – Bonduc Nut, Moloucca Bean, Physic Nut

Family – Fabaceae

Used part - Leaves

சுவை – கைப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

“விரைவாதஞ் சூலையறும் வெட்டையன லேகும்

நிரைசேர்ந்த குன்மம் நிலையா – துரைசேர்

அழற்சிவிலகும் அருந்திற் கசப்பாங்

கழற்சியிலை யென்றுரைக்குங் கால்.

CHEMICAL CONSTITUTENTS: caesalpinianone,triterpenoids(1-4)alphaamyrin(1)

ACTIONS : Antiperiodic, Tonic, Anthelmintic

PHARMACOLOGICAL ACTIVITES : Anti inflammatory, Anti microbial

ஓமம்

Botanical Name - *Carum Copticum*

English Name – The Bishops weed

Family –Apiaceae

Used part - Seed

சுவை – கார்ப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

“சீதசுரங் காசஞ் செரியாமந் தம்பொருமல்

பேதியிரைச் சல்கடுப்பு பேராமம் – ஓதிருமல்

பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ?

சொல்சொடுபோம் ஓம்மெனச் சொல்”.

CHEMICAL CONSTITUTENTS : Thymol, gamma-terpinene, p-cymenea

ACTIONS : Tonic, Carminative, Stomachic

PHARMACOLOGICAL ACTIVITES : Antiseptic, Carminative, Tonic

வசம்பு

Botanical Name - *Acorus Calamus*

English Name – Sweet-flag

Family – Acoraceae

Used part - Rhizome

சுவை – கார்ப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

"பாம்பாதி நஞ்சற் புதப்புண் வலிவிடபாகங் குன்மம்

சூம்பா ரிரத்தபித் தம்முக நாற்றம்வன் சூலைசன்னி

வீம்பாம்பை காசம் பிலீகஞ் சிலிபதம் வீறிருமல்

தாம்பால் கிருமி யிவையேகு மாசிவ சம்பினையே".

CHEMICAL CONSTITUTENTS : alpha-asarone, beta-asarone, methylisoeugenol

ACTIONS : Tonic, Antiperiodic, Disinfectant, Germicide

PHARMACOLOGICAL ACTIVITES : Anti microbial, Anti oxidant, Insecticide.

சுக்கு

Botanical Name - *Zingiber Officinale*

English Name – Dried Ginger

Family – Zingiberaceae

Used part - Rhizome

சுவை – கைப்பு, துவர்ப்பு, கார்ப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

"சூலைமந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை

மூலம் இரைப்பிருமல் மூக்குநீர் – வாலகப

தோடமதி சாரந் தொடர்வாத குன்மநீர்த்

தோடம்ஆ மம்போக்குஞ் சுக்கு".

CHEMICAL CONSTITUTENTS : zingiberene

ACTIONS : stimulant, stomachic, carminative

PHARMACOLOGICAL ACTIVITES: Anti inflammatory, Anti microbial

மிளகு

Botanical Name - *Piper Nigrum*

English Name – Black pepper

Family – Piperacea

Used part - Fruit

சுவை – கைப்பு, கார்ப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

“தீயாகி யெங்கும் திரியுமதை யாவத்து

மோயாம லெப்படியு முண்டாக்காற் – பாயாது

போந்திமிர்வா தங்கிரந்தி புண்ணீரும் மண்ணவக்கும்

காந்திமெய்வா தச்சலுப்பைக் காய்”.

CHEMICAL CONSTITUTENTS : Piperine, Piperidine, Chavicine

ACTIONS : Anti periodic, Antidote, Carminative, Stimulant

PHARMACOLOGICAL ACTIVITES: Anti bacterial, Anti inflfammatory

திப்பிலி

Botanical Name - *Piper Longum*

English Name – Long Pepper

Family – Pipeacea

Used part - Fruit

சுவை – கைப்பு, துவர்ப்பு, கார்ப்பு

தன்மை – வெப்பம்

பிரிவு – இனிப்பு

"ஈளை யிருமல் லிரைப்பு பசப்பிணிகள்

மாள வொழியாமல் வாட்டும் – யாளுமுறை

பாங்கா யறிந்து செய்வீர் பண்டிதத்தப் பண்டிதரே

வேங்கைவாய் பான்கனை மெய்".

CHEMICAL CONSTITUTENTS : Piperine, Piperlongumine

ACTIONS : Carminative, stimulant

PHARMACOLOGICAL ACTIVITES : Anti bacterial

பொடுதலைக் காய்

Botanical Name - *Phyla Nodiflora*

English Name – Purple lippie

Family – Verbenaceae

Used part - Fruit

சுவை – கைப்பு, துவர்ப்பு

தன்மை – வெப்பம்

பிரிவு – கார்ப்பு

"பொடுதலையின் பேருரைத்தால் போராமப் போக்கும்

அடுதலைசெய் காசம் அடங்கும் – கடுகிவரு

பேதியொடு சூலைநோய் பேசரிய வெண்மேகம்

வாதமும்போ மெய்யுரக்கும் வாழ்த்து".

CHEMICAL CONSTITUTENTS : Eupafolin, Tyrosinase

ACTIONS : Tonic, Expectorant, Astrigent

PHARMACOLOGICAL ACTIVITES : Anti inflammatory, Antimicrobial.

PREPARATION OF TRIAL DRUG

MANJANAATHI KUDINEER

Ref : Bala vagadam, Page No : 179

INGREDIENTS :

Nuna ilai	– 1 pidi (70gram)
Notchi thulir	– 1 pidi (70gram)
Uthamani ilai	– 1 pidi (70gram)
Kazharchi ilai	– 1 pidi (70gram)
Omam	– 1 varagan (4gram)
Vasambu	– 1 varagan (4gram)
Chukku	– 1 varagan (4gram)
Milagu	– 1 varagan (4gram)
Poduthalai kaai	– 1 varagan (4gram)
Thippili	– 1 varagan (4gram)

METHOD OF PREPARATION :

The drugs are taken in the ratio mentioned above and are purified. Then they are grinded to the powder form and mixed with pure water and this mixture is boiled until the concentrated decotation of the ingredient is obtained.

DOSE :

1 Sangalavu (8gram)- Twice a day daily

(Preparation of kudineer : Add 8gram of chooranam to 60ml of water. Then boil the water till reaches to 8ml of kudineer).

DURATION :

- 7 days

BIO- CHEMICAL ANALYSIS

BIOCHEMICAL ANALYSIS OF MANJANAATHI KUDINEER

PREPARATION OF EXTRACT

2gm of Manjanaathi kudineer sample is taken in 100ml beaker and 20ml of distilled water is added. The solution is boiled for 10minutes, cooled and then filtered. The filtrate is called extract.

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
1	TEST FOR ACID RADICALS		
A	**Test for chloride :** 2ml of extract is added with dilute Nitric acid till the effervescence ceases. Then 2ml of silver nitrate solution is added	Presence of white precipitate	Present
B	**Test for phosphate :** 2ml of extract is treated with 2ml of Ammonium molybdate solution and 2ml of concentrated nitric acide.	Absence of Yellow precipitate	Absent
C	**Test for carbonate :** 2ml of extract is treated with 2ml of Magnesium sulphate solution	Absence of white precipitate	Absent
D	**Test for sulphide :** 1gm of the substance is treated with 2ml of concentrated Hydrochloric acid	Absence of Rotten egg smelling	Absent

E	**Test for sulphate :** 2ml of the above prepared extracts is taken in a test tube. To this add 2ml of 4% Ammonium oxalate solution.	Absence of white precipitate	Absent
2	TEST FOR BASIC RADICALS		
A	**Test for copper :** One pinch of substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the non-luminous part of the flame.	Absence of Bluish green coloured flame	Absence
B	**Test for iron :** To the 2ml extract 2ml of Ammonium thiocyanate solution and 2ml of concentrated Nitric acid is added.	Presence of blood red colour	Present
C	**Test for Zinc :** To the 2ml of extract Sodium hydroxide solution is added in drops in excess.	White precipitate is obtained	Present
D	**Test for calcium :** To the 2ml of extract Ammonium oxalate solution is added.	Absence of white precipitate	Absent
E	**Test for magnesium :** To the 2ml of extract Sodium hydroxide solution is added	Absence of white precipitate	Absent

	in drops in excess.		
F	**Test for starch :** 2ml of extracts treated with weak iodine solution	Absence of blue colour	Absent
G	**Test for reducing sugar:** 5ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2minutes and added 10drops of the extract and again boiled for 2minutes. The colour changes are noted.	Absence of green colour	Absent
H	**Test for alkaloids :** 2ml of the extract is treated with 2ml of Potassium iodide solution.	Presence of red colour	Present
I	**Test for ammonium :** To the 2ml of extract few ml of Nessler's reagent and excess of Sodium hydroxide solution are added.	Absence of white precipitate	Absent

Inference :

The given sample Manjanaathi Kudineer contains

Acid Radical – Chloride

Basic Radical – Iron, Copper

TOXICITY STUDY

ACUTE ORAL TOXICITY STUDY OF *MANJANAATHI KUDINEER*

(OECD GUIDELINE – 423)

Introduction:

- The acute toxic class method is a stepwise procedure with the use of 3 animals of a single sex per step.
- Depending on the mortality and/or the moribund status of the animals, on average 2-4 steps may be necessary to allow judgement on the acute toxicity of the test substance.
- This procedure is reproducible, uses very few animals and is able to rank substances in a similar manner to the other acute toxicity testing methods.
- The acute toxic class method is based on biometric evaluations with fixed doses, adequately separated to enable a substance to be ranked for classification purposes and hazard assessment.
- In principle, the method is not intended to allow the calculation of a precise LD50, but does allow for the determination of defined exposure ranges where lethality is expected since death of a proportion of the animals is still the major endpoint of this test.
- The method allows for the determination of an LD50 value only when at least two doses result in mortality higher than 0% and lower than 100%.
- The use of a selection of pre-defined doses, regardless of test substance, with classification explicitly tied to number of animals observed in different states improves the opportunity for laboratory to laboratory reporting consistency and repeatability.

Principle of the Test:

It is the principle of the test that based on a stepwise procedure with the use of a minimum number of animals per step, sufficient information is obtained on the acute toxicity of the test substance to enable its classification. The substance is administered orally to a group of experimental animals at one of the defined doses. The substance is tested using a stepwise procedure, each step using three animals of a single sex. Absence

or presence of compound-related mortality of the animals dosed at one step will determine the next step, i.e.

− no further testing is needed

− dosing of three additional animals, with the same dose

− dosing of three additional animals at the next higher or the next lower dose level. The method will enable a judgment with respect to classifying the test substance to one of a series of toxicity classes.

Methodology:

Selection of Animal Species

The preferred rodent species is the wistar albino rat, although other rodent species may be used. Healthy young adult animals are commonly used laboratory strains should be employed. Females should be nulliparous and non-pregnant. Each animal, at the commencement of its dosing, should be between 6 to 8 weeks old and the weight (150-200gm) should fall in an interval within±20 % of the mean weight of any previously dosed animals.

Housing and Feeding Conditions

The temperature in the experimental animal room should be 22ºC + 3ºC. Although the relative humidity should be at least 30% and preferably not exceed 70% other than during room cleaning the aim should be 50-60%. Lighting should be artificial, the sequence being 12 hours light, 12 hours dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. Animals may be group-caged by dose, but the number of animals per cage must not interfere with clear observations of each animal.

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Test Animals and Test Conditions:

Sexually mature Female Wistar albino rats (150-200gm) were obtained from TANUVAS, Madhavaram, Chennai. All the animals were kept under standard environmental condition (22±3°C). The animals had free access to water and standard pellet diet (Sai meera foods, Bangalore).

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Preparation for Acute Toxicity Studies

Rats were deprived of food overnight (but not water 16-18 h) prior to administration of the, ***MANJANAATHI KUDINEER***.

The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of the animals and the study design

IAEC approved Number: 1248/AC/09/CPCSEA-9/DEC-2013/12

Test Substance	: **MANJANAATHI KUDINEER**
Animal Source	: TANUVAS,Madhavaram, Chennai.
Animals	: Wister Albino Rats (Female-3+3)
Age	**:** 6-8 weeks
Body Weight on Day 0	**:** 150-200gm.
Acclimatization	**:** Seven days prior to dosing.
Veterinary examination	**:** Prior and at the end of the acclimatization period.
Identification of animals	**:** By cage number, animal number and individual marking by using Picric acid.
Number of animals	: 3 Female/group,
Route of administration	: Oral

Diet	**:** Pellet feed supplied by Sai meera foods Pvt Ltd, Bangalore
Water	**:** Aqua guard portable water in polypropylene bottles.
Housing & Environment	**:** The animals were housed in Polypropylene cages provided with bedding of husk.
Housing temperature	**:** between 22ºC ± 3ºC.
Relative humidity	**:** between 30% and 70%,
Air changes	**:** 10 to 15 per hour and
Dark and light cycle	**:** 12**:**12 hours.
Duration of the study	**:** 14 Days

Administration of Doses:

MANJANAATHI KUDINEER was suspended in coconut water and administered to the groups of wistar albino rats in a single oral dose by gavage using a feeding needle. The control group received an equal volume of the vehicle. Animals were fasted 12 hours prior to dosing. Following the period of fasting, the animals were weighed and then the test substance was administered. Three Female animals are used for each group. The dose level of 5, 50, 300 and 2000 mg/kg body weight was administered stepwise. After the substance has been administered, food was withheld for a further 3-4 hours. The principle of laboratory animal care was followed. Observations were made and recorded systematically and continuously as per the guideline after substance administration. The visual observations included skin changes, mobility, aggressively, sensitivity to sound and pain, as well as respiratory movements. Finally, the number of survivors was noted after 24 hrs and these animals were then monitered for a further 14 days and observations made daily. The toxicological effect was assessed on the basis of mortality.

Observations:

Animals are observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours, and daily thereafter, for a total of 14 days, except where they need to be removed

from the study and humanely killed for animal welfare reasons or are found dead. It should be determined by the toxic reactions, time of onset and length of recovery period, and may thus be extended when considered necessary. The times at which signs of toxicity appear and disappear are important, especially if there is a tendency for toxic signs to be delayed. All observations are systematically recorded with individual records being maintained for each animal.

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor activity and behavior pattern. Attention was directed to observations of tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. The principles and criteria summarized in the Humane Endpoints Guidance Document taken into consideration. Animals found in a moribund condition and animals showing severe pain or enduring signs of severe distress was humanly killed. When animals are killed for human reasons or found dead, the time of death was recorded.

Acute oral toxicity study of MANJANAATHI KUDINEER

Table 1: Dose finding experiment and its behavioral Signs of acute oral Toxicity

Observation done:

SL	Group CONTROL	Observation	SL	Group TEST GROUP	Observation
1	Body weight	Normal	1	Body weight	Normally increased
2	Assessments of posture	Normal	2	Assessments of posture	Normal
3	Signs of Convulsion Limb paralysis	Normal	3	Signs of Convulsion Limb paralysis	Absence of sign (-)
4	Body tone	Normal	4	Body tone	Normal
5	Lacrimation	Normal	5	Lacrimation	Absence
6	Salivation	Normal	6	Salivation	Absence
7	Change in skin color	No significant color change	7	Change in skin color	No significant color change
8	Piloerection	Normal	8	Piloerection	Normal
9	Defecation	Normal	9	Defecation	Normal
10	Sensitivity response	Normal	10	Sensitivity response	Normal
11	Locomotion	Normal	11	Locomotion	Normal
12	Muscle gripness	Normal	12	Muscle gripness	Normal
13	Rearing	Mild	13	Rearing	Mild
14	Urination	Normal	14	Urination	Normal

Behaviour:

The animals will be observed closely for behaviour in the first four hours which includes abnormal gait, aggressiveness, exophthalmos, ptosis, akinesia, catalepsy, convolusion, excitation, head twitches, lacrimation, loss of corneal reflex, loss of traction, piloerection reactivity of touch, salivation, scratching, sedation, chewing, head movements, sniffing, straub, tremor and writhes, diarrhea, leathery, sleep and coma.

Body Weight:

Individual weight of animals was determined before the test substance was administered and weights will be recorded at day 1, 7, and 14 of the study. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and humanly killed.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Mortality:

Animals were observed for mortality throughout the entire period.

