AN OPEN CLINICAL STUDY ON "PAANDU NOI" (IRON DEFICIENCY ANAEMIA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG KARISALANKANNI CHOORANAM

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CERTIFICATE

This is to certify that the dissertation entitled "AN OPEN CLINICAL STUDY ON PAANDU NOI" (IRON DEFICIENCY ANEMIA) is a bonafide work done by Dr. K. Karpagavalli, 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.

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INTRODUCTION

Siddha system is said to be one among the Indian system of medicines, i.e., it is one in the AYUSH group. Siddhars are those who lived and maintained their body as they desired best. They were the devotees of Lord Siva and rejected everthing else in Tamil Saiva system which was inconsistent with pure theism.

There are various principles present in Siddha system said by different Siddhars. The major and common concept of Siddha deals with Five Boodhas and Three Humours, respectively Prithivi, Appu, Theyu, Vaayu, Aagayam along with Vatham, Pitham and Kapham.

"நிலந்தீ நீர்வளி விசும்போ டைந்தும் கலந்த மயக்கம் உலகம் ஆதலின்".

- தொல்காப்பியம்

The physiology, pathology, diagnosis and treatment in siddha is based on the above said three humours. When these Humours in the human body get affected, it is said to be Dhosha or kutram. The fluctuations of these humours leads to disease, the repair of these kutrams is the treatment procedure in Siddha.

" வாதமாய்ப்படைத்துப்பித்த வன்னியாய்க்காத்துச்சேத்ப சீதமாய்த்துடைத்துப்பாராந் தெகத்திற்குடியாமைந்து".

- நோய் நாடல் நோய்முதல் நாடல் 2

Our Siddhars, not only concentrated on the diagnosis and treatment, they have followed and given a various principles to lead a healthy and hygienic life. Siddha is built by vast number of Siddhars, such as Navanadha siddhar, padhinen siddhar, navakodi siddhar, nava siddhar. In this, padhinen siddhargal plays a major role in the Siddha system.

Agathiyar is said to be the first siddhar in padhinen sidhargal. He have described that there are 4448 diseases in his book Agathiyar rathna churukka naadi. It includes 62 types of diseases and its classifications. According to this, Paandu noi is classified into 10 types.

Paandu noi symptoms are more or less equivalent to Iron deficiency anaemia. Iron Deficiency Anaemia (IDA) is a very common disease prevalent in the society. Long term oral iron therapy is commonly used as first line therapy but iron salts such as ferrous sulphate are associated with a high incidence of gastrointestinal side effects such as nausea, vomiting, diarrhoea or constipation. Because of their adverse effects, a safe, effective, cheap, and easily available drug is needed. Many drugs are available in Siddha system of medicine which have remarkable effects in treating anaemia. One such medicine is Karisalankanni chooranam is indicated for anaemia mentioned in Siddha classical literature.

With the aim of that, this Poly Herbal preparation may be effective to manage childhood IDA without any synergistic effects. The present study was carried out to study the efficacy and safety of the Siddha poly herbal compound drug karisalankanni chooranam with the application of modern parameters.

AIM AND OBJECTIVE

AIM:

Paandu noi is an important haematological entity described in siddha literatures. It is essential to find out a simple drug to overcome this disease. The drug should be easily available, economic, easily, administered and also effective in smaller doses. Karisalankanni chooranam possess all the above characters. This is the reason for selecting this drug.

OBJECTIVES

- 1. To collect the literature of both siddha and modern aspects of the disease paandu noi.
- 2. To have an idea about the prevalence of paandu noi with reference to age, sex, socio-economic status, poverty, seasonal variations etc.
- 3. To know the aetiology, classification, symptoms, diagnostic methods and line of treatment compared with Iron deficiency anaemia.
- 4. To know the alteration of the disease under the topics mukkutram, udal kattukal, poripulangal, envagai thervukal, neerkuri, neikuri.
- 5. To make a clinical trial on patients with the trial medicine karisalankanni chooranam in the treatment of paandu noi.
- 6. To make use of modern parameters in the investigation side to confirm the diagnosis and to follow the progress of the patients.
- 7. To elicit bio-chemical analysis, toxicological analysis and pharmacological action of the trial medicine.
- 8. To make an awareness among the parents about the prevention of disease in children.

REVIEW OF LITERATURE SIDDHA ASPECT

வேறுபெயர்:

வெண்மைநோய், வெளுப்பு நோய், வெண்பாண்டம்.

இயல்பு:

இயற்கை நிறமாறி, உடல் வெளுத்து, கண்ணையும் நகக் கண்ணையும் நீக்கிப் பார்க்கின் குருதியின்றி வெளுத்திருக்கும்.

- நோய் நாடல் நோய்முதல் நாடல் பகுதி 2

தேகத்தின் இரத்தத்தில் உள்ள சிவந்த அணுக்கள் குறைந்து தேகம் வெளுத்துவிடுவதற்குபாண்டுநோய் என்று பெயர்.

பாண்டுநோய் இரத்தம் கெட்டு பலவாரான நோய் சேர்வதால் உண்டாகிறது.

- ஆத்மரட்சாமிர்தம்

நம் நாட்டில் குழந்தைகளிடையே அதிக அளவில் கணப்படும் மிக முக்கிய நோய்களில் ஒன்று வெளுப்பு நோய் ஆகும்.

இந்நோய் ஏழை எளிய குடும்பங்களிலும் சுற்றுப்புறச் சுகாதாரத்தை பேனாத சுழ்நிலையிலும் அதிகம் ஏற்படுகின்றது.

அதிக அளவிலுள்ள இந்நோயைக் கட்டுபடுத்த கருவுற்ற காலத்திலேயே தாய்க்கு போதுமான இரும்புச் சத்துள்ளமருந்துகளை அரசு வழங்கி, குழந்தைகளுக்கு இந்நோய் வராமல் தடுக்கிறது. இருப்பினும் பல்வேறு காரணங்களால் இந்நோய் குழந்தைகளுக்கு எளிதில் ஏற்படுகிறது.

வெளுப்பு நோய் குழந்தைகள் பிறந்தது முதல் குழந்தை பருவம் முழுவதும் தொடர வாய்ப்புண்டு. இந்நோய்க்கு சரியான முறையில் சிகிச்சை அளிக்காத நிலையில், இதனை தொடர்ந்து சோபை, காமாலை, இதயநோய்கள் போன்ற நோய்கள் உண்டாகும்.

நோய் ஏற்பட காரணங்கள்:

வெளுப்பு நோய்க்கு மிக முக்கியக் காரணம் குழந்தைப்பருவத்தில் ஏற்படும் ஊட்டச்சத்துக் குறைபாடு ஆகும். இரும்பு சத்துள்ள உணவு வகைகளைத் தவிர்க்கும் நிலையில் நோய் உண்டாகிறது.

- குருதியின் வலிமையைக் குறைக்க கூடிய உப்பு, புளிப்பு, துவர்ப்பு ஆகிய சுவையுள்ள பொருட்களை மிகுதியாக உண்ணும் போது குடலில் இரும்புச் சத்துஉட்கிரகிக்கப் படுவது குறைகிறது.
- > கல், மண், சாம்பல்,திருநீறு, கற்பூரம் போன்ற உண்ணத்தகாத பொருள்களை உண்ணல்(PICA).
- குழந்தை பருவத்தில் அதிகம் உண்டாகும் வாந்தி, கழிச்சல் நோய்களால்
 உடல் வன்மை குறைந்து பாண்டு நோய் ஏற்படலாம்.
- "குடற்கிருமிகள்" நோய் அனைத்துக் குழந்தைகளிடமும் காணப்படும் பொதுவான ஒரு நோய் ஆகும். இதில் கொக்கிப் புழுவின் (ноок worm) தாக்குதலால் வெளுப்பு நோய் உண்டாகிறது.
- குழந்தைகளுக்கு ஏற்படும் நோய்களான கணம், அக்கரம், வலிப்பு, தோடம்
 போன்ற நோய்களுக்கு சரிவர சிகிச்சை அளிக்காத நிலையில் வெளுப்பு
 நோய் ஏற்படுகிறது.
- பிறவி குறைபாடுகளின் காரணமாக குடலில் உள்ள குடல் உறிஞ்சிகளின் (INTESTINAL VILLI) சரியாக வளர்ச்சி அடையாத நிலையில் உட்கொள்ளும் உணவு உறிஞ்சப்படுவது குறைவதால் இந்நோய் ஏற்படலாம்.
- > உடலின் உட்புறம் ஏற்படும் குருதிக் கசிவு (எ.கா.) நிணக்கழிச்சல், இரைப்பைப் புண்.
- இளம் குழந்தைகளுக்கு நீண்ட காலம் பால் மட்டுமே பிரதான உணவாக வழங்கப்படும் நிலையில் ஊட்டச்சத்து குறைபாட்டால் வெளுப்பு நோய் உண்டாகிறது.
- உடலில் அடிப்பட்டு குருதிக்கசிவு அதிகம் ஏற்பட்டால் அதனை தொடர்ந்து
 பாண்டு நோய் உண்டாகலாம்.
- நாட்பட்ட சுரம், தொற்று நோய்களால் வெளுப்பு நோய் ஏற்படலாம். (எ.கா.)
 மலேரியா.
- நச்சுத்தன்மையுள்ள மருந்துகளை அளவுக்கு அதிகமாக உட்கொள்ளும்
 நிலையில் பாண்டு நோய் உண்டாகலாம்.
- நாட்பட்ட கல்லீரல் வீக்கம், மண்ணீரல் வீக்கம் போன்றவற்றை தொடர்ந்து
 வெளுப்பு நோய் ஏற்படலாம்.

நோய் வரும் வழி

பொதுவாக வளர் இளம் குழந்தைகள் குருதியின் வன்மையைக் குறைக்கக் கூடிய உப்பு புளிப்புள்ள பொருட்களை மிகுதியாகக் கொள்வதாலும், சுரம், பேதி, வாந்தி, கீல்வாயு முதலிய நோய்களுக்குட்படுவதாலும், குருதியை அளவு கடந்து வெளியாக்கும் குருதியழல் நோய், குருதி கழிச்சல், முளைநோய், குருதி வாந்தி முதலியவை எற்படுவதாலும் வெட்டுப்பட்டு மிகுதியாக குருதி வெளிப்படுதலாலும் இந்நோய் உண்டாகும். அன்றியும் நச்சுத்தன்மையுடைய மருந்துகளை நாளளவுக்குமிஞ்சி உண்பதாலும், உடலை இளைக்கச் செய்யும் வயிற்றுபுழுநோய், இளைப்புநோய், நிணக்கழிச்சல் முதலியவைகளாலும் கெடுக்கக்கூடிய குருதிபெருக்கைக் ஈரல்நோய்களாலும், புகையிலை, வெற்றிலைப்பாக்கு, மண், சாம்பல், திருநீறு, கற்பூரம் முதலியவைகளை அடிக்கடி கொள்வதாலும் பாண்டுநோய் வரும்.

நோய் நாடி நோய்முதல் நாடல் பகுதி2

"பிறந்தநாள் பிள்ளைக்குத் தானே நன்றாய் பிதாவாலே பிணியுடலின் மேலே தோன்றும்[®]

"வினையது வருகுநேர்மை விபரமா யுரைக்ககேளாய் அனையது வாகந்தானு மபானனாம் வாயுகூடி புனையது கிழ்மூலத்திற் புக்கினால் தடிக்கும் தேகம் கனலதுமெத்தக்காணும் கண்ணது வெளுக்குந்தானே".

பாலவாகடம்

"கருதிய மீனின் முள்ளும் கலந்துமி நெய்யில் வாலும் மருவிய எலும்புங் கல்லும் மங்கையர் மருந்தீடும் பழகிய பழஞ்சோற்றாலும் பழமல நிறைகையாலும் மருகிய மயிர்களாலும் வந்திடும் நோயதாமே புறவரை யுண்கையாலும் போக நீருண்கையாலும் சுரளவே முடக்கிக் கொண்டு முறக்கிடக்கையாலும் பெருக வெண்டொழியினாலும் பிறக்கநோயென்றே காணே" தேரையர் வாகடம்

தேரையர் வாகடத்தின் கூற்றுப்படி மீன் முள்ளினாலும், முடி, என்பு, கள், பழையசோறு, மாசுபடிந்த குடிநீர், தவறான முறையில் உறக்கம் கொள்வதாலும் பாண்டுநோய் உண்டாகிறது.

"திருந்திடும் பாண்டுரோகங் சேர்ந்திடுங் குணத்தை கேளாய் இருத்திடும் வாத பித்தச் சிலேற்பன மிவைதான் மாறும் பரிந்துதா னொன்றோடொன்று பொருந்துவதாலு மண்ணோடு அருந்துவதாலும் பாண்டு அணைந்திடு மென்னலாமே ஆகிய மூலந்தன்னி லணைந்த வுட்டணத்தினாலுந் தொகையர் மேகந்தாரும் துயர்மிகு சேர்தலாலும் தேகபோசனையுள்ளார்க்குத் தரித்திரஞ் சேர்தலாலும் வேகமாந்திரிதோருங்கள் மிஞ்சியே பாண்டுவாமே" - தன்வந்திரி வைத்தியம்

தன்வந்திரி வைத்தியம் கூற்றுப்படி முக்குற்றங்களின் மாறுபாட்டாலும் மண் முதலியவைகளை உண்பதாலும் பாண்டு நோய் உண்டாகின்றது.

"சொல்லாத கடிவிஷங்கள் குன்மம் பாண்டு துயர்தீராக் கன்மவினை செய்த பாவம் எல்லோரும் நகைக்க உடும்பெடுத்த பாவி இன்னமுண்டு விபரமாய் உலகிற் கேளே."

- அகத்தியர் பரிபூரணம் 400

அகத்தியர் பரிபூரணம் 400 கூற்றுப்படி பாண்டு கன்மவினையாலும் உண்டாகின்றது.

பரதந்திர காரணங்களினால் பாண்டு உண்டாகும் என சரபேந்திர வைத்திய முறைகள் பாண்டு காமாலை சிகிச்சை நூல் கூறியுள்ளது.

"வயல்தனிலே பூநாக மண்ணைத் தானே வருந்தியது பொத்து போல வத்தையாகும் பயில் மொழியீர் தேகத்தில் கிருமிதானே"

- குருநாடி

குருநாடி கூற்றுப்படி கிருமியால் பாண்டு நோய் உண்டாகிறது.
"குறிஞ்சிவரு நிலத்திற் கொற்ற முண்டி ரத்தம்
உறிஞ்சிவரு சுரமுண்டாம் அறிஞருரைக்
கையமே தங்குதரத் தாமை வல்லையுங் கதிக்கும்
ஐயமே தங்கும் அறி".

பதார்த்த குண் சிந்தாமணி

குறிஞ்சி நிலத்தில் வசிப்பவருக்கு பாண்டு நோய் உண்டாகும் என பதார்த்தகுண சிந்தாமணி கூறுகிறது.

நோய் முற்குறிகள்:

- சிறிது தூரம் நடந்தாலும் மூச்சுவாங்குதல்
- உணவில் விருப்பமின்மை
- வாய் குமட்டல்
- தலைசுற்றல்
- கண் இருளல்
- மார்பு துடித்தல்
- உடல் இளைத்தல்

உடலில் பித்தக்குற்றம் அதிகரித்து குருதியின் நிறத்தையும் எடையையும் கெடுத்து உடலுக்கு வேண்டிய ஊட்டச்சத்தினை அளிக்காமல் உடலை வெளுக்க செய்யும் போது மேற்கண்ட நோய் முற்குறிகள் உண்டாகின்றன.

நோய் பொது குறிகுணங்கள்:

இந்நோயில் உடல் வன்மை நாளுக்கு நாள் குறைந்து நடக்க இயலாமை, தலைநோதல், மயக்கமுண்டாதல், மூச்சுத்தடுமாறல், பசித்தீக்கெடல், உணவு வேண்டாமை, உண்ட சிறு உணவும் வாந்தியாதல் ஆகிய குறிகள் தோன்றும். இன்னும் மிகவும் வெளுத்துத் தோல் சுருங்கல், உடல் மெலிந்து பளபளத்து வெளுப்பாதல், நகக் கணுக்கள் தடித்து வெளுத்தல், நாவெடித்து புண்ணாதல் அல்லது நாவின் மேல்தோலைச் சீவியெடுத்தது போன்று சிவந்து காணுதல் தொண்டைக் கட்டல் என்னும் குறிகளும் காணும்.