Results:

All data were summarized in tabular form, (Table-1-4) showing for each test group the number of animals used, the number of animals displaying signs of toxicity, the number of animals found dead during the test, description of toxic symptoms, weight changes, food and water intake

No of animals in each group:3

Table 2 (Observational study Results)

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

1..Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhea 18. Writhing 19. Respiration 20. Mortality. (+ Present, - Absent)

Table 3 (Body weight Observation)

DOSE	DAYS		
	1	7	14
CONTROL	200.1±65.70	201.3 ± 41.11	201.6 ±02.12
HIGH DOSE	202.3± 6.64	202.7 ±7.42	203.2 ± 2.70
P value (p)*	NS	NS	NS

Table 3 (Water intake (ml/day) of Wistar albino rats group exposed to *MANJANAATHI KUDINEER):*

DOSE	DAYS		
	1	6	14
CONTROL	64 ± 3.20	64±6.10	58.3±5.44
HIGH DOSE	63.2±1.30	65.8±6.70	66.2±5.64
P value (p)*	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One-way ANOVA followed by Dunnett's test)

Table 4: Food intake (gm/day) of Wistar albino rats group exposed to *MANJANAATHI KUDINEER*

DOSE	DAYS		
	1	7	14
CONTROL	86.03±2.42	87.2±2.46	89.7±8.16
High DOSE	96.6±1.44	98.4±4.20	99.8±2.27

PHARMACOLOGICAL STUDY

ANTIMICROBIAL ACTIVITY:

The antimicrobial activity for test sample was done by Paper Disc Diffusion method. The sterilized (autoclaved at 120 ^{o} C for 30 min) medium (40-50 ^{o} C) was inoculated (1 ml / 100 ml of medium) with the suspension (10 ^{5} cfu mL $^{-1}$) of the microorganism (matched to Mc Farland barium sulphate standard) and poured in to a petridish to give depth of 3-4 mm. The paper impregnated with the test compound MANJANAATHI KUDINEER (25, 50, and 100 µg mL^{-1}in dimethyl farmamide) was placed on the solidified medium (Ashok Rathan, 2000). The plates were pre incubated for 1 hat room temperature and incubated at 37 degree Celsius for 24 and 48 h for anti bacterial activities respectively. Ciprofloxin was used as standard for anti bacterial respectively at the concentration of 50 mcg / disc. In-vitro antimicrobial activity of MANJANAATHI KUDINEER was screened against bacteria strains such as Streptococcus mutans, Staphylococcus aureus, Escherchia.coli, Klebsiella pneumoniae and Pseudomonas.aeruginosa. The test Sample concentration taken as 4ml – 400 ml of solvent in 10µl, 25 µl, 50 µl / disc.

Antimicrobial activity:

Table: 15. Antimicrobial activity of MANJANAATHI KUDINEER(MKR)

Organism	Standard drug Ciprofloxacin 50 mcg/disc	Test drug (µl/disc)		
		Zone of inhibition in mm		
		10□ l	25□ l	50□ l
Strep. mutans	32	24	36	38
Staph. aureus	31	25	27	29
E.coli	31	36	40	43
K.pneumoniae	31	24	28	34
P.aeruginosa	29	18	26	30

14 mm – Low sensitive, 15 mm – Moderate, above 16 mm – Highly sensitive

Inference:

1. Streptococcus mutans _ Highly sensitive in 10µl / disc
2. Staphylococcus aureus _ Highly sensitive in 10µl / disc
3. Escherchia.coli – Highly sensitive in 10µl / disc
4. Klebsiella pneumoniae – Highly sensitive in 10µl / disc
5. Pseudomonas aeruginosa _ Highly sensitive in

10µl / disc **Discussion:**

The anti microbial activity of **MKR** was compared with Standard drug Ciprofloxacin 50 mcg/disc for the following pathogens, they are Streptococcus mutans , Staphylococcus aureus , Escherchia.coli, Klebsiella pneumoniae and Pseudomonas aeruginosa. The results represents **MKR** potentially inhibit the growth of all above organism in 10µl, 25µl and 50µl / disc. The test drug results build known supports to achieve its antimicrobial activity

PHYTOCHEMICAL ANALYSIS

Project Report

Project ID	**NRS/AS/0342/02/2019**
Name and Address of the Researcher	**Dr.M.Hari Priya** **Government Siddha Medical College, Chennai** **Tamil Nadu, India**
Sample –ID	**Manjanaathi Kudineer Chooranam - MKC**

PHYTOCHEMICAL ANALYSIS

Test for alkaloids:

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

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 color.

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 tannins:

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

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 choloroform is added and shaken, choloroform layer is separated and 10% ammomia 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

A. Aanthocyanin:

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

Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

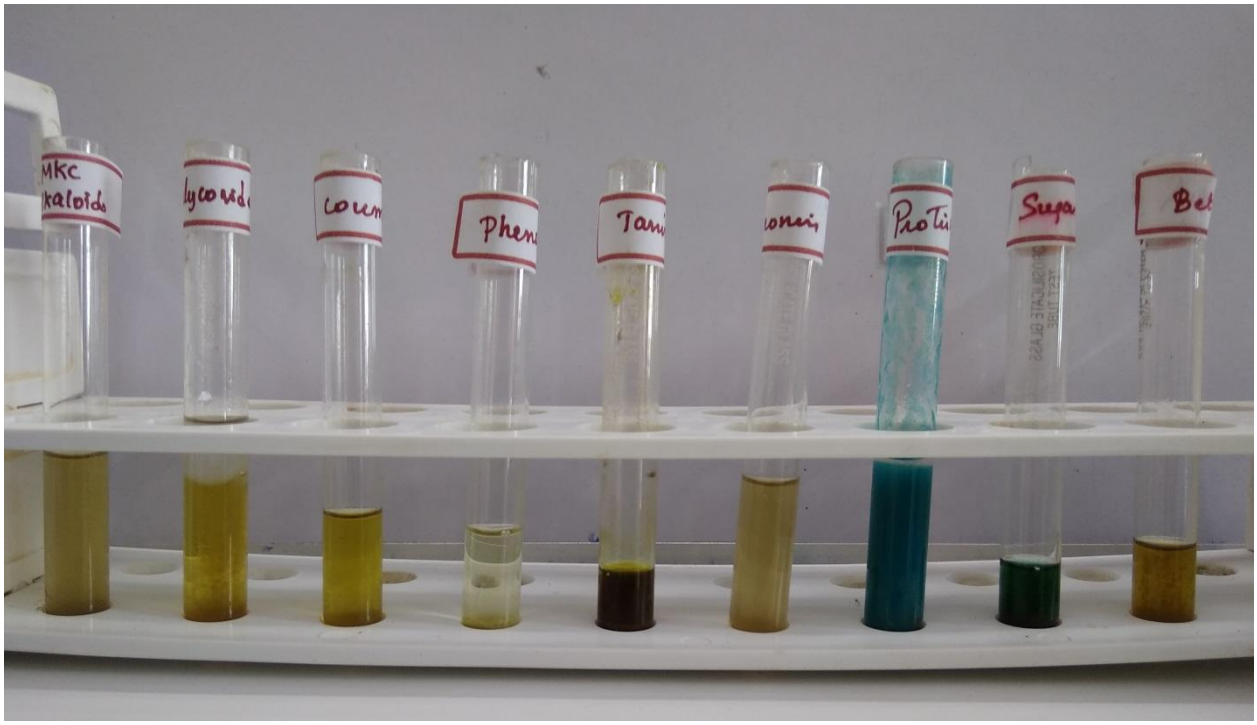
Proteins (Biuret Test)

To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide, formation of violet purple colour indicates the presence of proteins.

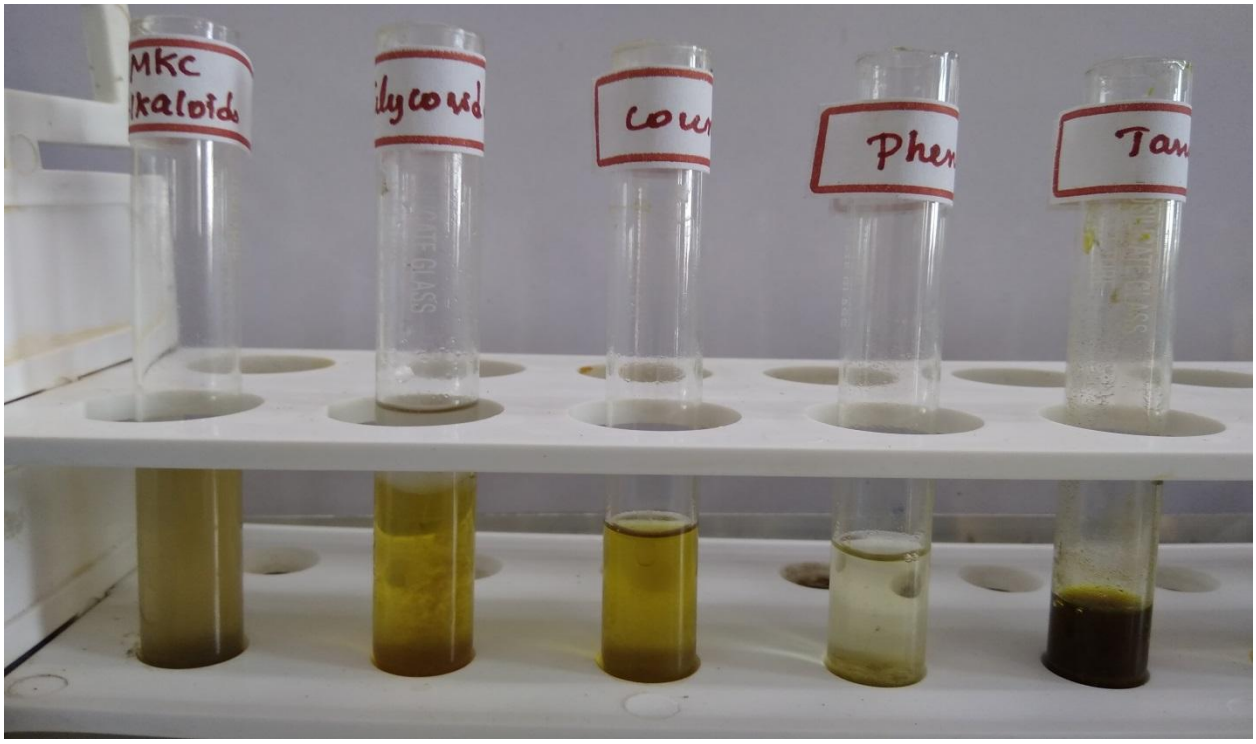
Reference

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

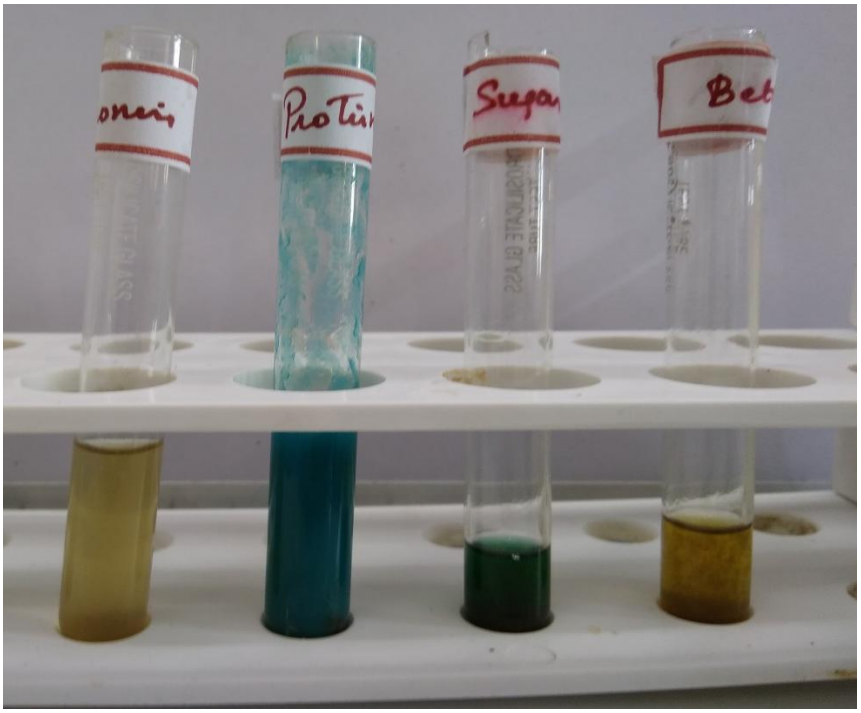
RESULTS



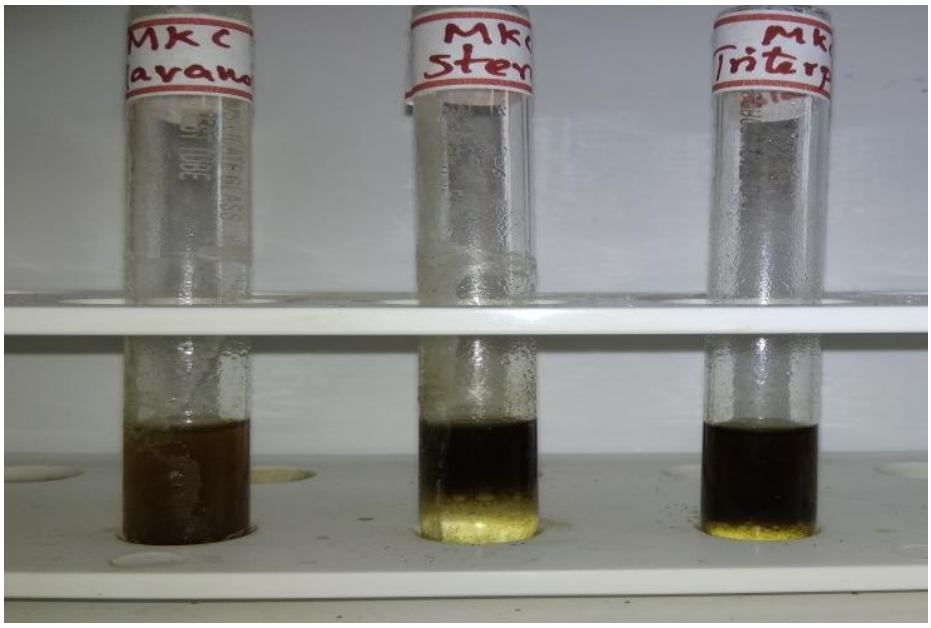
Test Results for Alkaloids, Glycosides, Coumarins, Phenols and Tanins



Test Results for Saponins , Proteins, Carbohydrate, Beta Cyanin Tanins



Test for Flavonoids, Steroids and Triterpenoids



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Name and Address of the Researcher	Dr.M.Hari Priya Government Siddha Medical College, Chennai, Tamil Nadu, India
Sample –ID	Manjanaathi Kudineer Chooranam - MKC
Parameter Requested for Analysis	Phytochemical Analysis
Sample Received	In Person
Method of Analysis	PLIM- Protocol – ASU Formulations
Analysis Type	Physicochemical Analysis
Result of Analysis	Test and Analytical Reports Attached As Annexures

Phytochemical Analytical Report

S.NO	TEST	OBSERVATION
1	ALKALOIDS	+
2	FLAVANOIDS	-
3	GLYCOSIDES	-
4	STEROIDS	+
5	TRITERPENOIDS	+
6	COUMARIN	+
7	PHENOL	+
8	TANIN	+
9	PROTEIN	-
10	SAPONINS	+
11	SUGAR	+
12	ANTHOCYANIN	-
13	BETACYANIN	+

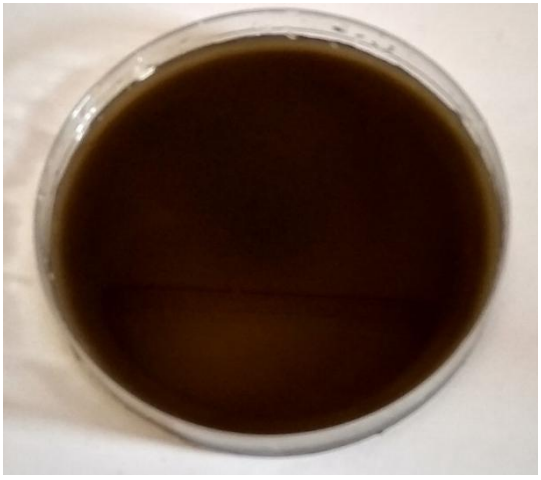
+ -> Indicates Positive and - -> Indicates Negative

PHYSICO CHEMICAL ANALYSIS

Physicochemical Evaluation

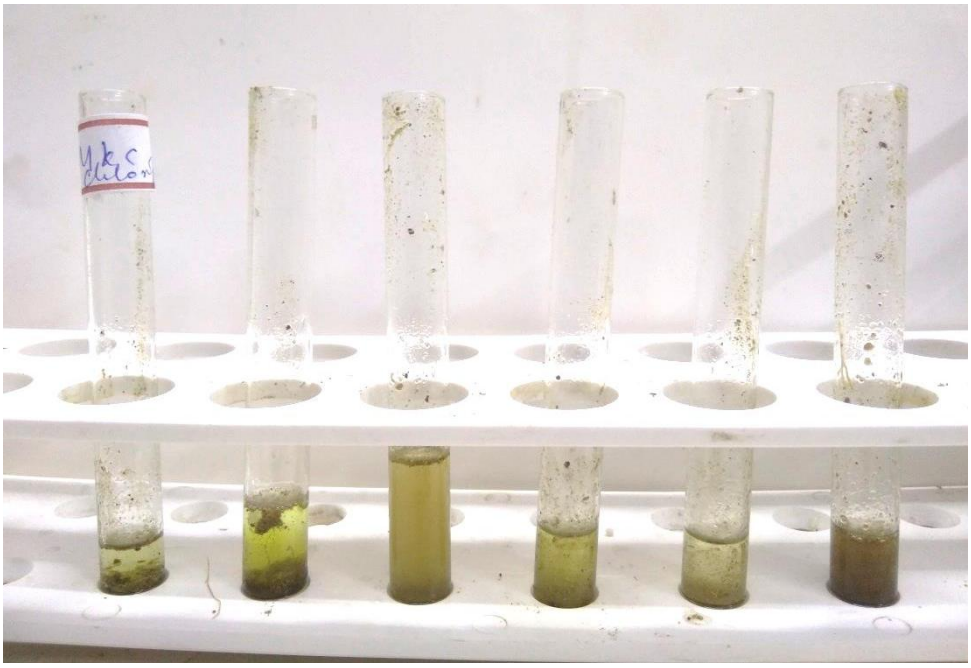
Project ID	**NRS/AS/0342/02/2019**
Name and Address of the Researcher	**Dr.M.Hari Priya** **Government Siddha Medical College, Chennai** **Tamil Nadu, India**
Sample –ID	**Manjanaathi Kudineer Chooranam - MKC**

Sample Description



State	Solid	Decoction- Water Extraction
Appearance	Pale greenish	Dark Reddish brown
Nature	Fibrous Coarse powder	Viscous Liquid
Odor	Strong Characteristic	Characteristic

Solubility Profile of MKC



S.No	Solvent Used	Solubility / Dispersibility
1	Chloroform	Insoluble
2	Ethanol	Insoluble
3	Water	Soluble
4	Ethyl acetate	Sparingly soluble
5	Hexane	Insoluble
6	DMSO	Soluble

Percentage Loss on Drying

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

Determination of Total Ash

Test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 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.