- யூகி வைத்திய சிந்தாமணி

"செடமது பித்த நீரால் தெளித்ததால் தேக மெங்கும் கடமது கனக்க வூதிக் கண்ணுமே வெளுக்குந் தானே வெளுத்திடு மிரண்டானால் வினையழ சூழக் கேளாய் களைத்திடு சடலந் தன்னில் கனலதாய் வறட்சி காணும் பழுத்திடுந் தேக மூதிப் பாண்டு போலாம்".

- பாலவாகடம்

பாலவாகடத்தின் கூற்றுப்படி கண் வெள்விழி வெளுத்தல், உடல் வறட்சி, உடல் சோர்வு, வீக்கம் உண்டாகும்.

> "உற்றதோர் அன்னபேதம் அரோசகம் முதரமந்தம் முற்றிமார்பு நோய் மூத்திரம் பொன்னின் வன்மை வெள்ளிசேர் புறங்கால் கைவிக்கமுடல் வெளுத்தல் வேர்த்தல்பற்றி தொக்கிற்காய் பணித்திய பாண்டுவாமே"

> > அகத்தியர் வைத்தியரத்தினச்சுருக்கம்

அகத்தியர் வைத்தியர் ரத்தினச் சுருக்கக் கூற்றுப்படி பசியின்மை, மார்புவலி, சிறுநீர் நிறம் மாற்றம், காணுக்கால் வீக்கம், கண் இரைப்பை வீங்கல், உடல் வெளுத்தல் உண்டாகும்.

சரும வெடிப்பு, அடிக்கடி காறி உமிழ்தல், தேகம் மெலிதல், மண் சாப்பிடுவதில் விருப்பம், கண்களைச் சுற்றிலும் வீக்கம், மலம் மூத்திரம் முதலியவைகள் மஞ்சள் நிறமடைதல், சாப்பாடு நன்றாக செரியாமை முதலான் குறிகள் ஏற்படும்.

"உண்டாகும் வேளைதன்னில் தேகநேர்மை உறுதியாய்ச் சொல்லுகிறேன் நன்றாய் பாரு குண்டான முகம் கண்கள் உதடு நாக்கு குறிப்பான வாய் வேகும் தேக முற்றும் வேண்டாக வேயுலர்ந்து வெண்மையாகி விரல் நகங்கள் முழுவதிலும் ரத்தம் வற்றி கண்டான கால்கள் தான் தணிந்து நிற்கும் கருவான நாடியது மெதுவாய்ப் போமே போமேதான் தீபனங்கள் மட்டுப்பட்டு பொலிவான கண்விழிகள் பெருத்துத் தோன்றும் ஆமெதான் அசதியு மாயாசங் கண்டு அவர் நடையும் தள்ர்ந்து பெருமூச்சுக் கண்டு மூமேதான் மூர்ச்சையுடன் மார்துடித்து

முடிவான கணுக்காலில் வீக்கமுண்டாய் தூமே தானிருதயத்தின் வதனந் தன்னிற் துருத்தி நிகர் சத்தமது கேட்கும்பாரே".

அகத்தியர் குணவாகடம்

அகத்தியர் குணவாகடத்தின் கூற்றுப்படி தோல் வறட்சி, முகம் கண், நாக்கு நகக்கண் வெளுத்தல், உடல்சோர்வு, நாடிநடை குறைவு, பசியின்மை, கண்இரைப்பை வீங்கல், மார்பு படபடப்பு, மூட்டு வீங்கல் உண்டாகும்.

பாண்டு நோயின் வகைகள்:

சித்த மருத்துவ நூல்களின் அடிப்படையில் பாண்டு நோயின் வகைகள் பலவாறாக வகைப்படுத்தப்படுகிறது.

யூகி சிந்தாமணி 800

- வாதப்பாண்டு
- பித்தப்பாண்டு
- கபப்பாண்டு
- முக்குற்றப்பாண்டு
- விடப்பாண்டு
- மண்ணுன் பாண்டு

டி.வி.சாம்பசிவம்பிள்ளை 6

- ♦ வாதப்பாண்டு
- பித்தப்பாண்டு
- கபப்பாண்டு
- முக்குற்றப்பாண்டு
- ♦ ஊது பாண்டு
- ♦ நீர்ப் பாண்டு

மதலை நோய்

- 💠 வாதப் பாண்டு
- பித்தப் பாண்டு
- சிலேற்பன பாண்டு
- இரத்தப் பாண்டு
- அசாத்தியப் பாண்டு

ஜீவ ரக்சாமிருதம்

- 💠 வாதப் பாண்டு
- பித்தப் பாண்டு
- 💠 கபப் பாண்டு
- 💠 திரிதோஷப் பாண்டு
- மிருதிகாப்புக்தப் பாண்டு

ரோக நிர்ணய சாரம்

- 💠 வாதப் பாண்டு
- பித்தப்பாண்டு
- கபப் பாண்டு
- 💠 முக்குற்றப் பாண்டு
- ♦ விடப் பாண்டு

வைத்திய சார சங்கிரகம்

- வாதப்பாண்டு
- ❖ பித்தப்பாண்டு
- 💠 மூலப் பாண்டு
- 💠 மூலபித்தப் பாண்டு
- விடப் பாண்டு

அகத்தியர் குணவாகடம்

- வாதப்பாண்டு
- பித்தப்பாண்டு
- ♦ கபப் பாண்டு
- 🌣 முக்குற்றப் பாண்டு
- ் விடப் பாண்டு

தன்வந்திரி வைத்தியம்

- வாதப்பாண்டு
- பித்தப்பாண்டு
- ♦ கபப் பாண்டு
- 💠 முக்குற்றப் பாண்டு
- பித்தவாதப் பாண்டு
- சன்னிவாதப் பாண்டு
- பைத்தியப் பாண்டு

பரராசசேகரம்

- ♦ வாதப்பாண்டு
- பித்தப்பாண்டு
- ♦ கபப் பாண்டு
- சன்னிப் பாண்டு
- மிருதிகாப்புக்தப் பாண்டு

அனுபோக வைத்திய தேவ ரகசியம்

- வாதப்பாண்டு
- பித்தப்பாண்டு
- ♦ கபப் பாண்டு
- 🌣 முக்குற்றப் பாண்டு
- ♦ விடப் பாண்டு
- மிருதிகாப் பாண்டு

சிகிச்சரத்ன தீபம்

- வாதப்பாண்டு
- பித்தப்பாண்டு
- 💠 சிலேத்துமப் பாண்டு
- திரிதோஒப் பாண்டு
- விஷப் பாண்டு

சரபேந்திர வைத்திய முறைகள் பாண்டு காமாலை சிகிச்சை

- வாதப்பாண்டு
- பித்தப்பாண்டு
- ♦ கபப் பாண்டு
- 💠 சந்நிபாதப் பாண்டுரோகம்
- ❖ மண் தின்றதால் ஏற்பட்ட பாண்டு

பாண்டு நோயின் குறிகுணங்கள்:

சிதம்பர தானுப்பிள்ளை அவர்களால் இயற்றப்பட்ட நூலில் குழந்தைகளில் உண்டாகும் பாண்டு ரோகம் மிகச்சிறப்பாக எடுத்தியம்பப்படுகிறது. அதன் விவரம் வருமாறு,

வாதப் பாண்டு

"வெளுத்துப்போம் வாதமெனும் பாண்டுதானும் வெளிறியங்கம் பொள்ளலுண்டாய் தமரு வீழும் கழுத்தின் கீழ் தேய்ந்து கக்கலிருமல் காட்டும் கண் வெளுத்து கறுப்பாக ரத்தம் வீழும் பழுத்த பழம்போல் பதுங்கும் உதரம்கண்டாய் பார்த்திடுகில் பளபளவென மின்னிக் கானும் செபுத்திடும் சோலைகுயில் மயிலே கேளாய் சேதங்கள் வாராது திறமாய்ச் செய்யே".

உடல் வெளுத்தல், கண் கருநிறமடைதல், தோல் பளபளப்படைதல் ஆகிய குறிகுணங்கள் வாதப் பாண்டு நோயில் காணப்படும்.

பித்தப் பாண்டு

"தொப்புளும் வயிரும் தள்ளி குடல்தன்னில் ஊற்ற முண்டாய் தப்பிளை போல் திரண்டு சரீரமும் வெளுப்பே யேறும் மைப்புறும் குழலினாலே வாயுலர்ந்திருக்கும் கண்டாய் இப்படி குணங்கள் கண்டால் பித்தபசளை பாண்டே".

பித்தப் பாண்டுவில் வயிறு ஊதல், கொப்புள் வீக்கம், குடல் வீக்கம், தோல் வறட்சி காணும்.

சிலேற்பனப் பாண்டு

"புக்கிடும் சேற்பபாண்டு பொருந்திய குணமே தன்னில் கக்கிடும் ரெத்தம் போலே கண்வெளுப்பாகும் மேனி சிக்கிடும் சிறுநீர் பேதி சிறுகவே கெண்டைப் பற்றி போக்கிடும் தொப்புள்சுற்றி பொருந்திய சுடலைசேரும்". சிலேற்பனப் பாண்டு நோயில் குருதிவாந்தி, கண் வெள்விழி மற்றும் உடல் வெளுத்தல், சிறுநீர்க்கட்டு, மலக்கட்டு, உந்தியில் நீர் சேர்தல் உண்டாகி மரணம் ஏற்படும்.

ரக்தப் பாண்டு

"சாருமே ரெத்த பாண்டு சரீரத்தை சுருக்கி மேலும் ஊருமே அங்கமெல்லாம் உணர்ந்திடும் உதரம் விம்மும் காறுமே மூக்கில் ரெத்தம் கண்மஞ்சள் நிறமே ஆருமோ அறிந்திடாமல் அய்யேழில் மரணமாமே".

ரக்தப் பாண்டு நோயில் உடல் எடை குறைதல், அரிப்பு, குருதிவாந்தி, கண் மஞ்சள் நிறமாக மாறி 5-7 நாட்களில் மரண்ம் ஏற்படும்.

<u>மண்ணுண் வெளுப்பு நோய்</u>

சிறு குழந்தைகளும் சிறு வயதின்ரும் மண் சாம்பல் செங்கல் திருநீறு கற்பூரம் இவற்றின் மீது தனித்த இச்சைக் கொண்டு அளவு கடந்து உண்பதால் காணும் நோயகும். உட்கொண்ட பொருளுக்கு ஏற்ப வயிறு ஊதல், செரியாமை, வாந்தி, கழிச்சல், சுரம், வயிற்றுப்புழு முதலிய நோய்கள் கண்டு மெலிந்து குருதி வற்றி வெளுத்து வீங்கி மார்பு துடித்தல் முதலிய குறிகுணங்களைக் காட்டும். அசாத்திய பாண்டு

"ஆற்மே அசாத்தியபாண்டு அங்கமும் வெளுப்பதாகி சீறுமே தொண்டைக்குள்ளே சில்லிட்டடைத்தாப் போலே நாறுமே தேகமெங்கும் நடுக்கிடும் உதரம் வற்றி பாறுமே பதினேழாம் நாள் பகர்ந்த நல்லிளைப் புண்டாமே

இளைத்திடும் காறுபூறாய் இருமலும் மூச்சும் முட்டி களைத்திடும் கையும் காலும் கண்ணது மூடிக் கொள்ளும் தளைத்திடும் பால்ர்க்கும் சதியது வாராதென்று விளைத்திடும் மயிலே கேளாய்".

அசாத்திய பாண்டு நோயில் உடல் வெளுப்பு, தொண்டைக் குளிரல், உடல் நடுக்கம், கெட்ட நாற்றம், மூச்சு திண்றல் ஏற்பட்டு 17 நாளில் மரணம் ஏற்படும்.

முக்குற்ற வேறுபாடுகள்

முன்பு நோய் வரும் வழியில் கூறியவாறு உடல் வன்மை குறைந்து பசீத்தீ கேடடைந்து உண்ட உணவு சரியாகச் செரியாமற் போகும். உணவு கேட்டால் இரச குருதிகளுக்கு ஊட்டம் பெறாது. தோலுக்கு நிறத்தைக் கொடுக்கும்அழல் மெலிந்து நிறத்திலும் எடையிலும் குறைந்து தீக்குற்றத்தைப் பெருக்கும். அதனளவாக மற்றைய குற்றங்களும் தன்னிலையில் திரிந்து பரவுகாலின் வன்மையைக் கெடுத்து நோயை உண்டாக்கும். நொயின் வன்மை பெருக பெருக ஐயமும் பெருகி வீக்கம் முதலியவைகளையும் துணைகொள்ளச் செய்யும்.

வாதம்

வாதம் வாழுமிடம்:

அபானம், மலம், உந்தியின் கீழ் மூலம், தோல், நரம்புக்கூட்டம், ஊன், பக்குவாசயம், காது.

இயற்கைப்பண்பு:

- > ஊக்கமுண்டாதல்
- முச்சுவிடல் வாங்கல்
- மனமொழி மெய்களுக்குச் செயலைத்தரல்
- மலம் முதலிய பதினாங்கு விரைவுகளை வெளிப்படுத்தல்
- > சாரம் முதலிய ஏழு உடற்கட்டுகும் ஒத்த நிகழ்ச்சியைத் தரல்
- ஐம்பொறிகட்கும் வன்மையைக் கொடுத்தல்

வகைகள்-10:

- 1. பிராணன்
 - பாண்டு நோயில் மூச்சுவிட சிரமம் , உணவு செரியாமை ஏற்படும்.
- 2. அபானன்
- பாண்டு நோயில் உணவின் சாரம் சேரவேண்டிய இடங்களில் சேர்ப்பிக்காது. கழிச்சல் மலக்கட்டு சிறுநீர் குறைவு உண்டாக்கும்.
 - 3. வியானன்
 - பாண்டு நோயில் உடல் வீக்கம் கண் உதடு வெளுத்தல் உண்டாகும்.
 - 4. உதானன்
 - பாண்டு நொயில் அதிக நீர்வேட்கை உண்டாகும்.

5. சமானன்

பாண்டு நோயில் பசியின்மை ஏற்படும்.

- 6. நாகன்
 - இயல்பு.
- 7. கூர்மன்
 - இயல்பு.
- 8. கிருகரன்

பசியின்மை உண்டாகும்.

9. தேவதத்தன்

பாண்டு நோயில் தூக்கமின்மை உண்டாகும்.

10. தனஞ்செயன்

பாண்டு நோயில் பாதிப்படையாது.

<u>பித்தம்</u>

பாண்டு நோய் வர முதல் காரணம் பித்தக் குற்றமாகும்.

பித்தம் வாழுமிடம்

பிங்கலை, பிராணவாயு, நீர்ப்பை, மூலாக்கினி, இருதயம், தலை, கொப்பூழ், உந்தி, இரைப்பை, வியர்வை, நாவிலூறுகின்ற நீர், செந்நீர், சாரம், கண், தோல்.

இயற்கைப் பண்பு

தன் இயற்கை நிலையில் நின்று செரிப்பித்தல், வெம்மை, பார்வை,பசி, நீர்வெட்கை, சுவை, ஒளி, நினைப்பு, அறிவு, வன்மை, மென்மை என்பவை உண்டாக்கி உடற்குத் துணை புரியும்.

பித்தத்தின் தொழில்கள்

- உடலில் வெப்பமுண்டாதல்
- செந்நிற அல்லது மஞ்சள் நிறம் தோன்றல்
- உண்ட உணவுப் பொருட்கள் பக்குவடையும் போதும் செரிக்கும்
 சமயத்திலும் வெப்பமுண்டாதல்
- வியர்த்தல்
- மயக்கம் ஏற்படல்
- 💠 செந்நீர் தன் அளவில் மிகுதல் அவ்வாறு மிகுந்த செந்நீர் வெளிப்படுதல்

- தோல் கண் மலம் சிறுநீர் முதலியன மஞ்சள் நிறமடைதல்
- சீற்றம் வணக்கமின்மை அசைவின்மை நினைவு வெறி மெலிவு எரிவு
 உண்டாதல்
- எச்சுவையும் கைப்பாகவேனும் புளிப்பாகவேனும் காணுதல் ஆகியவை
 அழலின் தொழில்களாகும்.