Determination of Acid Insoluble Ash

The ash obtained by total ash test will be 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.

Determination of Alcohol Soluble Extractive

Test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it 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.

Determination of Water Soluble Extractive

Test sample was macerated with 100 ml of water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it 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.

Final Test report MKC

S.No	Parameter	Mean (n=3) SD
1.	***Loss on Drying at 105 °C (%)***	0.6333 ± 0.32
2.	***Total Ash (%)***	11.53 ± 1.858
3.	***Acid insoluble Ash (%)***	0.8267 ± 0.03
5.	***Alcohol Soluble Extractive (%)***	5.167 ± 0.75
6.	***Water soluble Extractive (%)***	18.1 ± 0.755

Reference:

1. India Pharmacopeia I Volume I, Government of India, Ministry of Health and Family welfare, Indian Pharmacopeia commission, 2014.
2. Pharmacopoeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of indian medicine which include drugs of Ayurveda, Unani and Siddha systems. Department AYUSH .Ministry of Health & Family Welfare, Govt. of India

TLC AND HPTLC ANALYSIS REPORT

TLC Analysis

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

REFERENCE

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

HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY ANALYSIS

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

Chromatogram Development

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

Scanning

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

REFERENCE

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

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Project ID	NRS/AS/0342/02/2019
Name and Address of the Researcher	Dr.M.Hari Priya Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested for Analysis	HPTLC Analysis
Sample Received	In Person
Sample –ID	Manjanaathi Kudineer Chooranam - MKC
Method of Analysis **Instrument** **TLC Plate** **Mobile Phase**	CAMAG TLC SCANNER III Aluminium Coated Silica Gel – Merck Chloroform: n-Butanol: Methanol: Water: Acetic Acid (4:1:1:0.5:0.5)
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached as Annexure

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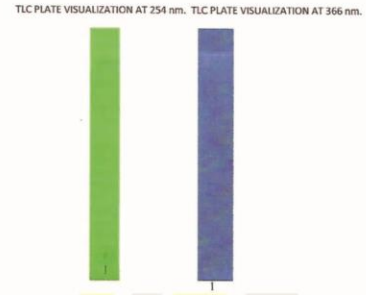
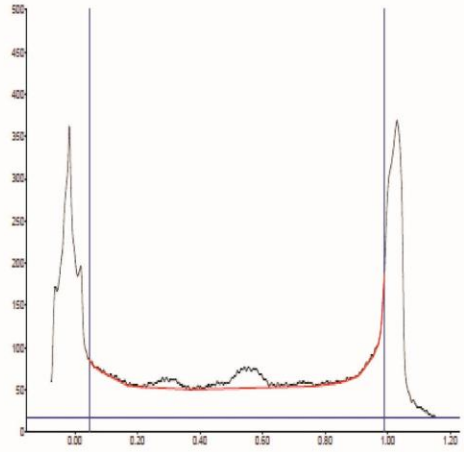
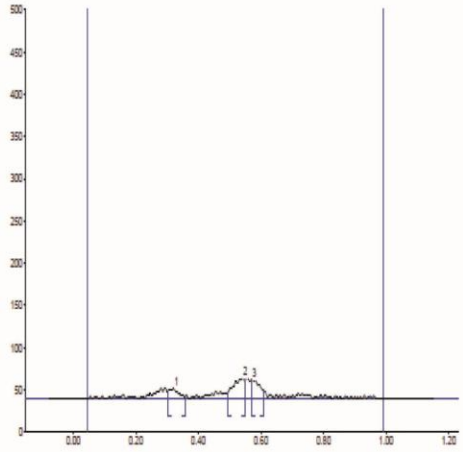
TLC Analysis



HPTLC finger printing of Sample MKC





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

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Peak Table

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.30	8.3	0.32	11.8	19.55	0.36	2.4	283.3	20.35
2	0.49	7.0	0.54	25.2	41.91	0.55	20.7	649.2	46.64
3	0.57	22.0	0.57	23.2	38.54	0.61	9.8	459.5	33.01

REPORT

HPTLC finger printing analysis of the sample reveals the presence of three prominent peaks corresponds to presence of three versatile phytocomponents present with in it. Rf value of the peaks ranges from 0.30 to 0.57. Further the peak 2 and 3 occupies the major percentage of area of 46.64 and 33.01 % which denotes the abundant existence of such compound.

SPECIFIC PATHOGEN TEST

Test Report

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 color with respect to pattern of colony formation in each differential media.

Detail of Specific Medium and their abbreviation

Organism	Abbreviation	Medium
E-coli	***EC***	***EMB Agar***
Salmonella	***SA***	***Deoxycholate agar***
Staphylococcus Aureus	***ST***	***Mannitol salt agar***
Pseudomonas Aeruginosa	***PS***	***Cetrimide Agar***

Observation

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

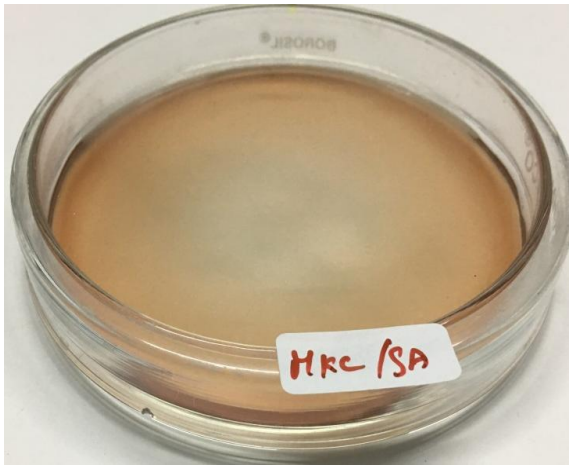
Result

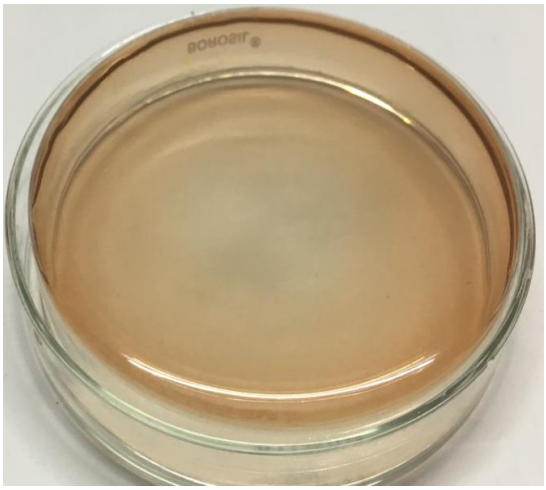
No growth / colonies were observed in any of the plates inoculated with the test sample.

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

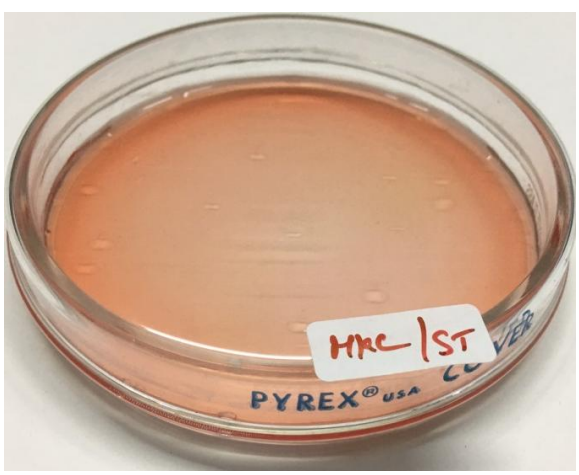
Culture plate with E-coli (EC) specific medium

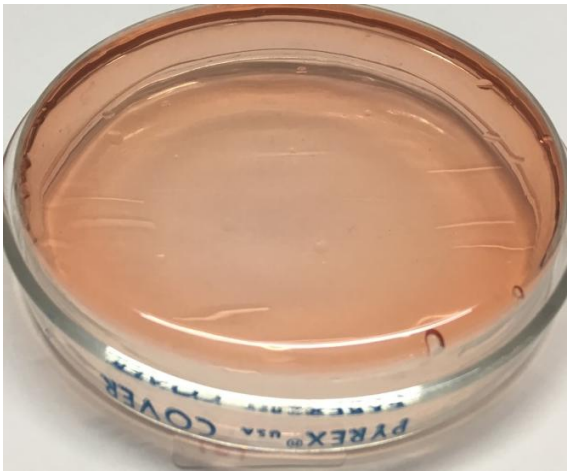
Culture plate with Salmonella (SA) specific medium



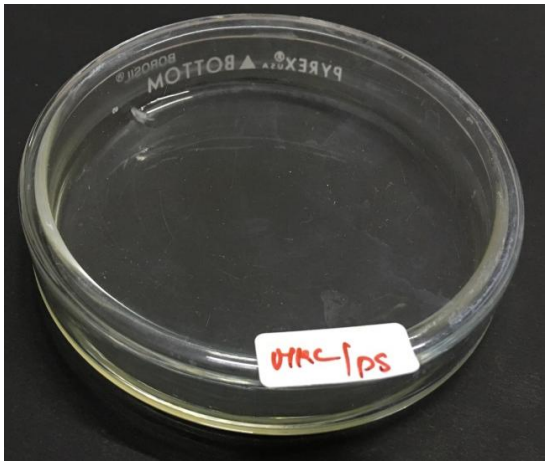


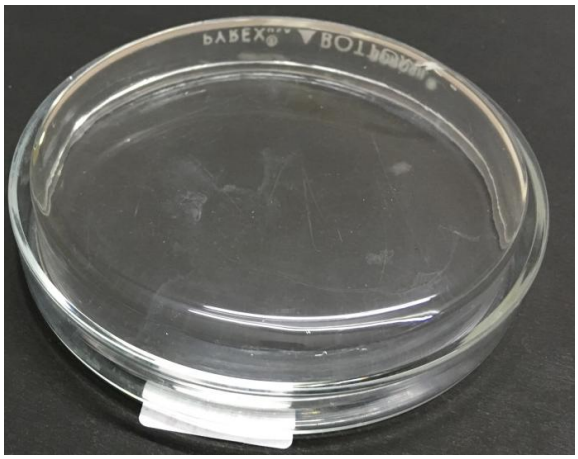
Culture plate with Staphylococcus Aureus (ST) specific mediu





Culture plate with Pseudomonas Aeruginosa (PS) specific medium





STERILITY TEST

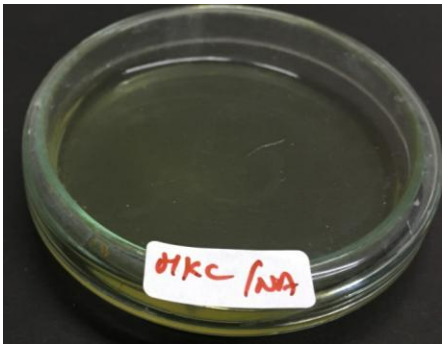
STERILITY TEST BY POUR PLATE METHOD

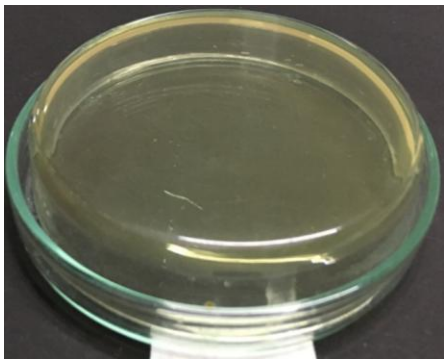
Objective

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

Methodology

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





Observation

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

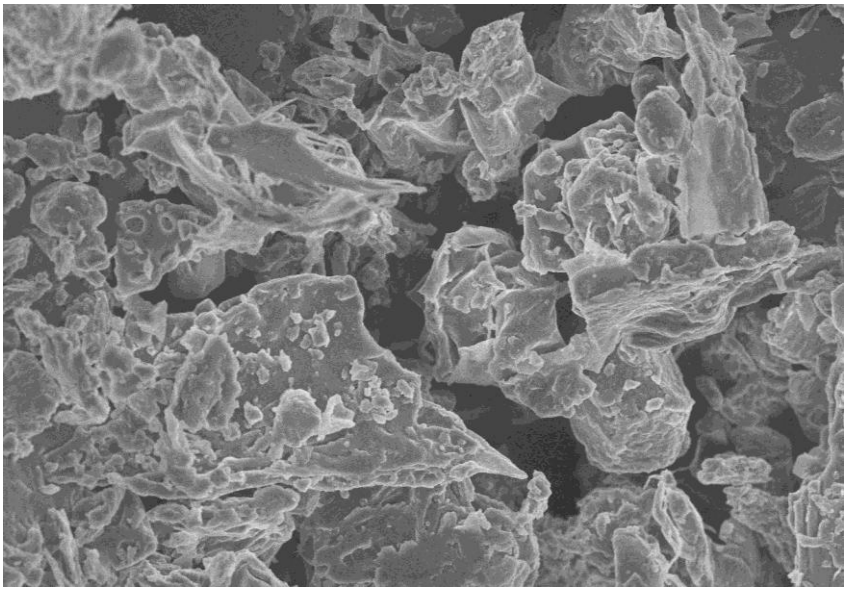
Result

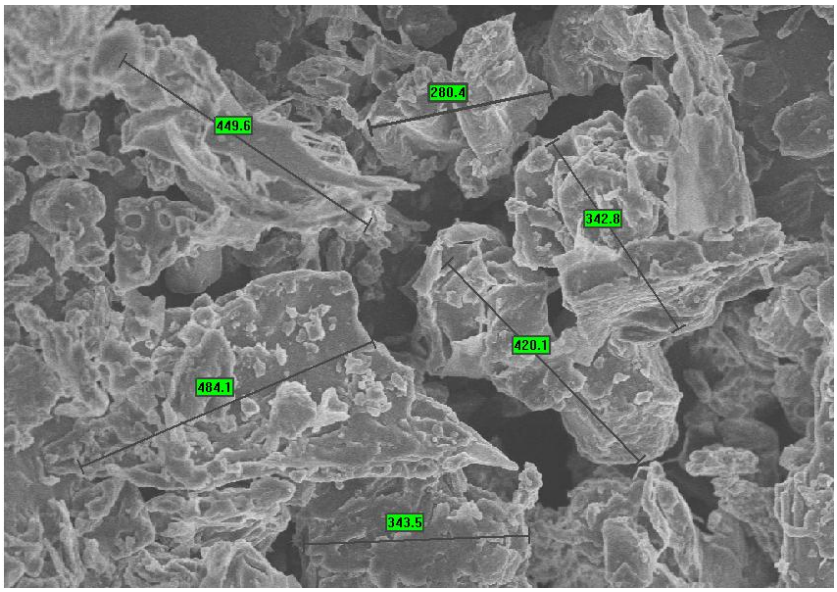
No growth / colonies were observed in any of the plates inoculates with the test sample.