பித்தத்தின் வகைகள்

1. அனற் பித்தம்

பாண்டு நோயில் பசியின்மை உண்டாகும்

2. இரஞ்சக பித்தம்

பாண்டு நொயில் கண் வெள்விழி தோல் வெளுத்திருக்கும்

3. சாதக பித்தம்

அன்றாட பணிகளை சரிவர செய்ய இயலாமல் உடல்சோர்வு உண்டாகும்

4. ஆலோசக பித்தம்

இயல்பு

5. பிராசக பித்தம்

பாண்டு நோயில் கண் வெள்விழி, தோல் வெளுத்திருக்கும்.

பாண்டு நோயில் எண்வகைத் தேர்வு

எண்வகைத் தேர்வுகள்

பிணியை அறியும் வழி மருத்துவ நூல் வல்லுநர்களால் எண் வகையாய் வகுக்கப்பட்டுள்ளது.

"நாடிப்பரிசம் நாநிறம் மொழிவிழி மலம் மூத்திரமிவை மருத்துவராயுதம்"

- நோய் நாடல் நோய்முதல் நாடல்

என்பதனாலும்

"மெய்க்குறி நிறந்தொனி விழிநாவிருமலம் கைக்குறி" என்னும் தேரையர் வாக்கினாலும் அறியலாம்.

"கொண்டிடவே கயரோகி காச ரோகி குறிப்பாகச் சிற்றின்பம் செய்த பேர்கள் அண்டிடவே தரித்திரர்கள் விருத்தர் பாலர் அன்பாகத் தண்ணீரில் மூழ்கினோர்கள் கொண்டிடவே இவர்களது உறுப்பின் தாது கூறவே முடியாது எவர்க்கும்க் கிட்டும் பண்டிடவே இப்பரீட்சை யார்தான் காண்பார் பராபரத்தின் மகிமையிது பாரு பாரே".

- நோய் நாடல் நோய் முதல் நாடல்

பாலர்களுக்கு நாடி நடையின் உண்மை சரியாகப் புலனாகாவாம். எனவே பாண்டு நோயினால் பாதிக்கப்பட்ட குழந்தைகளின் நாடிநடை இயன்றவரையில் ஆய்வாளரால் எடுத்துக் காட்டப்பட்டுள்ளது.

பாண்டு நோயின் நாடிநடை

பித்த நாடி:

"ஆமேதான் அத்திசுரம் பாண்டு சோகை
ஆழான விடாச்சுரமும் பிரமே கந்தான்
போமேதான் காமாலை பித்த வெட்டை
பொல்லாத பாண்டுடனே சிவந்த நீராம்
தேகமேதான் சிவப்பாயு மஞ்ச ளாயுஞ்
சிறுசிறுத்து இருண்டுவருங் கழிவி ழுந்து
நாமேதான் சோன்னோமே பித்தக் கூறு
நவின்றிட்டார் வாசமுனி நவின்றிட் டாரே"

ஐய நாடி

"சேத்தும நாடி யிளகினால் பான	ன்டாகும் ".
"கானமுள்ள சேத்துமந்தான்னிஎ	ாகில்
பாண்டுரோகம் _"	

ஐயவாத நாடி

"கண்டாயோ சிலேற் பனத்தில் வாதநாடி கலந்திடுகில்பாண்டு....." "உண்டாயோ சேத்துமத்தில் வாதநாடி கலந்திடுமேல் பாண்டு பிறக்குந்தானே."

ஐயபித்த நாடி

"இடமான சேத்துமத்திற் பித்தநாடி எழுந்தணுகில் பாண்டாகும்."

2. ஸ்பரிசம்

தோல் வறட்சி, சொறசொறப்பு காணும்.

பாண்டு நோயில் நாவெடித்துப் புண்ணாதல், நாவின் மேல் தோலைச் சீவியெடுத்தது போன்று சிவந்து காணும் அல்லது நாக்குப் பட்டுத்துணிபோல் வழுவழுத்து வெளுத்தல், சுவையின்மை உண்டாகும்.

4. <u>ந**ிறம்**</u>

உடல், கண் வெள்விழி, நகக்கண் வெளுப்பு உண்டாகும்.

5. <u>மொழி</u>

இயல்பு

6. <u>விழி</u>

பாண்டு நோயில் கண் வெள்விழி வெளுத்திருக்கும்.

7. <u>மலம்</u>

மலக்கட்டு கழிச்சல் ஏற்படும்.

8. <u>மூத்திரம்</u>

பாண்டு நோயில் அடிக்கடி சிறுநீர் இழிதல் உண்டாகும்.

நீர்க்குறி

பாண்டு நோய் உற்பத்தியைக் காட்டும் நீரின் எஞ்சிலக்கணம்
"இயற்கை நீர் சுருங்கினும் இதுவும் சலப் பொருள்
செயற்கை யாயிருந்தினும் சிறுத்து நீரிதுவும்
பாண்டு நோய்ச் சம்பவத்தைத் தருமிதில்
தூண்டுறாப் பேதியும் சோர்வும் பிறக்குமே."

நோய்நாடல் நோய்முதனாடல் திரட்டு

ஒரு காரணமுமின்றி இயற்கை அளவுக்குக் குறைந்து இழியும் நீரும்; நீர்ப் பொருள்களை மிகுதியாயுண்ணினும் குறைந்திழியும் நீரும்; பாண்டு நோய் உற்பத்திக்கு வழியாகும். இதனால் நீக்கக்கூடாத பேதியும்.

நெய்க்குறி

"விரைவுடன் கதிர்போல் நீண்டு வேற்றுமைக் குணங்கள் கண்டால் குருதிதான் கெட்டு நாசம் குன்றிய குணம்தென்னே."

- தேரையர்

பாண்டு நோயில் நெய்க்குறி கதிர் போல பரவும்.

<u>பருவகாலங்கள்</u>

கார் காலம் மற்றும் கூதிர் காலம். இவ்விரு காலங்களில் பித்தம் தன்னிலை வளர்ச்சி மற்றும் வேற்றுநிலை வளர்ச்சி அடையும்.

நிலம்

குறிஞ்சி நெய்தல் மற்றும் பாலை நிலத்தில் வாழும் மக்களுக்கு பாண்டு நோய் வருவதற்கான வாய்ப்புகள் உள்ளன.

பாண்டு தீரும் தீராக் குறி

"அசாத்தியமாம் சிலேத்துமமும் தொந்தம் ரெத்தம் அகலுமே வாதபித்தம் சாத்தியமாகும்."

- குழந்தை நோய்கள்சிதம்பரதானுபிள்ளை

க**ுழந்தைகளுக்கு உண்டாகும் ஐந்து வகை பாண்டு நோய்களில் வாதப்** பாண்டு, பித்தப் பாண்டு இரண்டும் சாத்தியம்.

சிலேத்துமப் பாண்டு, தொந்தப் பாண்டு, ரத்தப் பாண்டு ஆகிய மூன்றும் அசாத்தியம்.

அசாத்திய பாண்டு

பாண்டு ரோகிக்கு வீக்கம், சோம்பல், தாகம், அரோசகம், வாந்தி, விக்கல், இருமல், பேதி என்னும் இக்குணங்கள் உண்டாகி எந்த பொருளைப் பார்த்தாலும் மஞ்சள் நிறமுண்டானால் அசாத்தியம்.

· அகத்தியர் வைத்திய பிள்ளைத்தமிழ்

<u>கண்ணுசாமியம்</u>

"பாண்டு பிரமேகம் பன்வாத சூலை குன்மம் வேண்டா சயஞ்சன்னி வெண் சோபை- நீண்ட அதிநீரே காமாலை யானபிணி தம்மு ளதி சாரமா காதறி

சொல்லு பித்தத்திற் சோபை சோபைதனில் வாயுதொந்தம் வல்லவதிற் பாண்டுவன் பாண்டில் - நல்ல வயிற்றுக் கடுப்பு வளர்கடுப்புற் சீதம் பயிலிற் கெடுதி யெனப்பன்

வெப்புப் பிணியதனில் வெம்மேகத்தால் வருந்தின் தப்பு மிகை நீரே தானிறங்கின்- செப்பும் கிராணியிற் பாண்டில் கிளர் நீர்சுருங்கிற் பிராணன் பிரியுமெனப் பேசு."

சரபேந்திரர் வைத்திய முறைகள்

வீக்கத்தில் மஞ்சள் நிறம் காணப்பட்டால் குணம் ஏற்படாது. மலச்சிக்கலோ அல்லது பச்சை நிறமான அதிசாரமோ ஏற்பட்டால் அசாத்தியம். பலவீனம், வாந்தி, மூர்ச்சை, அதிக நாளான பாண்டு ரோகம் சிகிச்சைக்கு வசப்படாது. நாவறட்சி, இரத்தக் குறைவினால் உடல் வெளுப்பு முதலியவைகலுடன் கூடிய ரோகியும் குணமடைவது சிரமம்.

பற்கள், நகம், கண் இவைகள் அதிகம் வெளுத்தாலும் எல்லவற்றையும் வெண்ணிறமாக பார்த்தாலும் அந்த ரோகம் அசாத்தியமாகும். அசாத்திய ரோகத்தை முற்றிலும் குணப்படுத்த முடியவிட்டாலும் சிறிது குறிகுணங்களை குறைத்து ஆயுளையும் சில காலம் நீடிக்கச் செய்யலாம்.

கைகள் கால்கள் தலை முதலான இடங்களில் வீக்கம் ஏற்பட்டு இளைத்து கைகால்களும் இளைத்து வயிறு பெருத்துமுள்ள் பாண்டு ரோகியையும் ஆண்குறி, தொடையிடுக்கு ஆகிய இடங்களில் வீக்கம், அடிக்கடி மயக்கம், அதிசாரம், சுரம் ஆகியன கண்டு வரும் ரோகியையும் குணப்படுத்துவது அசாத்தியமாகும்.

<u>மாதவ நிதானம்</u>

பாண்டுவின் அசாத்திய இலட்சணங்கள்

- நீடித்து தொடர்வதும் மிக்க முதிர்ந்து போனதுமான பாண்டு சிகிச்சைக்கு வசப்படாது.
- அவயங்கள் வீங்கிப் போய் எல்லாப் பொருளும் மஞ்சளாக தோன்றினால் தீராது.
- இறுகிய சொற்ப மலத்துடன் மஞ்சள் நீராகவும் கபத்துடன் கூடியதாகவும்
 அதிசாரம் உண்டானால் அசாத்தியம்.
- அதிக தீத்தன்மை அடைந்து அவயங்கள் வெண்மையாகி வாந்தி மூர்ச்சை நாவறட்சி உண்டானால் அசாத்தியம்.
- 5. இரத்தம் கெட்டு உடல் முற்றும் வெளுத்தால் தீராது.
- 6. தேகத்தின் கை, கால், தலை வீக்கம் உடல்வற்றி இளைத்துப் போனால் குதம், ஆண்குறி, பீஜம் வீக்கம் இருந்தால் தீராது.
- 7. மிக்க இளைப்பு மயக்க நிலை காணப்பட்டால் தீராது.
- 8. அதிசாரம் சுரம் கொண்ட பாண்டு தீராது.

<u>மருத்துவப் பரிகாரம்</u>

பிணிக்கப்பட்ட வளி, அழல், ஐயம் என்னும் முக்குற்றத்தைத் தன்னிலைப் படுத்துதல் மருத்துவம் என வழங்கப்படும். பிணிக்கப்பட்ட முக்குற்றங்கள் ஐம்புலங்கள், ஏழு உடற்தாதுக்கள் ஆகியவைகளை தன்னிலைப்படுத்தும் தன்மையுடையவை மருந்தாகும்.

மருந்து அகமருந்தென்றும் புறமருந்தென்றும் இருபிரிவாகக் கொள்ளினும் முக்கியமாக தாவரப்பொருள், தாதுப்பொருள், சங்கமப் பொருள் என மூன்று வகையாக வகுத்தனர். இதனை தேரன் கூறிய பிரகாரம் "கற்பங்க ளாதி கழறு மருந்து முறை விற்பனங் களாக விளங்குவதற்கு- முற்பங்கு மூலிக் கருப்பொருள் மூலப்பொருள் வகைகள் வேலிக்கு நேரா குமே."

சித்த மருத்துவ முறைப்படி நோய்க்கு மட்டும் மருத்துவமின்றி அதனை வராது தடுக்கவும் காயகற்பமாகவும் மருந்துகள் பயன்படும்

> "உற்றா னளவும் பிணியளவுங் காலமுங் கற்றான் கருதிச் செயல்."

. திருக்குறள்

நோயினன் அடைந்த குற்ற வேறுபாடுகளின் மிகுதல் குறைதல் அளவையும் அதனால் நோயுற்றான் பெற்ற நோயின் கால அளவை அறிந்து சிந்தித்து தகுந்த மருத்துவம் புரிவது அவசியம்.

<u>மருத்துவ வழிமுறை</u>

கேடடைந்த முக்குற்றம் வாயுக்கள், இரத்தத்தாது இதனை சமப்படுத்தும் மருந்துகளாக இருக்க வேண்டும். நாம் கொடுக்கும் மருந்துகளானது இரஞ்சகப்பித்தத்தை சமப்படுத்தி இரத்தத்தாதுவை தன் இயல்பான வேலைகள் செய்வதாக மாற்ற வேண்டும்.

"விரேசனத்தால் வாதந் தாழும் வமனத்தால் பித்தந் தாழும் நசியஅஞ்சனத்தால் கபந் தாழும்."

அதிகரித்த பித்தத்தை தன்னிலைப்படுத்த வாந்தி மருத்துவம் செய்தல் வேண்டும். பாண்டு நோயில் நோயாளி சோர்வாகவும், தளர்வுடனும் இருப்பதால் வாந்தி முறை மருத்துவமானது கொடுப்பதில்லை.

உணவு

நோய் தொடக்கத்தில் பசியைத்தூண்டக்கூடியதும், உடலின் குருதியை பெருக்கக்கூடியதுமான உணவும் எளிதில் செரிக்கக்கூடியதாகவே இருத்தல் வேண்டும்.

கீரை வகைகள்

கரிசாலை, பொன்னாங்காணி, அறுகீரை, சிறுகீரை, மணத்தக்காளி, தாளீக்கீரை.

காய்கறிகள்

கத்தரிப் பிஞ்சு, முருங்கைப் பிஞ்சு, வாழைக்கச்சல், அவரைப் பிஞ்சு. <u>பழங்கள்</u>

கொடிமுந்திரிகை, சாத்துக்குடி, ஆப்பிள், அத்திப்பழம், மாதுளைப் பழம், நெல்லி.

<u>கறிவகைகள்:</u> வெள்ளாட்டுக் கறி, காடை, கௌதாரி.

MODERN ASPECT

The commonest nutritional deficiency disorder present throughout the world is

iron deficiency anaemia.

Body is formed by solids and fluids. The fluid part is more than two third of

the whole body water forms most of the fluid part of the body.

Blood is a connective tissue in fluid form. It is considered as the fluid of life,

because it carries oxygen from lungs to all parts of the body and carbon dioxide from

all parts of body to the lungs. It is known as the fluid of growth because it carries

nutritive substances from the digestive system and hormones from endocrine gland to

all the tissues. The blood is also called the fluid of health because it protects the body

against the diseases and gets rid of the waste products and unwanted substances by

transporting them to the excretory organs like kidneys.

Blood contains iron in the form of haemoglobin and as cytochromes etc. Any

form of iron deficiency cause anaemia.

PROPERTIES OF BLOOD

COLOUR:

❖ Blood is red in colour.

❖ Arterial blood is scarlet red because it contains more oxygen

❖ Venous blood is purple red because of more carbon dioxide

VOLUME:

Average volume of blood in

❖ 5 litre in a normal adults

❖ 450 ml in a new born babies (it increases during growth and reaches 5 litre at

the time of puberty)

❖ 4.5 litre in females

SPECIFIC GRAVITY:

Total blood: 1 052

1 052 - 1 061

Blood cells: 1.092

1.092 - 1.101

Plasma: 1 022

- 1 026

25

VISCOSITY:

Blood is five times more viscous than water due to red blood cells and plasma proteins

COMPOSITION OF BLOOD:

Blood contains the blood cells which are called formed elements and the liquid portion known as plasma.

- ❖ Blood consists of a solid protein 45% and a fluid protein 55%
- ❖ Solid protein constitutes RBC, WBC and platelets
- Fluid portion is plasma

BLOOD CELLS:

Blood cells are of three types

- * Red blood cells or erythrocytes
- White blood cells or leucocytes
- Platelets of thrombocytes

FUNCTIONS OF BLOOD:

1. NUTRITIVE FUNCTION:

Nutritive substances like glucose, amino acid, lipids and vitamins derived from digested food are absorbed from gastrointestinal tract and carried by blood to different parts of the body for growth and production of energy.