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	

PARTICLE SIZE

Electron Microscopic Observation of Particle Size for the Test Sample- MKC





Mean	**386.3**
Std. Deviation	**77.14**
Std. Error	**31.49**

REPORT

Microscopic observation of the particle size analysis reveals that the average particle size of the sample was found to be 386.13 ± 77.14 µm

Reference

1.Morgan AJ. X-ray microanalysis in electron microscopy for biologists. Oxford University Press; 1985

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

HEAVY METAL ANALYSIS REPORT

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Project ID	NRS/AS/0342/02/2019
Name and Address of the Researcher	Dr.M.Hari Priya Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested for Analysis	Heavy Metal analysis by AAS
Sample Received	In Person
Sample –ID	Manjanaathi Kudineer Chooranam - MKC
Description of the Sample	Solid
Method of Analysis **Instrument** **Extraction Solvent**	 Model: AA 240 Series HCl and HNO3
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached as Annexure

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HEAVY METAL ANALYSIS BY AAS

Standard: Hg, As, Pb and Cd – Sigma

Methodology

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

Sample Digestion

Test sample was 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 HNO_3

Test Report

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

BDL- Below Detection Limit

Report and Inference

- Results of the present investigation have clearly shows that the sample has no traces of heavy metals such as Mercury, Arsenic, Cadmium and Lead.

PESTICIDE RESIDUE ANALYSIS

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Project ID	NRS/AS/0342/02/2019
Name and Address of the Researcher	Dr.M.Hari Priya Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested by the Customer for Analysis	Organochlorine pesticides Organophosphorus pesticides Pyrethroids
Sample Received	In Person
Sample –ID	Manjanaathi Kudineer Chooranam - MKC
Description of the Sample	Solid
Extraction	Acetone and Toulene
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached

Extraction

Test sample 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 milliliters of toluene R and heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered through membrane filter.

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Test Result Analysis of the Sample MKC

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

BQL- Below quantification Limit

Result: The results showed that there were no traces of pesticides residues such as Organo chlorine, Organo phosphorus and pyrethroids in the sample provided for analysis.

Reference

1. WHO guideline for assessing the quality of herbal medicines with reference to contaminants and residues. WHO Geneva. 2007.
2. Lohar. D.R. Protocol for testing of ASU medicines. Pharmacopoeial Laboratory for Indian Medicines. Ministry of AYUSH. 2007.

AFLATOXIN ASSAY

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Project ID	NRS/AS/0342/02/2019
Name and Address of the Researcher	Dr.M.Hari Priya Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested by the Customer for Analysis	Aflatoxin Assay By TLC (B1,B2,G1,G2)
Sample Received	In person
Sample –ID	Manjanaathi Kudineer Chooranam – MKC
Description of the Sample	Solid
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached

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Standard

Aflatoxin B1

Aflatoxin B2

Aflatoxin G1

Aflatoxin G2

Solvent

Standard samples was dissolved in a mixture of chloroform and acetonitrile (9.8 : 0.2) to obtain 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.

Aflatoxin	Sample MKC	AYUSH Specification Limit
B1	Not Detected - Absent	0.5 ppm
B2	Not Detected - Absent	0.1 ppm
G1	Not Detected - Absent	0.5 ppm
G2	Not Detected - Absent	0.1 ppm

Result: The results shown that there was no spots were been identified in the test sample loaded on TLC plates when compare to the standard , which indicates that the sample were free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2.

Reference

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. 2001.

MATERIALS AND METHODS

MATERIALS AND METHODS

CLINICAL STUDIES :

After finishing the toxicity studies 40 paediatric cases were selected on the basis of inclusion criteria from the OPD of Kuzhanthai Maruthuvam Department, Arignar Anna Govt. Hospital, Chennai. They were treated with the trial drug **Manjanaathi Kudineer** and observed for prognosis clinically.

STUDY DESIGN

A clinical trial on **Neer kana Maantham** was carried out in the Post Graduate Department of Kuzhanthai Maruthuvam in Govt.Siddha Medical College attached to Arignar Anna Hospital of Indian Medicine, Chennai-106 during the period of 2018-19.

The study was approved by Institutional Ethics Committee (IEC) and the approval number is **IEC No : GSMC-CH-ME-2/016/2017**

SAMPLE SIZE :

The study is conducted in 40 selected patients of both genders between age groups of 2-12Years.

INCLUSION CRITERIA :

Age 2-12years
Running nose
Cough
Fever
Malaise
Diarrhea

Patients having any three symptoms of the above criteria will be included in my clinical trial.

EXCLUSION CRITERIA

Allergic Rhinitis

Bronchitis

Bronchial Asthma

Severe Diarrhea with other complications.

WITH DRAWAL CRITERIA :

Exacerbation of the symptoms

Occurrence of any adverse effects

Patients turned unwilling during follow up.

ASSESSMENTS AND INVESTIGATIONS :

Clinical Assessment :

- Rhinorrhea
- Cough
- Fever
- Malaise
- Loss of appetite

Siddha Assessment

- Naa
- Niram
- Mozhi
- Vizhi
- Sparism
- Malam
- Naadi
- Moothiram-Neer Kuri, Nei Kuri

ROUTINE TESTS AND INVESTIGATIONS

Blood **:** TC, DC, ESR ,Hb.

Urine : Albumin, Sugar, Deposits.

METHODOLOGY OF TREATMENT

Study Enrolment:

Patient reporting at the OPD associated with clinical features of Running nose, cough, fever, malaise, fatigue are chosen for enrolment based on the inclusion criteria. The patients who are enrolled are informed about the study trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and then informed consent/assent would be obtained from the patient/patient's parent using Consent/Assent form.

Conduct of the Study:

The trial drug will be given in the OPD of P.G. Kuzhanthai Maruthuvam, GSMC, Chennai. The patients will be asked to have a regular follow up in the OPD once in 3days. In each and every visit the clinical assessment will be recorded in the prescribed proforma. The laboratory investigations will be done before and after treatment and recorded in the prescribed format.

DATA COLLECTION FORMS:

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

Form I : Screening and selection proforma.

Form II : History taking proforma.

Form III : Clinical assessment proforma.

Form IV : Clinical assessment during and after trial.

Form V : Laboratory Investigation proforma.

Form VI : Informed Consent/Assent form.

Form VII : Withdrawal form.

Form VIII : Patient information sheet.

DATA ANALYSIS:

After enrolling the patients in the study, a separate file for each patient will be maintained and all forms will be kept in the file. Whenever the patient visits OPD during the study period, necessary entries will be made in the assessment forms.

The data entries and adverse events if any will be monitored by the Head of the Department.

OUTCOME OF TREATMENT:

Primary Outcome:

Primary outcome is mainly assessed by comparing the reduction in clinical symptoms and recurrence before and after treatment.

Secondary Outcome:

Secondary outcome is assessed by comparing the safety parameters before and after treatment.

ADVERSE EFFECT AND SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reactions, the patient will be referred to the Pharmacovigilance department of SCRI and documented for any adverse effect and then the investigator will be giving proper management for the adverse reaction in the OPD.

ETHICAL ISSUES:

1. Informed Consent/Assent will be obtained from the patient/patient's parent or guardian after explaining about the clinical trial in an understandable language.
2. After the Consent/Assent of the patient or patient's parent (through Consent/Assent) if they fit in the criteria, they will be enrolled in the study.
3. Treatment will be provided free of cost.
4. Concomitant medicines will be used if there is any need.
5. The patients who are excluded (as per the exclusion criteria) will be referred to OPD.

RESULTS AND OBSERVATIONS

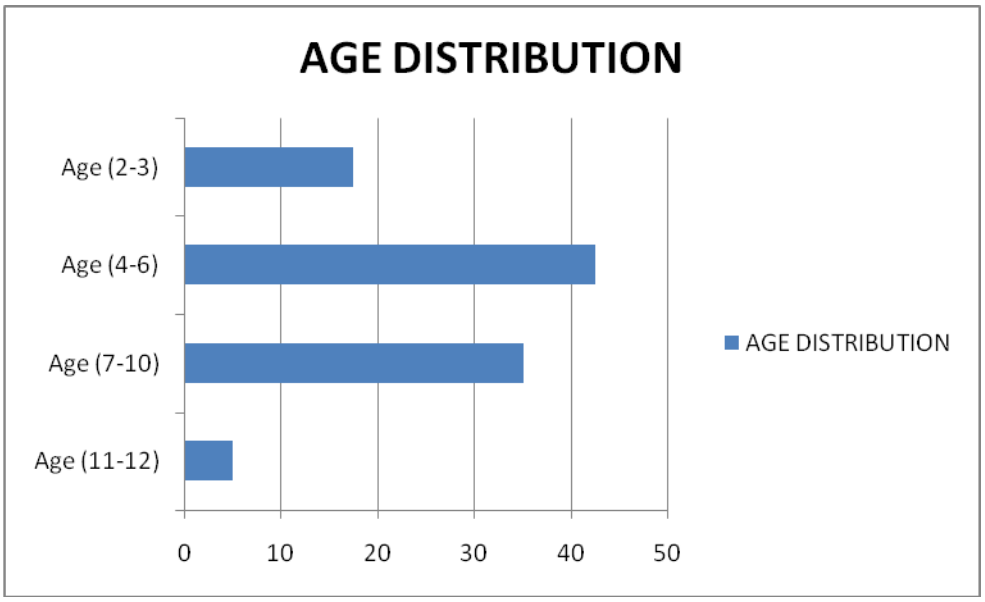
RESULTS AND OBSERVATIONS

A total number of 40 child patients with signs and symptoms of Neer Kana Maantham attending PG-IV, Kuzhanthai Maruthuvam Out Patient Department in Govt. Siddha Medical College attached to Arignar Anna Hospital were observed in the present study. The observation were made and tabulated with regards to the following features :

1. Age Distribution
2. Gender Distribution
3. Family History
4. Diet History
5. Socio-Economic status
6. Uyirthathukkal
7. Udarthathukkal
8. Envagai Thervugal
9. Neikkuri
10. Thinai
11. Paruvakaalam
12. Clinical Features
13. Prognosis
14. Result

1. AGE DISTRIBUTION

S.NO	AGE	No.of Cases (Out of 40)	Percentage
1	2-3years	7	17.5%
2	4-6years	17	42.5%
3	7-10years	14	35%
4	11-12years	2	5%

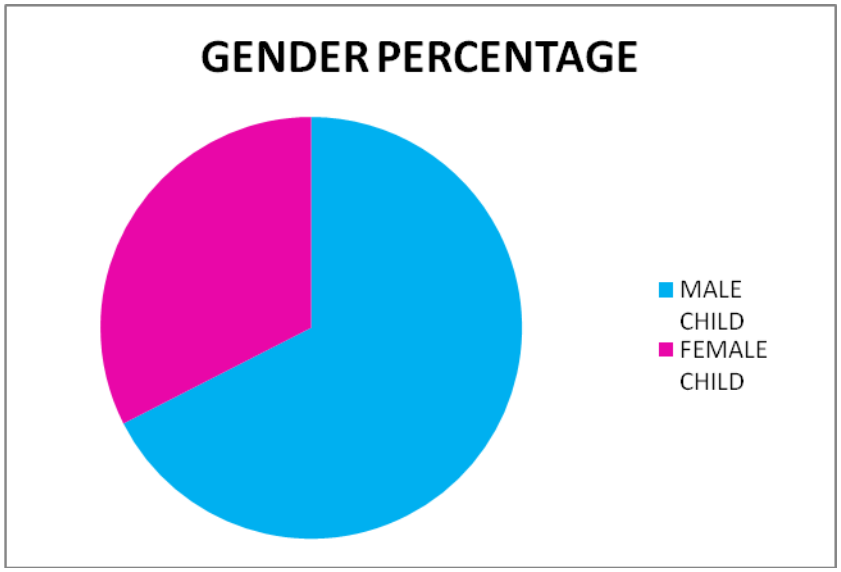


Inference :

The above table indicates that children coming under 2-3years of age group were 17.5%, 4-6years were 42.5%, 7-10years of age group were 35%, 11-12years of age were 5% respectively.

2.GENDER DISTRIBUTION

GENDER	NO.OF PATIENTS	PERCENTAGE
MALE	27	67.5%
FEMALE	13	32.5%

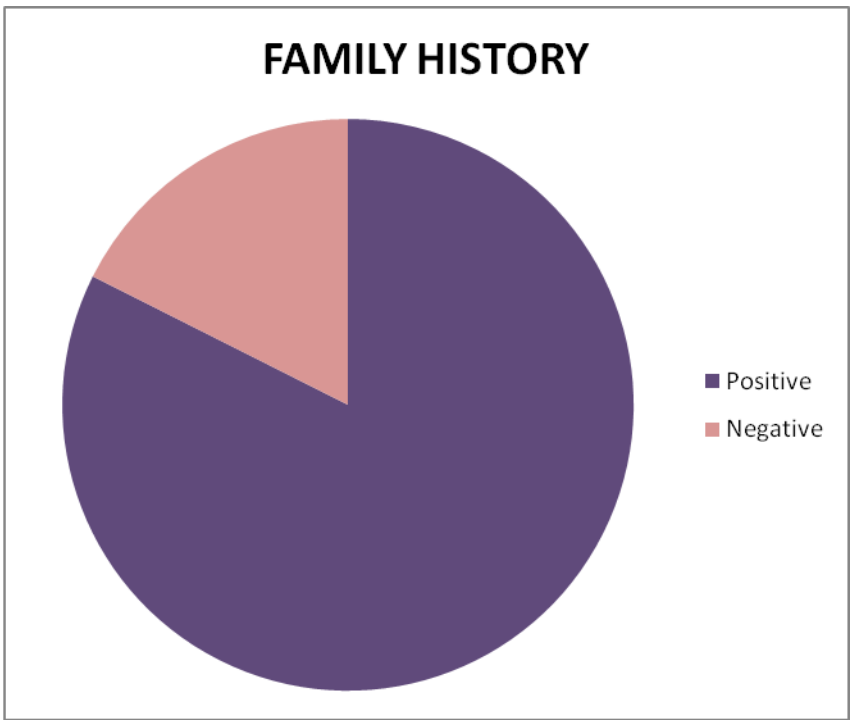


Inference :

Among 40 cases for this study, 27 children – 67.5% were male child and 13 children – 32.5% were female child.

3.FAMILY HISTORY

S.NO	FAMILY HISTORY	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Positive	6	15%
2	Negative	34	85%



Inference :

Out of 40 cases, family history is positive in 6 cases ie 15% and negative in 34 cases ie 85%.

4.DIET HISTORY

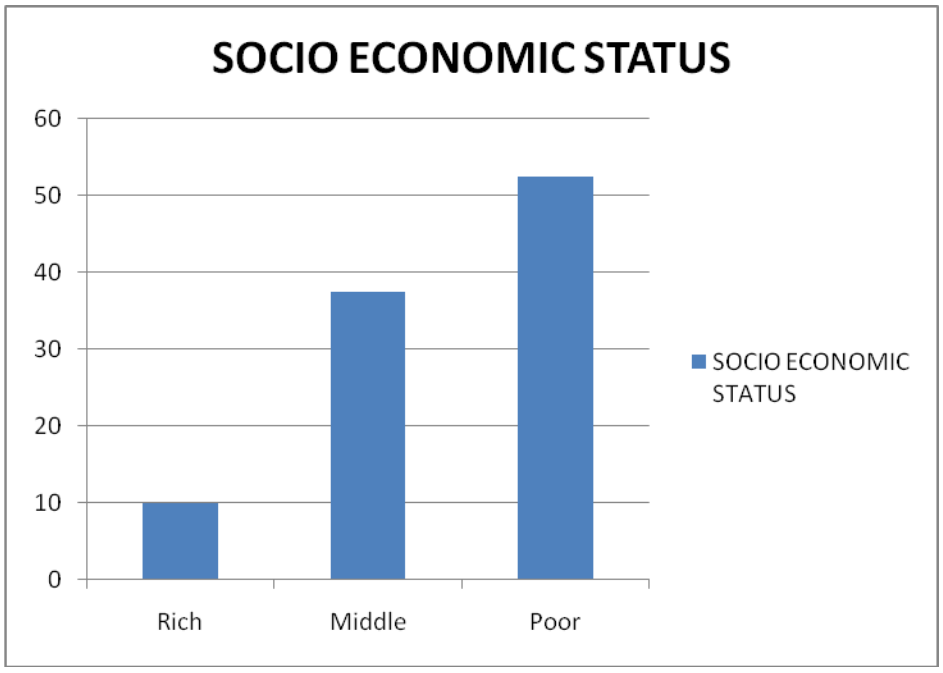
DIETARY HABITS	NO.OF CASES(OUT OF 40)	PERCENTAGE
Vegetarian	5	12.5%
Non vegetarian	35	87.5%

Inference :

Out of 40 cases, 5 cases were vegetarian – 12.5%, 35cases were non-vegetarian – 87.5% respectively.