2. RESPIRATORY FUNCTION:

Transport of respiratory gases is done by blood. It carries oxygen from alveoli of lungs to different tissues and carbon dioxide from tissues to alveoli.

3. EXCRETORY FUNCTION:

Waste products formed in the tissues during various metabolic activities are removed by blood and carried to the excretory organs like kidney, skin, liver, etc. for excretion.

4. TRANSPORT OF HORMONES AND ENZYMES:

Hormones which are secreted by ductless glands are released directly into the blood. The blood transports these hormones to their target organs/ tissues. Blood also transports enzyme.

5. REGULATION OF WATER BALANCE:

Water content of the blood is freely interchangeable with interstitial fluid. This helps in the regulation of water content of the body.

6. REGULATION OF ACID BASE BALANCE:

Plasma proteins and hemoglobin act as buffers and help in the regulation of acid -base balance

7. REGULATION OF BODY TEMPERATURE:

Because of the high specific heat of blood, it is responsible for maintaining the thermoregulatory mechanism in the body, i.e. the balance between heat loss and heat gain in the body.

8. STORAGE FUNCTION:

Water and some important substances like proteins, glucose, sodium and potassium are constantly required by the tissues. Blood serves as a readymade source for these substances. And, these substances are taken from blood during the condition like starvation, fluid loss, electrolyte loss, etc.

9. DEFENSIVE MECHANISM:

Blood plays an important role in the defense of the body. The white blood cells are responsible for this function. Neutrophils and monocytes engulf the bacteria by phagocytosis. Lymphocytes are involved in development of immunity. Eosinophils are responsible for detoxification, disintegration and removal of foreign proteins.

RED BLOOD CELLS

Red blood cells are the non-nucleated formed elements in the blood. Red blood cells are also known as erythrocytes. The red colour of the red blood cells is due to the presence of colouring pigment called hemoglobin. RBCs plays a vital role in transport of respiratory gases.RBCs are larger in number compared to the other two cells namely white blood cells and platelets.

NORMAL VALUE

The RBCs count ranges between 4 and 5.5 millions/cu mm of blood

In adult males -5 millions/cu mm

In adult females -4.5 millions/cu mm

MORPHOLOGY

Normal Shape: Disc shaped and biconcave (Dumb-bell shaped).

Normal Size : 7.2μ (6.9 – 7.4μ) in diameter.

Thickness : Periphery-2.2µ (Thicker)

Centrally - 1 μ (Thinner)

Surface Area : 120sq.µ

Volume : 90 -95cu. μ

ERYTHROPOIESIS:

Erythropoiesis is the process of the origin, development and maturation of erythrocytes.

SITE OFERYTHROPOIESIS:

IN FETAL LIFE:

In fetal life, the erythropoiesis occurs in three stages:

1. Mesoblasticstage

During the first two months of intrauterine life, the RBCs are produced from mesenchyme of yolk sac.

2. Hepaticstage

From third months of intrauterine life, liver is the main organ that produces RBCs. Spleen and lymphoid organs are also involved in erythropoiesis.

3. Myeloid stage

During the last three months of intrauterine life, the RBCs are produced from red bone marrow and liver.

IN NEWBORN BABIES, CHILDREN AND ADULTS

- 1. Up to the age of 20 years: RBCs are produced from red bone marrow of all bones.
- 2. After the age of 20 years:RBCs are produced from membranous bones like vertebra, sternum, ribs, scapula,iliac bones and skull bones and from the ends of the long bones. After 20 years of the age, the shaft of the long bones becomes yellow bone marrow because of fat deposition and loose the erythropoietic function.

In adults, liver and spleen may produce the blood cells if the bone marrow is destroyed or fibrosed. Colletively bone marrow is almost equal to liver in size and weight. It is also as active as liver.

PROCESS OF ERYTHROPOIESIS:

STEM CELLS:

The stem cells are the primitive cells in the bone marrow, which give rise to all the blood cells. Stem cells are defined as a cell which is capable of both self-renewal and differentiation.

Pluripotent haemopoietic stem cells (PHSC) are derived from stem cells. PHSC are defined cells that can give rise to cells of all groups of haemopoietic cells like myeloid cells and lymphoid cells.

In the early stages, the PHSC are not designates to form a particular type of blood cell, and it is also not possible to determine the blood cell to be developed from these cells, hence the name uncommitted PHSC.

In adults only a few number of these cells are present. Best source of the cells is the umbilical cord blood.

When the cells are designated to form a particular type of blood cells the uncommitted PHSCs are called committed PHSCs.

Committed PHSCs are of two types:

- 1. Lymphoid stem cells (LSC) which gives rise to Lymphocytes and natural killer (NK) cells
- 2. Colony forming blastocytes- Which gives rise to myeloid cells. Myeloid cells are the blood cells other than lymphocytes. When grown in cultures these cells form colonies hence the name colony forming blastocytes.

The different units of colony forming cells are:

- Colony forming unit Erythrocytes (CFE-E). The Cells of this unit develop into erythrocytes.
- II. Colony forming unit granulocytes –Monocytes (FU-GM). These cells give rise to granulocytes (Neutrophils, Basophils and Eosinophils and Monocytes)
- III. Colony forming unit- Megakaryocytes (CFU-M). Platelets are formed from these cells

CHANGES DURING ERYTHROPOIESIS:

The Cells of CFU-E pass through different stages finally become matured RBCs. During these changes four important changes are noticed.

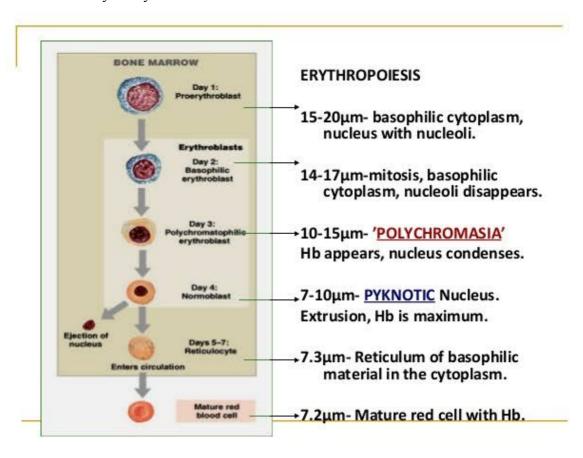
a) Reduction in size of the cells

- b) Disappearance of nucleoli and nucleus
- c) Appearance of haemoglobin
- d) Changes in the staining properties of the protoplasm.

STAGES OF ERYTHROPOIESIS:

Various stages between CFU-E cells and matured RBCs are

- 1. Proerythroblast
- 2. Early normoblast
- 3. Intermediate normoblast
- 4. Late Normoblast
- 5. Reticulocyte
- 6. Mature Erythrocyte



Stages of erythropoiesis

FACTORS NECESSARY FOR ERYTHROPOIESIS:

- General factors
- Maturation factors
- Factors necessary for haemoglobin formation

General factors

General factors necessary for erythropoiesis are

- Erythropoietin
- Thyroxine
- Hemopoietic growth factor
- ❖ Vitamins-B, C, D and E

Maturation factors

- ➤ Vitamin B12(Cyanocobalamin)
- > Intrinsic factor of castle
- > Folic acid

Vitamin B12 (Cyanocobalamin)

Vitamin B12 is called extrinsic factor because it is obtained mostly from diet. Vitamin B12is stored mostly in the liver and in small quantity in muscle. When necessary, it is transported to the bone marrow to promote maturation of RBCs.

Intrinsic factor of castle

The extrinsic and intrinsic factors are together called haematinic principle.

Folic acid

It is also essential for maturation. It is required for the synthesis of DNA. In the absence of folic acid the synthesis of DNA decreases causing failure of maturation. This leads to anaemia.

Factors necessary for Haemoglobin formation:

Various materials are essential for the formation of haemoglobin in the RBCs. Such factors are,

- 1. First class protein and aminoacids
- 2. Iron: It is necessary for the formation of heme part of the haemoglobin
- 3. Copper: It is necessary for the absorption of iron from the gastrointestinal tract.
- 4. Cobalt and nickel: It is essential for the utilization of iron during haemoglobin formation.
- 5. Vitamins: Vitamin C, Riboflavin, nicotinic acid and pyridoxine is also essential for the formation of haemoglobin.