5.SOCIO-ECONOMIC STATUS

S.NO	STATUS	NO.OF CASES(OUT OF 40)	PERCENTAGE
1	Rich	4	10%
2	Middle	15	37.5%
3	Poor	21	52.5%



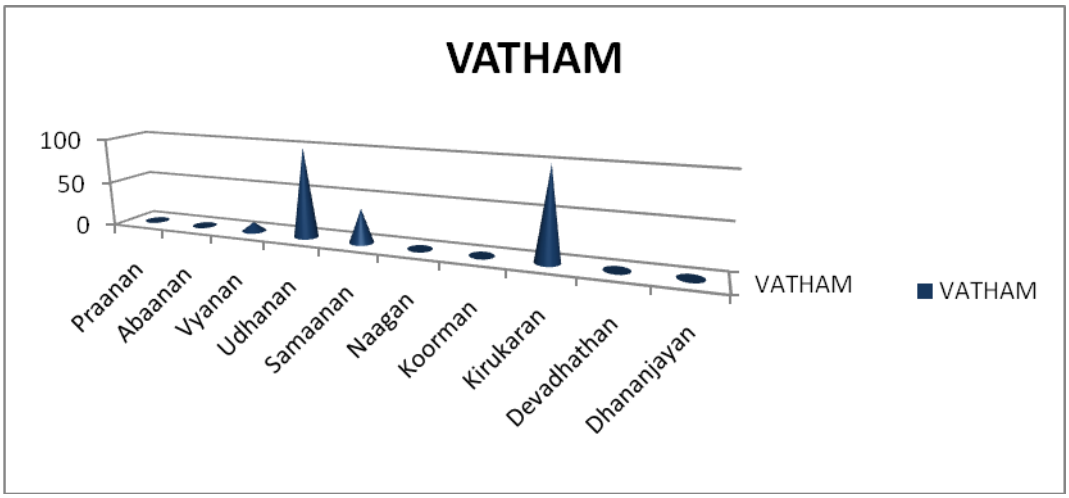
Inference :

Out of 40 cases, 4 cases were rich – 10% in status, 15 cases were middle -37.5% in status and 21cases were poor – 52.5% in status.

7.UYIRTHATHUKKAL

1.Vatham

S.NO	VATHAM	NO.OF CASES(OUT OF 40)	PERCENTAGE
1	Praanan	-	-
2	Abaanan	-	-
3	Vyanan	4	10%
4	Udhanan	40	100%
5	Samaanan	15	37.5%
6	Naagan	-	-
7	Koorman	-	-
8	Kirukaran	40	100%
9	Devadhathan	-	-
10	Dhananjayan	-	-

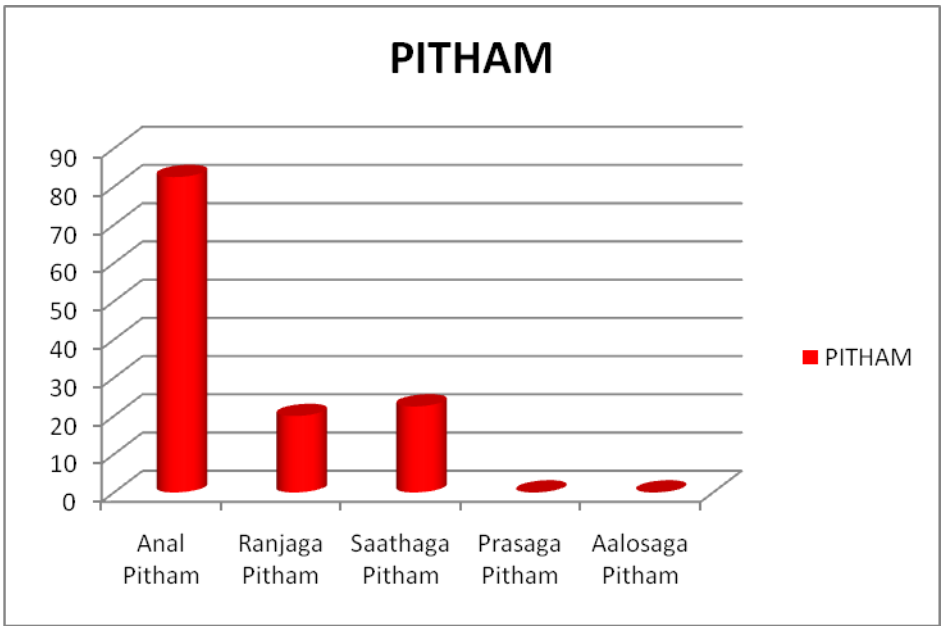


Inference :

In vatham, Vyanan was affected in 4 cases ie 10%, Udhanan was affected in 40 cases ie 100%, Samaanan was affected in 15 cases ie 37.5%, Kirukkaran was affected in 40 cases ie 100%.

2. **Pitham**

S.NO	PITHAM	NO.OF CASES(OUT OF 40)	PERCENTAGE
1	Anal Pitham	33	82.5%
2	Ranjaga Pitham	8	20%
3	Saathaga Pitham	9	22.5%
4	Prasaga Pitham	-	-
5	Aalosaga Pitham	-	-

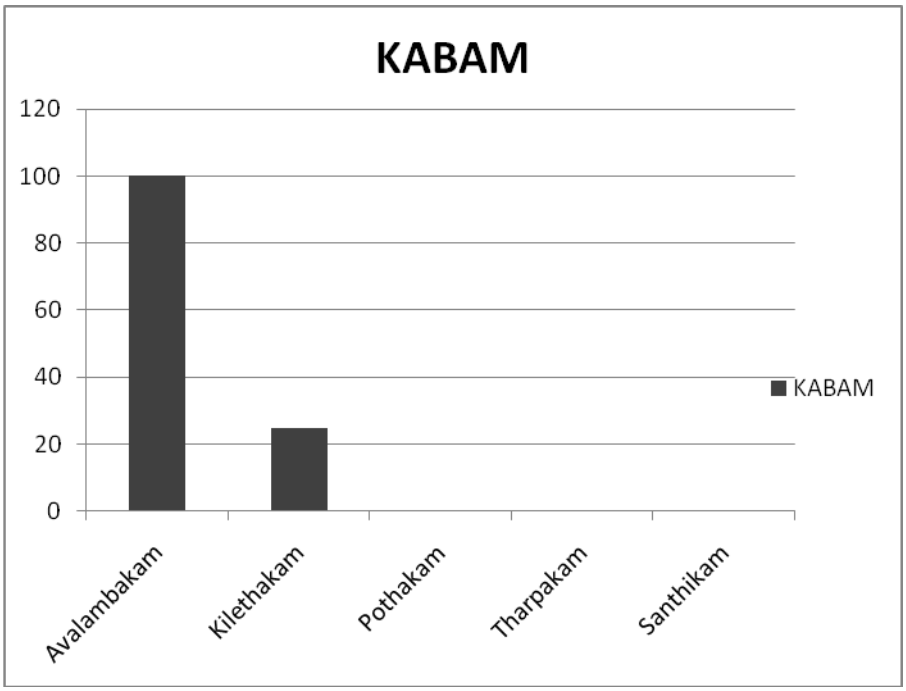


Inference :

In pitham, Anal pitham was affected in 33cases ie 82.5% , Ranjaka pitham was affected in 8 cases ie 20% and Saathaga Pitham was affected in 9 cases ie 22.5%

3.Kabam

S.NO	KABAM	NO.OF CASES(OUT OF 40)	PERCENTAGE
1	Avalambakam	40	100%
2	Kilethakam	10	25%
3	Pothakam	-	-
4	Tharpakam	-	-
5	Santhikam	-	-

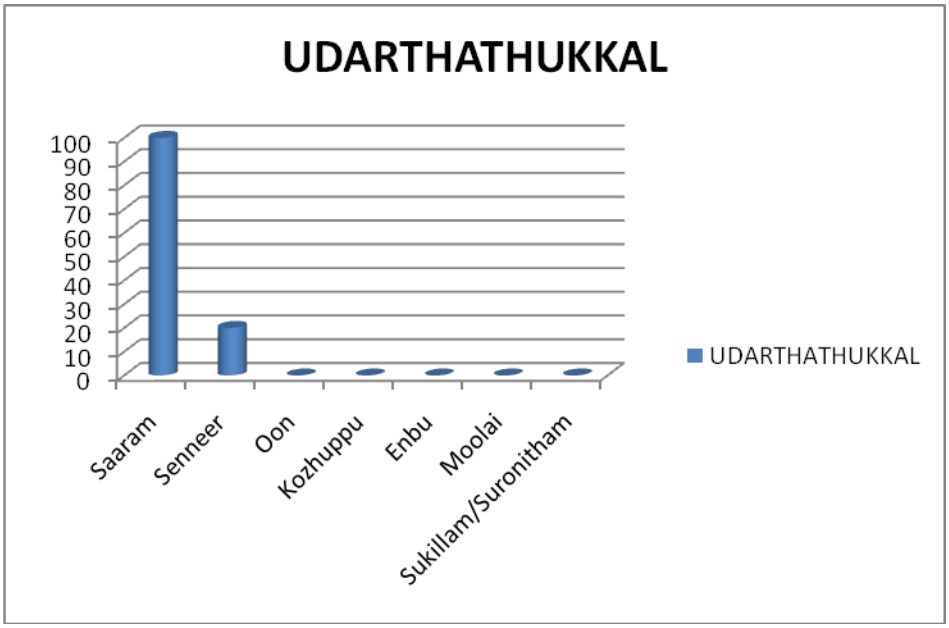


Inference :

In kabam, Avalambakam was affected in 10 cases ie 100% and Kilethakam was affected in 10 cases ie25%.

7.UDARTHATHUKKAL

S.NO	UDARTHATHUKKAL	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Saaram	40	100%
2	Senneer	8	20%
3	Oon	-	-
4	Kozhuppu	-	-
5	Enbu	-	-
6	Moolai	-	-
7	Sukillam/Suronitham	-	-

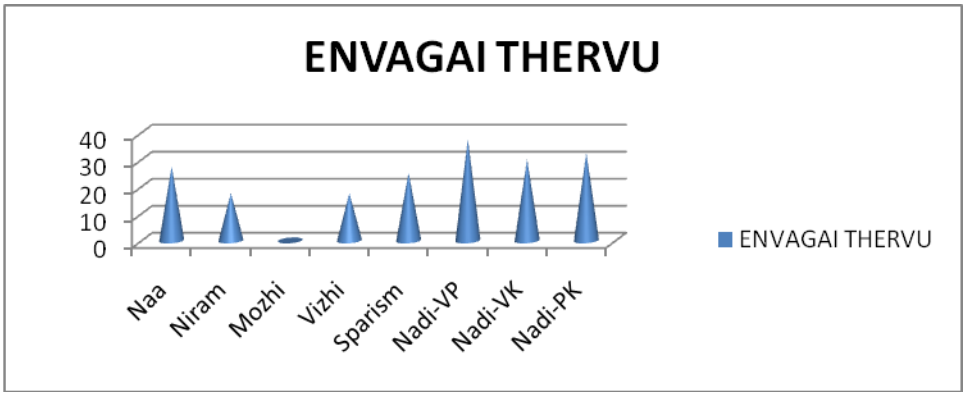


Infernece :

In udharthathukkal, Saaram was affected in 40 cases ie 100% and Senneer was affected in 8 cases ie 20% respectively.

8.ENVAGAI THERVUGAL

S.NO	SIDDHA PARAMETER	NO.OF CASES AFFECTED (OUT OF 40)	PERECENTAGE
1	Naa	11	27.5%
2	Niram	7	17.5%
3	Mozhi	-	-
4	Vizhi	7	17.5%
5	Sparism	10	25%
6	Malam	-	-
7	Moothiram	-	-
8	Naadi		
	A. Vathapitham	15	37.5%
	B. Vathakabam	12	30%
	C. Pithakabam	13	32.5%

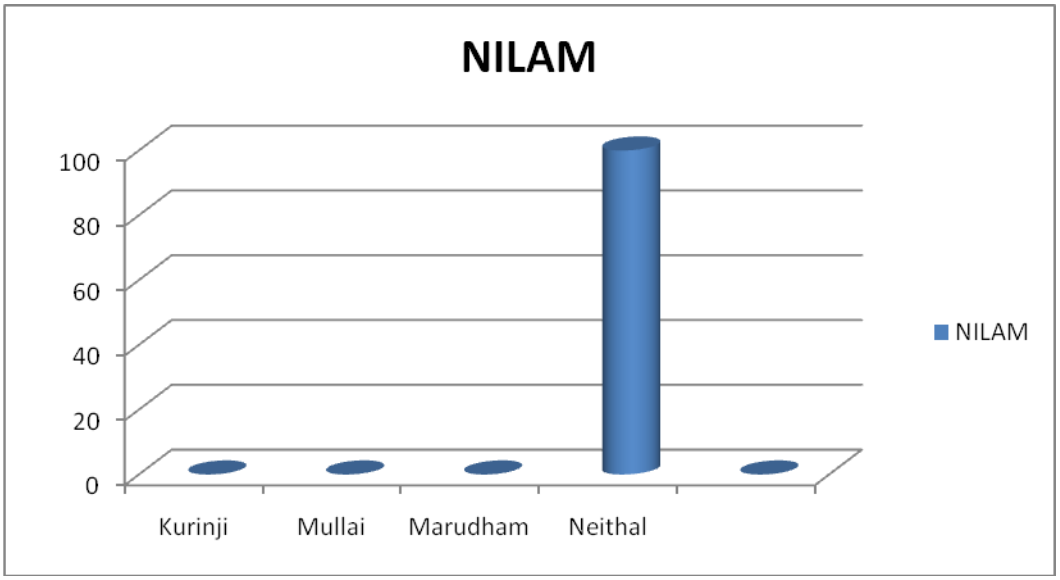


Inference :

In envagai thervugal, Naa affected in 27.5% cases, Niram and Vizhi was affected in 17.5% cases, Sparism was affected in 25% cases. In case of Naadi Vathapitham was seen in 15 cases ie 37.5%, Vathakabam was seen in 12 cases ie 30% and Pithakabam was seen in 13 cases ie 32.5% respectively.

9.NILAM

S.NO	NILAM	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Kurinji	-	-
2	Mullai	-	-
3	Marudham	-	-
4	Neithal	40	100%
5	Paalai	-	-

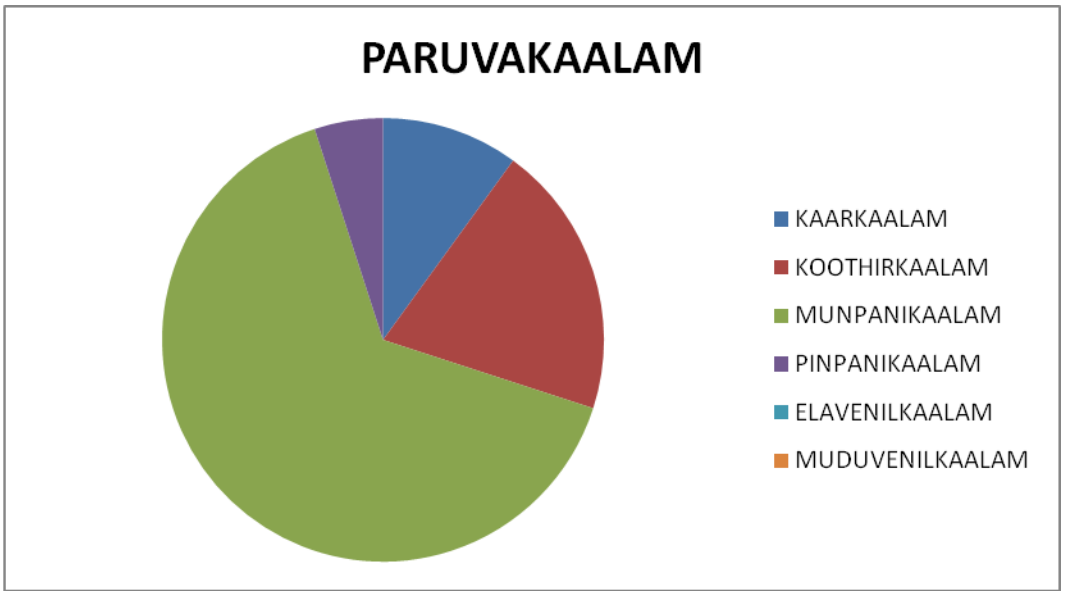


Inference :

All the cases were reported from surroundings of Chennai which is belongs to Neithal Nilam.

10.PARUVA KAALAM

S.NO	PARUVAKAALAM	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Kaarkaalam	4	10%
2	Koothirkaalam	8	20%
3	Munpanikaalam	26	65%
4	Pinpanikaalam	2	5%
5	Elavenilkaalam	0	0%
6	Muduvenilkaalam	0	0%

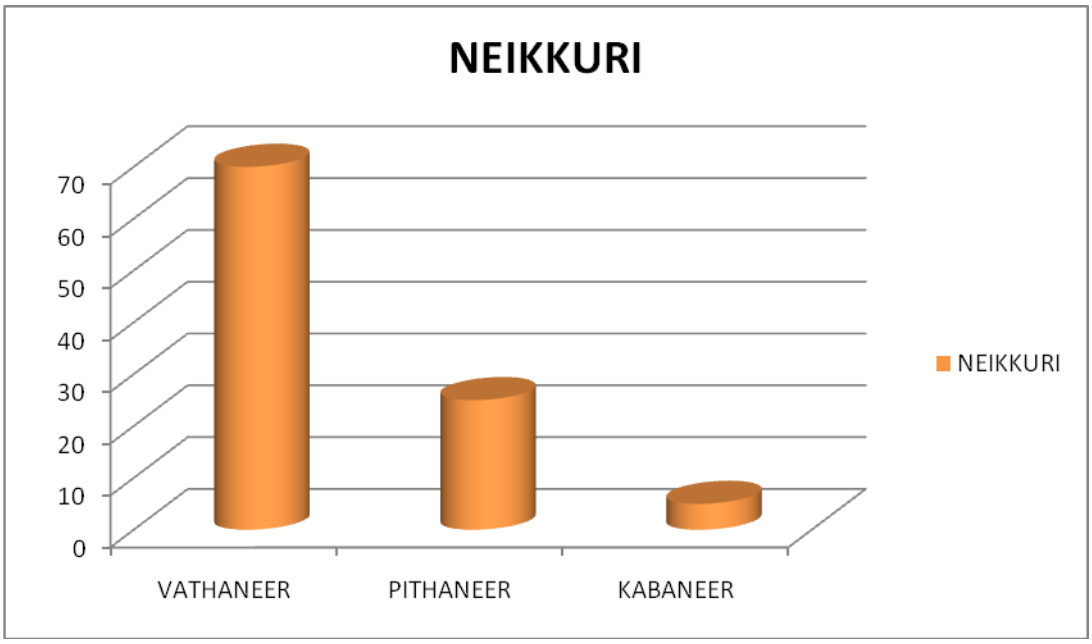


Inference :

The more prevalence of the disease is under Munpanikaalam – 65%. 20% of children were affected in Koothirkaalam, 10% of children were affected in Kaarkaalam and 5% were affected in Pinpanikaalam.

11.NEIKKURI

S.NO	NEIKKURI	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Vathaneer	28	70%
2	Pithaneer	10	25%
3	Kabaneer	2	5%

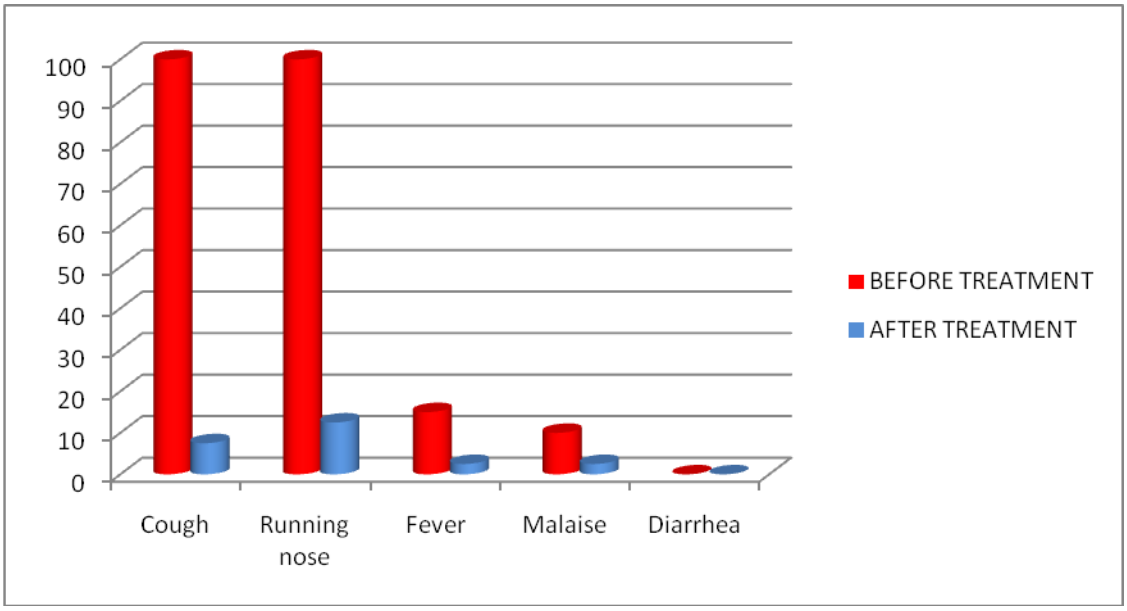


Inferenece :

Among 40 cases, vathaneer was observed in 70% of cases, pithaneer was observed in 25% of cases and kabaneer was observed in 5% of cases.

12.CLINICAL PROGNOSIS

S.NO	CLINICAL FEATURES	BEFORE TREATMENT		AFTER TREATMENT	
		NO.OF CASES (OUT OF 40)	PERCENTAGE	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Cough	40	100%	3	7.5%
2	Running Nose	40	100%	5	12.5%
3	Fever	6	15%	1	2.5%
4	Malaise	4	10%	1	2.5%
5	Diarrhea	0	0%	0	0%

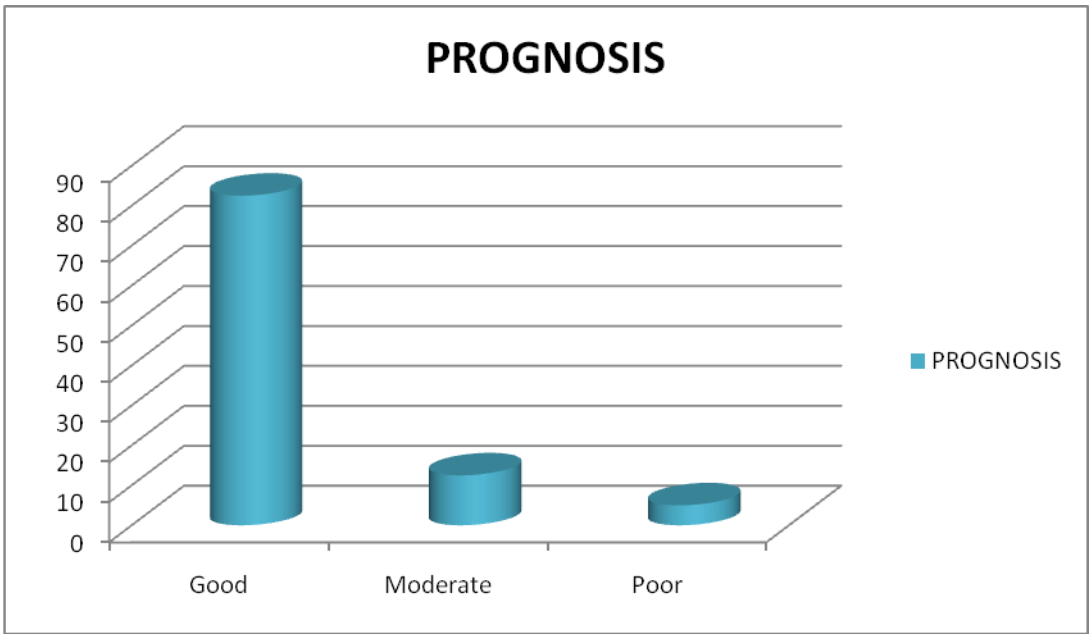


Inference :

The above table reveals that, among 40 cases, 100% had cough before treatment and was reduced to 7.5%, 100% cases had running nose before treatment and was reduced to 17.5%. 15% cases had fever before treatment and was reduced to 2.5%, 10% cases had malaise before treatment and was reduced to 2.5% after treatment.

13.RESULTS OF NEER KANA MAANTHAM

S.NO	PROGNOSIS	NO.OF CASES (OUT OF 40)	PERCENTAGE
1	Good	33	82.5%
2	Moderate	5	12.5%
3	Poor	2	5%



Inference :

Among 40 cases, 33 cases ie 82.5% showed good prognosis, 5 cases ie 12.5% showed moderate prognosis and 2 cases ie 5% showed poor prognosis.

CASE SUMMARY OF THE PATIENTS

S.NO	OP. NO	NAME	AGE/SEX	DAYS TREATED	REMARKS
1.	4660	PREM	21/2yrs/ MC	11	Good
2.	4687	BASHA	3yrs / MC	9	Good
3.	9036	DHANIYA	5yrs / FC	9	Good
4.	9076	JANANI	5yrs / FC	8	Moderate
5.	2554	MANGALYA	6yrs / FC	10	Good
6.	3749	AJAY	9yrs / MC	11	Good
7.	3802	DHANVANTHIRAN	4yrs / MC	8	Good
8.	3816	MAITHRAIYAN	6yrs / MC	8	Good
9.	8563	VISHAL	9yrs / MC	9	Moderate
10.	2086	SARVESH	41/2yrs/ MC	9	Good
11.	2035	THANISH	21/2yrs/ MC	11	Good
12.	2920	MAZHI ANBU	21/2yrs/ MC	5	Moderate
13.	4430	KAKHAN	5yrs / MC	10	Good
14.	4741	AJAY	11yrs / MC	7	Good
15.	4742	NAKSHATRA	8yrs / FC	6	Poor
16.	4722	IRSHANTH	21/2yrs/ MC	10	Moderate
17.	5327	NIRASH	41/2yrs/ MC	6	Good
18.	5480	ABISHEK	8yrs / MC	6	Good
19.	6049	KAYAL	4yrs / FC	6	Moderate
20.	6758	FATHUMUTHUZOHARE	9yrs / FC	5	Good

21.	7248	DEEPIKA	8yrs / FC	11	Good
22.	7290	HARISH MAIYAPPAN	3 1/2yrs/ MC	7	Good
23.	7247	MITHILESH SAI	3 1/2yrs/ MC	8	Good
24.	7502	MANIMARAN	6yrs / MC	6	Good
25.	7686	SAISARAN	4yrs / MC	5	Good
26.	4774	SRIMATHI	10yrs / FC	5	Good
27.	6353	JOSHIKA	5yrs / FC	6	Good
28.	7574	SHYAM	8yrs / MC	10	Good
29.	7706	ALIYAN	6yrs / MC	10	Good
30.	8248	SRINITHI	6yrs / FC	5	Good
31.	9070	BHUVANESH	3yrs / MC	8	Good
32.	9140	DHARANI	9yrs / FC	8	Good
33.	8999	LOHITH	8yrs / MC	9	Good
34.	393	SAIKRISH	3yrs / MC	10	Good
35.	392	THARUN RAM	7yrs / MC	8	Good
36.	1513	RANJITH	3 1/2yrs/ MC	7	Good
37.	1640	NAKSHATHIRA	8yrs / FC	10	Good
38.	2912	DHANALAKSHMI	7yrs / FC	6	Poor
39.	6264	JAGATHRAJ	9yrs / MC	6	Good
40.	6591	SRIPRIYA	11yrs / FC	8	Good

S.NO	OP. NO	NAME	AGE/ SEX	HEMATOLOGICAL ANALYSIS												Hb(gm%)		URINE ANALYSIS					
				BEFORE TREATMENT						AFTER TREATMENT								BT				AT	
				TC (Cu)	DC			ESR(mm)		TC (Cu)	DC			ESR(mm)		BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
					P %	L %	E %	1/2 hr	1hr		P %	L %	E %	1/2 hr	1hr									
1	4660	PREM	21/2yrs/MC	7500	44	48	8	15	26	8600	52	45	3	10	20	12.1	12.2	Nil	Nil	Nil	Nil	Nil	Nil
2	4687	BASHA	3yrs/MC	13100	43	51	6	14	20	10900	49	47	4	7	15	11.8	12	Nil	Nil	Nil	Nil	Nil	Nil
3	9036	DHANIYA	5yrs/FC	9400	49	45	6	6	15	9600	50	47	3	4	9	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
4	9076	JANANI	5yrs/FC	6800	73	24	3	21	38	7500	75	23	2	15	23	10.7	11	Nil	Nil	Nil	Nil	Nil	Nil
5	2554	MANGALYA	6yrs/FC	7500	48	45	7	14	20	7900	49	47	4	5	10	11	11.2	Nil	Nil	Nil	Nil	Nil	Nil
6	3749	AJAY	9yrs/MC	9500	61	31	8	13	22	10300	63	32	5	8	14	12.4	13	Nil	Nil	Nil	Nil	Nil	Nil
7	3802	DHANVANTHIRAN	4yrs/MC	8400	46	47	7	8	15	9200	48	48	4	5	10	14.4	14.6	Nil	Nil	Nil	Nil	Nil	Nil
8	3816	MAITHRAIYAN	6yrs/MC	8200	52	42	6	5	12	8900	53	44	3	2	5	9.3	10	Nil	Nil	Nil	Nil	Nil	Nil
9	8563	VISHAL	9yrs/MC	12500	60	33	7	20	38	13100	61	34	5	15	32	11.9	12.1	Nil	Nil	Nil	Nil	Nil	Nil
10	2086	SARVESH	41/2yrs/MC	8900	44	48	8	14	22	9200	47	49	4	10	17	11.3	11.7	Nil	Nil	Nil	Nil	Nil	Nil
11	2035	THANISH	21/2yrs/MC	8500	41	49	10	10	22	8900	42	51	7	7	16	11.5	11.8	Nil	Nil	Nil	Nil	Nil	Nil
12	2920	MAZHI ANBU	21/2yrs/MC	16100	69	25	6	30	59	10900	71	25	4	19	39	11.5	11.9	Nil	Nil	Nil	Nil	Nil	Nil
13	4430	KAKHAN	5yrs/MC	12500	77	17	6	3	5	11900	79	18	3	2	4	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
14	4741	AJAY	11yrs/MC	8500	47	46	7	15	24	8900	50	46	4	8	16	13.5	13.6	Nil	Nil	Nil	Nil	Nil	Nil
15	4742	NAKSHATRA	8yrs/FC	9900	56	36	8	25	58	10000	58	38	4	18	45	12.6	12.7	Nil	Nil	Nil	Nil	Nil	Nil
16	4722	IRSHANTH	21/2yrs/MC	8900	47	45	8	18	38	9200	48	46	6	14	32	9	9.2	Nil	Nil	Nil	Nil	Nil	Nil
17	5327	NIRASH	41/2yrs/MC	15500	54	37	9	12	25	8400	52	41	7	4	10	8.8	8.9	Nil	Nil	Nil	Nil	Nil	Nil
18	5480	ABISHEK	8yrs/MC	9000	49	42	9	7	12	9900	51	44	5	4	9	12	12.4	Nil	Nil	Nil	Nil	Nil	Nil
19	6049	KAYAL	4yrs/FC	9600	48	43	9	22	36	9900	51	44	5	14	22	9.2	9.4	Nil	Nil	Nil	Nil	Nil	Nil
20	6758	FATHUMUTHUZOHARE	9yrs/FC	7500	44	48	8	15	26	8500	52	48	5	12	22	12.1	12.8	Nil	Nil	Nil	Nil	Nil	Nil

S.NO	OP. NO	NAME	AGE/ SEX	HEMATOLOGICAL ANALYSIS												Hb(gm%)		URINE ANALYSIS					
				BEFORE TREATMENT						AFTER TREATMENT						BT	AT	BT			AT		
				TC (Cu)	DC			ESR(mm)		TC (Cu)	DC			ESR(mm)									
					P %	L %	E %	1/2 hr	1hr		P %	L %	E %	1/2 hr	1hr			Alb	Sug	Dep	Alb	Sug	Dep
21	7248	DEEPIKA	8yrs/FC	16300	76	19	5	10	19	12300	77	20	3	6	13	13	13.6	Nil	Nil	Nil	Nil	Nil	Nil
22	7290	HARISH MAIYAPPAN	31/2yrs/MC	10300	72	23	5	7	15	10500	73	24	3	3	10	11.4	11.8	Nil	Nil	Nil	Nil	Nil	Nil
23	7247	MITHILESH SAI	31/2yrs/MC	8600	62	29	9	6	10	9300	63	33	4	3	7	11.8	12.1	Nil	Nil	Nil	Nil	Nil	Nil
24	7502	MANIMARAN	6yrs/MC	6900	40	51	9	5	15	8100	44	52	4	2	12	10.5	10.9	Nil	Nil	Nil	Nil	Nil	Nil
25	7686	SAISARAN	4yrs/MC	7400	42	51	7	7	15	8200	53	43	4	4	12	11.4	11.8	Nil	Nil	Nil	Nil	Nil	Nil
26	4774	SRIMATHI	10yrs/FC	8600	62	3	7	5	15	8500	58	39	3	3	9	13	13.1	Nil	Nil	Nil	Nil	Nil	Nil
27	6353	JOSHIKA	5yrs/FC	10000	57	38	5	13	20	9800	58	39	3	6	13	12.4	12.6	Nil	Nil	Nil	Nil	Nil	Nil
28	7574	SHYAM	8yrs/MC	7200	64	30	6	5	12	8100	66	30	4	3	9	10.2	10.6	Nil	Nil	Nil	Nil	Nil	Nil
29	7706	ALIYAN	6yrs/MC	9500	68	26	6	10	22	9800	69	27	4	6	15	11	11.4	Nil	Nil	Nil	Nil	Nil	Nil
30	8248	SRINITHI	6yrs/FC	13100	65	30	5	10	25	12400	67	30	3	5	18	12.5	12.8	Nil	Nil	Nil	Nil	Nil	Nil
31	9070	BHUVANESH	3yrs/MC	4600	61	34	5	7	14	6300	62	35	3	4	9	11.9	12.1	Nil	Nil	Nil	Nil	Nil	Nil
32	9140	DHARANI	9yrs/FC	8000	40	53	7	3	5	8600	51	45	4	2	4	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
33	8999	LOHITH	8yrs/MC	10000	58	36	6	9	15	9800	59	37	4	4	8	13	13.2	Nil	Nil	Nil	Nil	Nil	Nil
34	393	SAIKRISH	3yrs/MC	11200	37	56	7	2	10	10800	58	38	4	2	5	11.4	11.8	Nil	Nil	Nil	Nil	Nil	Nil
35	392	THARUN RAM	7yrs/MC	15300	71	23	6	12	22	10900	69	28	3	5	16	12.1	12.4	Nil	Nil	Nil	Nil	Nil	Nil
36	1513	RANJITH	31/2yrs/MC	5800	58	35	7	7	15	7200	59	36	5	4	9	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil
37	1640	NAKSHATHIRA	8yrS/FC	6500	60	32	8	5	12	7300	62	34	4	3	8	12	12.4	Nil	Nil	Nil	Nil	Nil	Nil
38	2912	DHANALAKSHMI	7yrs/FC	5700	48	45	7	25	58	6300	50	46	4	12	40	10.6	10.8	Nil	Nil	Nil	Nil	Nil	Nil
39	6264	JAGATHRAJ	9yrs/MC	5200	47	45	8	3	5	6800	50	46	4	2	4	12.3	12.8	Nil	Nil	Nil	Nil	Nil	Nil
40	6591	SRIPRIYA	11yrs/FC	6800	52	38	10	7	15	7300	56	40	4	4	11	12.9	13	Nil	Nil	Nil	Nil	Nil	Nil

DISCUSSION

DISCUSSION

Neer kana maantham is a most common, repeated disease of the children mainly affecting the upper respiratory tract with or without inflammation. The disease is characterized by cough, running nose, fever, malaise, diarrhea and lack of appetite.

In this study, 40 cases were selected according to the proforma with undergone investigation and treated with the trail drug **MANJANAATHI KUDINEER** for 7days with after treatment investigation in the **OPD of PG-Dept of Kuzhanthai Maruthuvam, Govt.Siddha Medical College** attached to **Arignar Anna Hospital of Indian Medicine, Chennai-106.** The data were collected and prognosis of the disease with the trial drug was clearly observed.

This study evaluate the effect of **"MANJANAAATHI KUDINEER " on NEER KANA MAANTHAM (ACUTE NASO PHARYNGITIS)**.

The observation are described here

1.Age distribution

According to children age under 2-3years of age group were 17.5%, 4-6years were 42.5%, 7-10years of age group were 35%, 11-12years of age were 5% respectively. Hence this study reveals that Neer Kana Maantham was prevailed more in 4-6years children.

2. Gender distribution

Among the cases for this study, 27(67.5%) children were male and 13(32.5%) children were female. According to modern theory there is no apparent gender prediction.

3.Family history

According to family history, 6(15%) cases were reported positive family history and 34(85%) cases have negative family history. Hence family history may impact on Neer Kana Maantham.

4.Diet History

According to 40 patients 5(12.5%) were vegetarians and 35(87.5%) were noon-vegetarians.

5.Socio-Economic status

Regarding socio-economic status, 21(52.5%) cases were belong to poor status, 15(37.5%) cases were belong to middle class and 4(10%) cases belong to high class. The highest incidence was observed in poor class children due to poor hygiene.

6.Uyir Thathukkal

Disturbance of Vatham

In 40 cases, among 10types of Vatham, Vyanan, Udhanan, Samanan and Kirukaran are affected. Udhanan and Kirukaran are affected in 40(100%) of cases, Vyanan is affected in 4(10%) of cases and Samanan is affected in 15(37.5%) of cases.

Disturbance of Pitham

In 40 cases, among 5types of Pitham, Anal pitham is affected in 33(82.5%)of cases, Ranjaga pitham is affected in 8(20%) of cases and Sathaga pitham is affected in 9(22.5%) of cases.

Disturbance of Kabam

In 40 cases, among 5types of Kabam, Avalambakam is affected in 40(100%) of cases and Klethakam is affected in 10(25%) of cases.

7.Udarthathukkal

In Udarthathukkal, Saaram was affected in 40(100%) of cases and Senneer was affected in 8 (20%) of cases.

8.Ennvagai Thervugal

Among 40 cases, Naa is affected in 11(27.5%) of cases, Niram is affected in 7(17.5%) of cases, Vizhi is affected in 7(17.5%)of cases, Sparism is affected in 10(25%) of cases and Naadi is felt among 40 cases were Vathapitham in 15(37.5%) cases, Vathakabam in 12(30%) cases and Pithakabam in13(32.5%) cases.

9.Nei kkuri

Among 40 cases, Vatha veer was observed in 28(70%) cases, Pitha neer was observed in 10(25%) cases, Kaba neer was observed in 2(5%) cases.

10.According to Paruvakaalam

Regarding Paruvakaalam among 40 cases, 4(10%) cases were reported in Kaarkalam, 8(20%) cases were reported in Koothir kaalam,0 cases were reported in Elavenil kaalam, 26(65%) cases were reported in Munpani kaalam, 2(5%) cases were reported in Pinpani kaalam and 0 cases were reported in Muduvenil kaalam respectively.

11.Distribution of Nilam

All the 40 cases reported were from surroundings of Chennai which belongs to Neithal nilam.

12.Clinical Presentation

Out of 40 patients, before treatment all the 40 patients (100%) had cough, 40(100%) had running nose, 6(15%) had fever and 4(10%) had malaise. After treatment most of the patients were relieved from the symptoms of cough, fever, running nose and malaise. Improvement in appetite is increased din most of the cases additionally.

13.Phytochemical analysis

The phytochemical analysis of the trial drug shows that the drug contains alkaloids, flavonoids, carbohydrates, iron, chloride, tri terpenoids, phenol, glycosides, tannins and protein.

14.Toxicity study of the drug

Acute toxicity study of the trial drug was carried out in Wistar Albino rat's reveals that the drug has no adverse effects, so it is safe for human beings.

15.Physicochemical analysis

Ash value – 11.53%

16. Bio Chemical Analysis

Bio chemical analysis of the drug showed the presence of chloride, iron and zinc.

17.Pharmacological analysis

Pharmacological analysis showed the drug has convincing Anti-microbial activity against the gram positive bacteria, gram negative bacteria.

18.Statistical Analysis

The preclinical studies of the trial medicine statistically analyzed and showed significant result.

19.Results

The outcome of this study showed encouraging results. Among the 40 patients good improvement was observed in 33(82.5%)cases, moderate improvement was observed in 5(12.5%)cases and mild improvement in 2(5%)cases and no adverse events observed clinically during the course of treatment.

SUMMARY

SUMMARY

The disease Neer Kana Maantham was taken for the clinical study with Manjanaathi Kudineer as internal medicine. For the clinical study, 40 patients were selected based on Inclusion and Exclusion criteria. The study is conducted after the drug being screened by the Screening Committee and the trial is also approved by the Institutional Ethical Committee (IEC). Animal studies are carried out after obtaining proper permission from the Institutional Animal Ethical Committee (IAEC). Hence the study is safely executed on human volunteer patients and there was no adverse drug reactions noted during the study period. 40 children with Neer Kana Maantham diagnosed clinically treated in out patient department of Arignar Anna Hospital of Indian Medicine, Chennai-106. They were observed for clinical improvement, laboratory investigation done and treated with trial drug.

I like to summarize this study with the following highlights.

- The efficacies of the trial drug Manjanaathi Kudineer were studies and observed in this study.
- Clinical diagnosis of Neer Kana Maantham was done on the basis of clinical features described in Bala Vagadam .
- The cost of the trial medicines are low, comparatively economic.
  These drugs are easily available and the dosage is also convenient.
- The potency of the trial drug were studied by phytochemical analysis, physic chemical analysis and pharmacological analysis.

Phytochemical analysis of the trial drug reveals that the presence of alkaloids, flavonoids, carbohydrates, iron, chloride, tri terpenoids, phenol, glycosides, tannins and protein.

- The physico chemical analysis of the trial drug shows the Ash value 11.53. So it shows the safety and effectiveness of the drug.
- The pharmacological analysis of the drug reveals that it possesses convincing Anti-microbial property.

- Among the 40 cases treated 33 cases(82.5%) had shown Good improvement, 5cases(12.5%) had shown Moderate improvement, 2cases(5%) had shown Mild improvement.
- Observation made during the clinical study showed that the trial drug was clinically effective and has no adverse effect.

CONCLUSION

CONCLUSION

Neer Kana Maantham is a common disease in children and mainly caused by derangement of the Kaba kuttram. In this clinical study Manjanaathi Kudineer was taken as Internal medicnine respectively. The deranged kabam is settled down by the kaarppu suvai in the trial medicine there by the medicine acts as Ethirurai maruthuvam to cure the disease. Toxicological studies showed no acute toxicity. The drug has got Anti-microbial activity. The cost of the trial medicine are low. During the clinical study no adverse events were observed.

The clinical study confirms the efficacy of the trial drugs by reducing the clinical signs and symptoms like cough, cold, running nose, fever and loss of appetite. Clinical study results found to be Good in 33cases(82.5%), Moderate in 5 cases(12.5%) and Mild in 2 cases (5%). The clinical trial conducted in selected patients was satisfactory and encouraging. The trial medicine is effective for Neer Kana Maantham in children. Through this study, the effectiveness of trial drug is confirmed and re-established by the author and concluded that the trial drug "**Manjanaathi Kuineer**" is effective in treatment of Acute Nasopharyngitis (Common cold).

BIO STATISTIC ANALYSIS

BIO STATICAL ANALYSIS

Treatment for Neer Kana Maantham(Acute Naso Pharyngitis)

The most popular non parametric statistical tool, namely, McNemer Test analysis has been employed to analyze the effectiveness with the help of hypothesis.

S.NO	Clinical Features	Before Treatment	After treatment
		n%	n%
1	Cough	40(100)	3(7.5)*
2	Running nose	40(100)	5(12.5)**
3	Fever	6(15)	1(2.5)***
4	Malaise	4(10)	1(2.5)***
5	Diarrhea	0	0

McNemar's test : C.I:95% *P*<0.001 **P= 0.063 ***P<0.2500

Software : spss 16 version

Number of cases : 40

Inference :

Since the p value is significant in all signs and symptoms. So there is significant reducing of signs and symptoms among the patients for the treatment of Neer Kana Maantham (Acute Naso pharyngitis). Hence it is concluded that the treatment effective and **significant**.

ANNEXURES

CERTIFICATES

GOVERNMENT SIDDHA MEDICAL COLLEGE
Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-2/016/2017

Protocol title: AN OPEN CLINICALSTUDYON NEER KANA MANTHAM(ACUTE NASO PHARYNGITIS) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIALDRUG MANJANAATHI KUDINEER CHOORANAM.	
Principal Investigator:	Dr. M.HARIPRIYA
Name & Address of Institution: Government Siddha Medical College, Arumbakkam, Chennai-106	
☑ New Review	☐ Revised Review ☐ Expedited Review
Date of review (DD/MM/YY):	06-04-2017
Date of Previous Review, If Revised Application:	
Decision of the IEC	
☐ Recommended	☑ Recommended with suggestions
☐ Revision	☐ Rejected
Suggestions / Reasons / Remarks:1.Dosage: based on Age 15 ml. 2.No Need preclinical Study. 3.Add Tonsilitis and Rheumatic fever in Exclusion criteria. 4. Add Throat swab in investigation.Not need X-Ray PNS.	
Recommended for a period of 1 year from date of completion of preclinical studies:	

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.K.Kanakavalli
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date : 06.04.2017
Sub : IEC Review of research proposals
Ref : Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
Dr.P JEYAPRAKASH NARAYANAN. M.D(S)., Chairman	✓	
Dr. K. KANAKAVALLI., MD(S)., Member secretary	✓	
Dr.SATHYA RAJESWARAN M.D(S), Clinician - Siddha	✓	6/4/17
Dr.KABILAN M.D(S), Clinician - Siddha	✓	6/4/17
Dr.R.VASUDEVAN, M.D(S)., PG.DIP (Clinical research), Msc (Medical sociology), Sociologist	✓	6/4/17
Dr.L.MUKUNTHAN, M.B.B.S.,DNB (Medicine)., Modern medicine specialist,	✓	6/4/17
Dr. JOSEPH MARIYA ADAIKKALAM, M.D(S)., Msc epidemiology., Social scientist,	✓	06/04/17
Dr.G.DAYANAND REDDY, M.Pharm, Ph,D., Biomedical scientist	✓	06/04/17
Mr.B.PADMANABHA PILLAI, Philosopher		
Mrs. PREETHA SARAVANAN, Public person		

Dr.P.Jeya prakash narayanan M.D(s).,
Chairman

Dr.K.Kanakavalli, M.D(s)
Member secretary

Government Siddha Medical College
Department of Medicinal Botany

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,
Asst. Professor
Head of the Department

6, Anna Arch Rd,
NSK Nagar,
Arumbakkam, Chennai,
Tamil Nadu 600106.

AUTHENTICATION CERTIFICATE

Based upon the organoleptic/macroscopic/microscopic examination of fresh/market sample, it is certified that the specimen given to Dr. M. Haripriya B.S.M.S. doing M.D. (S) in Department of Kuzhanthai maruthuvam at Government Siddha Medical College, Arumbakkam, Chennai-106 is identified below as

S.NO	DRUG NAME	BOTANICAL NAME	FAMILY NAME
1	NOTCHI THULIR	*VITEX NEGUNDO*	LAMINACEAE
2	VASAMBU	*ACORUS CALAMUS*	ACORACEAE
3	OMAM	*CARUM COPTICUM*	APIACEAE
4	VASAMBU	*CAESALPINIA BONDUC*	FABACEAE
5	UTHAMANI ILAI	*PERGULARIA DAEMIA*	ASCLEPIADACEAE
6	PODUTHALAI KAAI	*PHYLA NODIFLORA*	VERBENACEAE
7	CHUKKU	*ZINGIBER OFFICINALE*	ZINGIBERACEAE
8	NUNA ILAI	*MORINDA TINCTORIA*	RUBIACEAE
9	MILAGU	*PIPER NIGRUM*	PIPERACEAE
10	THIPPILI	*PIPER LONGUM*	PIPERACEAE

References: Flora of Presidency, Gamble, J. S

Date: 05.04.2018

Place: Chennai

05/04/2018

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,

Head
Dept. of Maruthuva Thavaraiyal
(Medicinal Botany and Pharmacognosy)
Govt. Siddha Medical College,
Arumbakkam, Chennai - 600 106

Phone : 24960151, 24962592, 24960425
e-mail : clbaidmethacollege@gmail.com
Website : www.clbaidmethacollege.com

C.L. Baid Metha College of Pharmacy

An ISO 9001:2008 approved institution
Old Mahabalipuram Road,
Thoraipakkam, Chennai - 600 097.

Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai.
Approved by Pharmacy Council of India, New Delhi, and
All India Council for Technical Education, New Delhi

CERTIFICATE

This is to certify that the project title "An open clinical study on NEER KANA MAANTHAM (ACUTE NASOPHARYNGITIS) in children with the evaluation of siddha trial drug MANJANAATHI KUDINEER CHOORANAM" for its toxicological, ANTI MICROBIAL activity in Wistar albino rats has been approved by IAEC.

IAEC No: LV/09/CLBMCP/2018

C.L. Baid Metha College of Pharmacy ★ CHENNAI-97 ★ Thoraipakkam

Dr.P.Muralidharan

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

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

This Certificate is awarded to Dr/~~Mr~~/~~Mrs~~.....M..HARIPRIYA.....

For participating as ~~Resource Person~~ / Delegate in the Twenty Fourth 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 24th to 28th April 2017.

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

Prof.**Dr.T.BALASUBRAMANIAN,** M.D.,D.L.O.,
REGISTRAR

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

Ministry of AYUSH

Global Acceptance for Siddha System of Medicine : Scope and Challenges

A NATIONAL CONFERENCE

Certificate of Appreciation

This certificate is proudly presented to Dr. Hariniya. M.

for authoring / ~~co-authoring~~ / ~~presenting~~ / ~~co-presenting~~ the ~~oral~~ / poster presentation entitled " A Literature Review of using clay vessels"

in the National Conference on "Global Acceptance for Siddha System of Medicine: Scope and Challenges" organised by Central Council for Research in Siddha (CCRS) with the support of Ministry of AYUSH held on 28th & 29th September, 2018 at Amma Arangam, Shenoy Nagar, Chennai - 600 030.

Dr. S. Selvarajan
Organising Secretary
Research Officer (Siddha) S-II, CCRS

Dr. N.J. Muthukumar
Chairman & Convener
Director General, CCRS

CENTRAL COUNCIL FOR RESEARCH IN SIDDHA
Ministry of AYUSH, Govt. of India
Arumbakkam, Chennai – 600106.

LOYOLA COLLEGE

(Autonomous, Affiliated to University of Madras)
College of Excellence, NAAC Acredited A++, Chennai - 600 034. Tamil Nadu.

National Conference on

Biochemistry and Therapeutics of Diabetes and Cancer Treatment & Challenges

(BTDCTC - 2019)

February 28 & March 1, 2019

Organised by

Ethnopharmacology and Microbial Biotechnology Lab,
Department of Plant Biology and Biotechnology

Certificate

This is to certify that ~~Mr./Ms.~~/Dr. M. Hasipsiya of Govt. Siddha Medical College, Chennai has participated / ~~presented~~ a paper (Oral/Poster) in the National Conference on Biochemistry and Therapeutics of Diabetes and Cancer Treatment & Challenges (BTDCTC-2019) held on February 28 & March 1, 2019.

D. Agastian
Dr. P. AGASTIAN
CONVENOR, BTDCTC-2019
Dept. of Plant Biology & Biotechnology

Rev. Dr. F. ANDREW, S.J
PRINCIPAL
Loyola College

International Conference on

"Sports Medicine, Yoga, Fitness Therapy & Rehabilitation"

SYFTR-2019

Date: 11th and 12th March 2019

CERTIFICATE

This is to certify that Mr/Ms/Dr/Prof M. HARIPRIYA, GSMC has participated/Chaired a session in the International conference, organized by Research and Development wing, Sree Balaji Medical College & Hospital, Chromepet, Chennai, Tamil Nadu, India. He/she has presented a Paper entitled on_____ and the CME Points Awarded_____

Prof . S. Benjamin Prakash
German University of Physical Education & Sports Sciences Cologne,Germany

Prof. Senthamil R. Selvan
Principal Scientist, Biomarker Strategies Rockville, MD,USA

Prof.W.M.S. Johnson
Dean -Incharge
SBMCH

Prof. P. Ramasamy
Director -Research
SBMCH

FORMS

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORNAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASOPHARYNGITIS) IN CHILDREN

FORM l - SCREENING AND SELECTION PROFORMA

1. OP NO : .....

2. NAME : …….....

3. AGE : …… 4.GENDER : …….....

5. F.OCCUPATION : …… 6.F.INCOME: ……

7. ADDRESS : …….....

…….....

…….....

8. CONTACT NO : ……

INCLUSION CRITERIA:

- Age : 2-12 Years Yes/ No
- Running Nose Yes/ No
- Cough Yes/ No
- Fever Yes/ No
- Malaise Yes/ No
- Diarrhea Yes/No
- Patients who are willing to undergo Laboratory investigation. Yes/No
- Patients who are willing to sign the informed consent stating that he/she will continuously stick to the treatment during 7 days but can opt out of the trial of her own conscious discretion. Yes/No

I will include patient having atleast 2 to 4 symptoms.

EXCLUSION CRITERIA:

- Allergic Rhinitis
- Bronchitis
- Bronchial Asthma
- Severe Diarrhea with other complications

ADMITTED TO TRIAL:

YES **NO**

If yes, **OPD/IPD**

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORANAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM" (ACUTE NASOPHARYNGITIS) IN CHILDREN

FORM II -HISTORY TAKING PROFORMA

1. SERIAL NO. OF THE CASE: ……..... 2. OP/IP .....

3. NAME: …… 4. AGE: ……..... 5. GENDER: …….....

5. F. OCCUPATION: …… 6. F. INCOME: …….....

7. COMPLAINTS & DURATION:

8. PERSONAL HISTORY:

9. HISTORY OF PREVIOUS ILLNESS:

10. BIRTH HISTORY:

11. DIETARY HABIT:

1.Vegetarian

2.Non-vegetarian

12. FAMILY HISTORY:

Whether this problem runs in family?

1. Yes 2. No

If yes, mention the relationship of affected person(s) _____

History of previous investigations if any _____

Date:

Station

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SDIDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORNAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASOPHARYNGITS) IN CHILDREN

FORM III ASSESSMENT PROFORMA

1. SERIAL NO: …….....

2. OP / IP NO: .....

3. NAME: ……..... 4.AGE: ……..... 5.GENDER: .....

GENERAL EXAMINATION:

Height (cms) : …….

Weight (kg) : …….

Temperature(°F) : …….

Pulse rate(/min) : …….

Heart rate(/min) : …….

Respiratory rate(/min) : …….

Blood pressure(mm/Hg) : …….

	Present	Absent
Pallor		
Jaundice		
Cyanosis		
Lymphadenopathy		
Pedal edema		
Clubbing		
Jugular vein pulsation		

SYSTEMIC EXAMINATION

CardioVascular System : …….

Respiratory system : …….

Gastro-intestinal system : …….

Central Nervous System : …….

Urogenital system : …….

Endocrine System : …….

SIDDHA SYSTEM OF EXAMINATIONS:

1. THEGI: [BODY CONSTITUTION]

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

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

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

3. KAALAM:

1. Kaar kaalam
2. Koothir kaalam
3. Munpani kaalam
4. Pinpani kaalam
5. Ilavenil kaalam
6. Muthuvenil kaalam

4. GUNAM:

1.Sathuvam 2.Raasatham 3.Thaamatham

5. IMPORIGAL (SENSORY ORGANS):

Normal / Affected

Mei ----------

Vaai ----------

Kann ----------

Mukku ----------

Sevi ----------

6. KANMENDHIRIYAM (MOTOR ORGANS):

Kai ----------

Kal ----------

Vaai ----------

Eruvai ----------

Karuvaai ----------

7. KOSANGAL (SHEATH):

Annamaya kosam ----------

Pranamaya kosam ----------

Manomaya kosam ----------

Vignana maya kosam ----------

Anandamaya kosam ----------

8. UYIR THAATHUKKAL: **[THREE HUMORS] (VALI, AZHAL, IYAM)**

A) VALI

Pranan _____

Abanan _____

Samanan _____

Uthanan _____

Vyanan _____

Naagan _____

Koorman _____

Kirukaran _____

Devathathan _____

Dhananjayan _____

B) AZHAL

Analakam _____

Ranjakam _____

Sathakam _____

Prasakam _____

Alosakam _____

C) IYAM

Avalambagam _____

Kilethagam _____

Pothagam _____

Tharpagam _____

Santhigam _____

9. SEVEN UDAL THATHUKKAL: (SEVEN SOMATIC COMPONENTS)

Saram _____

Senneer _____

Oon _____

Koluppu _____

Enbu _____

Moolai _____

Sronitham _____

10. ENVAGAI THERVU:

I. NAADI: [PULSE PERCEPTION]

II. SPARISAM: [PALPATION]

III. NAA: [TONGUE]

IV. NIRAM: [COMPLEXION]

1. Vadham
2. Pitham
3. Kabam

V. MOZHI: [VOICE]

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

VI. VIZHI: [EYES]

VII. MALAM: [BOWEL HABITS / STOOLS]

Niram

Irugal

Ilagal

Others

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Niram

Manam

Edai

Nurai

Enjal

NEIKKURI:

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORNAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASOPHARYNGITIS) IN CHILDREN

FORM IV: LABORATORY INVESTIGATIONS PROFORMA

1. SERIAL NO. OF THE CASE: …….....

2.OP / IP NO:.....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

A) BLOOD INVESTIGATIONS:

BLOOD INVESTIGATIONS		**BEFORE TREATMENT**	**AFTER TREATMENT**
Hb (gm/dL)			
Absolute eosinophil count (Cells/ul)			
ESR (mm)	**½ hr.**		
	1 hr.		
T.WBC (Cells / Cu.mm)			
Differential Count (%)	**Polymorphs**		
	Lymphocytes		
	Monocytes		
	Eosinophils		
	Basophils		

B) URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar		
Deposits		

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORNAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASOPHARYNGITIS) IN CHILDREN

FORM V: INFORMED CONSENT FORM

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

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

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

Date:

Signature of the participant:

In case of illiterate participant

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

Date:

Signature of a witness Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE, CHENNAI

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORNAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASOPHARYNGITS) IN CHILDREN

FORM VI - WITHDRAWAL FORM

SI NO :

OP / IP NO :

NAME :

AGE / GENDER:

DATE OF TRIAL COMMENCEMENT :

DATE OF WITHDRAWAL FROM TRIAL :

REASONS FOR WITHDRAWAL:

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

Date:

Station:

Signature of the Guide **Signature of the Investigator**

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORNAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASOPHARYNGITS) IN CHILDREN

FORM VII – PATIENT INFORMATION SHEET

Name of Co- Investigator: M.Haripriya

Name of the college:

Govt.Siddha Medical College

Arumbakkam

Chennai-106.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL

M.Haripriya studying M.D (Siddha) at Govt. Siddha Medical College, Chennai, is doing a clinical trial on "**MANJANAATHI KUDINEER**" in the treatment of **''NEER KANA MAANTHAM" – ACUTE NASOPHARYNGITS** in children.

It is becoming a most common disease, occurring throughout the world. In this regard, I am in need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine ‘‘MANJANAATHI KUDINEER " (Internal medicine) for 7days.

The information I am collecting in this study will remain between you and the Co-investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.

The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact M.Haripriya, PG Scholar cum Co- investigator of this study, attached to Government Siddha Medical College, Chennai-106. You can also contact the Member-secretary of Ethics committee, Govt. Siddha Medical College, Chennai.

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON **"MANJANAATHI KUDINEER CHOORNAM"** IN THE TREATMENT OF

"NEER KANA MAANTHAM'' (ACUTE NASOPHARYNGITIS) IN CHILDREN

FORM X - ADVERSE REACTION REPORTING FORM

SERIAL NO :

OP/IP NO :

NAME : AGE: GENDER:

DATE OF TRIAL COMMENCEMENT:

DATE OF OCCURRENCE OF THE ADVERSE REACTION: TIME:

DESCRIPTION OF ADVERSE REACTION:

MANAGEMENT:

Date:

Station:

Signature of the Guide **Signature of the Investigator**

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106
அறிஞர் அண்ணா மருத்துவமனை, சென்னை.

நீர்க்கண மாந்தம் நோய்க்கான் சித்த மருத்தின் (**மஞ்சணாத்திக் குடிநீர்**)
பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான் தகவல் படிவம்.
ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

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

நான் எனது குழந்தையின் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுத்ய வேண்டுமானாலும் இந்த ஆய்விலிருந்து எனது குழந்தையின் விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு நோய்க்கான **மஞ்சணாத்திக் குடிநீர்** மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

தேதி: சாட்சிக்காரர் கையொப்பம்:

இடம்: பெயர்:

உறவுமுறை:

துறைத்தலைவர் கையொப்பம்: ஆராய்ச்சியாளர் கையொப்பம்:

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106

அறிஞர் அண்ணா மருத்துவமனை, சென்னை.

நீர்க்கண மாந்தம் நோய்க்கான் சித்த மருத்தின் (**மஞ்சணாத்திக் குடிநீர்)**

பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான் தகவல் படிவம்.

ஆராய்ச்சியாளர் பெயர் : ம.ஹரிப்பிரியா.

நிறுவனத்தின் பெயர் : அரசு சித்த மருத்துவக் கல்லூரி

அரும்பாக்கம், சென்னை-106.

அரசு சித்த மருத்துவக் கல்லூரியில் பட்ட மேற்படிப்பு பயின்று வரும் நான் மருத்துவர். ம.ஹரிப்பிரியா. **நீர்க்கண மாந்தம்** என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இந்த நோய் கிருமிகளினால் எற்படுகின்றன. இது பரவக் கூடிவ நோய்.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான் ஆய்வகப் பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன்.

இந்த ஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக **மஞ்சணாத்திக் குடிநீர்** 2 வேளை(காலை, மாலை) உணவுக்கு பின் 7 நாட்கள் உட்கொள்ள வேண்டும்.

இந்த மருந்து சிறப்பாக நீர்க்கண மாந்தம் நோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது.

இந்த ஆராய்ச்சியில் தங்களை அனுமதித்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் ஆராய்ச்சியில் இருந்து விலகிக் கொள்ள உரிமை உள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக நோயின் தன்மை பற்றியும் மற்ற விபரங்களுக்கும் ஆராய்ச்சியாளர் மருத்துவர் : ம.ஹரிப்பிரியா (பட்ட மேற்

படிப்பாளர் குழந்தை மருத்துவ துறை) அவர்களை எந்த நேரத்திலும் தொடர்பு கொள்ளலாம். கைப்பேசி எண் : 8220321809.

மேலும் இந்த ஆராய்ச்சிக்கு தக்க அனுமதிச் சான்று(IEC) பெறப்பட்டுள்ளது.

இந்த மருந்து முற்றிலும் பாதுகாப்பான மூலிகை பொருட்களைக் கொண்டு தயாரிக்கப்பட்டுள்ளது. பக்க விளைவுகளை ஏற்படுத்தாது.

மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்த படுகிறது.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப் பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் அறிஞர் அண்ணா மருத்துவமனையில், தக்க சிகிச்சை அளிக்கப்படும்.

CASE SHEET PROFORMA

Department of PG Kuzhanthai Maruthuvam			
Dissertation study on NEER KANA MAANTHAM			
Guide: Dr.R.Meenakumari M.D.(S),		**Investigator:Dr.** M.Haripriya PG Scholar	
Aringar Anna hospital OPD,Chennai-106			
NAME		**OP.NO**	
AGE/SEX		**DATE**	
CONTACT NO		**DIAGNOSIS**	
ADDRESS			

COMPLAINTS AND DURATION		
a)cough	☐ Yes	☐ No
b)Runningnose	☐ Yes	☐ No
c)Fever	☐ Yes	☐ No
d)Malaise	☐ Yes	☐ No
e)Diarrhoea	☐ Yes	☐ No
Other complaints		

PAST HISTORY					
FAMILIAL HISTORY					
MODE OF ONSET	☐ Acute	☐ Chronic			
FOOD HABITS	☐ Veg	☐ Non-veg			
ECONOMIC STATUS	☐ Poor	☐ middle	☐ rich		

ON EXAMINATION	
Height	
weight	
CVS	
RS	
Others	

Department of PG Kuzhanthai Maruthuvam						
Dissertation study on NEER KANA MAANTHAM with evaluation of MANJANAATHI KUDINEER						
Guide:Dr.R.MEENAKUMARI ,MD(s)			**Investigaor:Dr.M.HARIPRIYA ,PG scholar**			
Aringar Anna hospital OPD,Chennai-106						
ENVAGAI THERVU						
Naa						
Niram						
Mozhi						
Vizhi						
Sparism						
Malam						
Moothiram						
Naadi						
INVESTIGATION						
Before treatment			**After treatment**			
Blood			**Blood**			
TC			**TC**			
DC			**DC**			
ESR			**ESR**			
HB			**HB**			
Others			**Others**			
MEDICINE						
PROGNOSIS						
WEEKS/DATE	**COUGH**	**RUNNING NOSE**	**FEVER**	**MALAISE**	**DIARRHOEA**	**M.OSIGN**

RECURRENCE

RESULT

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