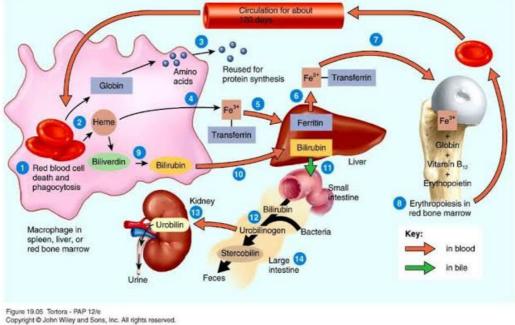
LIFE SPAN AND FATE OF RBC:-

Average life span of red blood cells is about 120 days. The senile red blood cells are destroyed in reticulo-endothelial system.

When the cells become older the cell membrane becomes more and more fragile. So these cells are destroyed while trying to squeeze through the capillaries. The destruction occurs mostly in the capillaries of the spleen because the splenic capillaries have a thin lumen. So the spleen is usually called "Grave yard" of red blood cells.

Daily 10 % of RBCs, which are senile, are destroyed in normal young healthy adults. It causes release of about 0.6g% of haemoglobin into plasma.

RBC Lifecycle and Hemoglobin Circulation for about 12th days



HAEMOGLOBIN

Hemoglobin is the iron containing coloring matter of red blood cell. It is a chromoprotein forming 95% of dry weight of RBC and 30% to 34% of wet weight. Function of hemoglobin is to carry the respiratory gases, oxygen and carbon dioxide. It acts as a buffer. Molecular weight of hemoglobin is 68,000.

NORMAL HEMOGLOBIN CONTENT

Average hemoglobin content in blood is 14 to 16 g/dL. However, the value varies depending upon sssthe age and sex of the individual.

AGE

❖ At birth Hb level : 25g/dL
 ❖ After 3rd month : 20g/dL
 ❖ After 1 year : 17g/dL

❖ From puberty onwards : 14 to 16g/dL

❖ At the time of birth, hemoglobin content is very high because of increased number of RBCs

SEX

In adult males : 15g/dL In adult females : 14.5 g/dL

FUNCTIONS OF HEMOGLOBIN

> Transport of respiratory gases

• Oxygen from the lungs to tissues

• Carbon dioxide from tissues to lungs

➤ Buffer action

Hemoglobin acts as a buffer and plays an important role in acid- base balance

STRUCTURE OF HAEMOGLOBIN

Haemoglobin is a conjugated protein. It consists of a protein combined with an iron containing pigment in heme. The protein part is globin and the iron containing pigment is heme.

- Heme also forms a part of structure of myoglobin (oxygen binding pigment in muscles)
- Neuroglobin(Oxygen binding pigment in brain)

Iron:

Normally it is present in ferrous form Fe++. It is in unstable or loose form.

Porphyrin:

The pigment part is called porphyrin. It is formed by four pyrole ring called I, II, III, IV. The Pyrole rings are attached to one another by methane (CH4) bridge The iron is attached to

- -N of the each pyrole ring and
- -N of the globin molecule

Globin:

This contains four polypeptide chains

- α chains-2
- β chains -2

TYPES OF HAEMOGLOBIN

Haemoglobin is of two types

- 1. Adult haemoglobin- HbA
- 2. Fetal haemoglobin- HbF

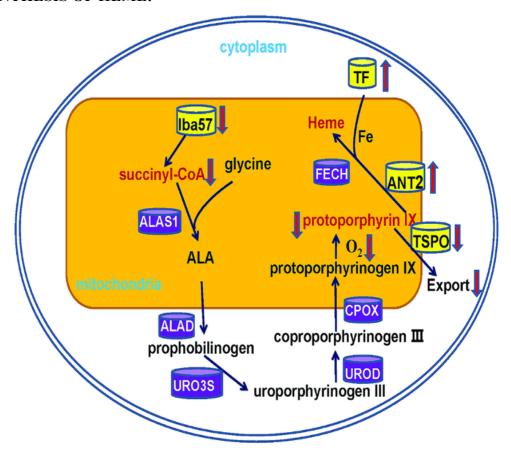
There are structural differences between the two types of haemoglobin. In adult haemoglobin, the globin contains two α chains and two β chains. In fetal haemoglobin, there are two α chains and two γ chains instead of β chains.

SYNTHESIS OF HEMOGLOBIN

Synthesis of hemoglobin actually starts in proerythroblastic stage. However, hemoglobin appears in the intermediate normoblastic stage only. Production of hemoglobin is continued until the stage of reticulocyte.

The heme protein of hemoglobin is synthesized in mitochondria. And the protein part, globin is synthesized in ribosomes.

SYNTHESIS OF HEME:



Heme is synthesized from succinyl-Co A and the glycine. The sequence of events in synthesis of hemoglobin:

- 1. First step in heme systhesis takes place in the mitochondrian. Two molecules of succinyl-Co A combines with two molecules of glycine and condense to form α aminolevulinic acid (ALA) by ALA synthase.
- 2. ALA is transported to the cytoplasm. Two molecules of ALA combine to form porphobilinogenin the presence of ALA dehydratase.
- 3. Porphobilinogen converted into urophobilinogen I by urophobilinogen I synthase
- 4. Uroporphobilinogen I is converted into uroporphobilinogen III byporphobilinogen III cosynthase.
- 5. From uroporphobilinogen III, a ring structure called coporphobilinogen III is formed by uroporphobilinogen decarboxylase.
- 6. Coprophobilinogen III is transported back to the mitochondrion, where it is oxidized to form protoporphyrinogen IX by coproporphyrinogen oxidase.

- 7. Protoporphyrinogen IX is converted into protoporphyrin IX by protoporphyrinogen oxidase.
- 8. Protoporphyrin IX combines with iron to formheme in the presence of ferrochelatase.

FORMATION OF GLOBIN

Polypeptide chains of globin are produced in the ribosomes. There are four types of polypeptide chains namely, alpha, beta, gamma and delta chains. Each of these chains differs from others by the amino acid sequence. Each globin molecule is formed by the combination of 2 pairs of chains and each chain is made of 141 to 146 amino acids. Adult hemoglobin contains two alpha chains and two beta chains. Fetal hemoglobin contains two alpha chains and two gamma chains.

CONFIGURATION

Each polypeptide chain combines with one heme molecule. Thus, after the complete configuration, each hemoglobin molecule contains 4 polypeptide chains and 4 heme molecules.

SUBSTANCES NECESSARY FOR HEMOGLOBIN SYNTHESIS

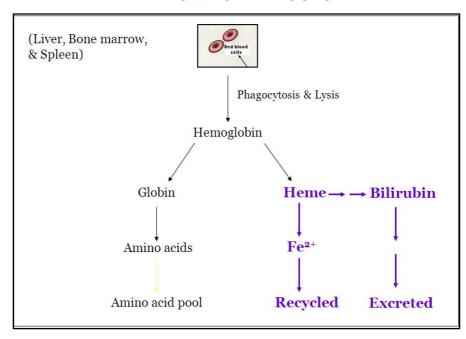
Various materials are essential for the formation of hemoglobin in the RBC.

DESTRUCTION OF HEMOGLOBIN

After the lifespan of 120 days, the RBC is destroyed in the reticuloendothelial system, particularly in spleen and the hemoglobin is released into plasma. Soon, the hemoglobin is degraded in the reticuloendothelial cells and split into globin and heme.

Globin is utilized for the resynthesis of hemoglobin. Heme is degraded into iron and porphyrin. Iron is stored in the body as ferritin and hemosiderin, which are reutilized into a green pigment called biliverdin. In human being, most of the biliverdin is converted into a yellow pigment called bilirubin. Bilirubin and biliverdin are together called bile pigments.

BREAKDOWN OF HEMOGLOBIN



NORMAL VALUES OF HAEMOGLOBIN OF DIFFERENT AGE GROUP

AGE GROUP	MEAN(G/dl)	RANGE(G/dl)	
Cord blood	17.1	13.7-20.5	
7 days	18.8	14.6-23.0	
20 days	15.9	11.3-20.5	
45 days	12.7	9.5-15.9	
75 days	11.4	9.6-13.2	
120 days	11.9	9.9-13.9	
1 year	12.2	10-13.0	
5 year	12.5	12-13	
10 year	13.5	13-14	
Older	15	14-15	

PACKED CELL VOLUME AND BLOOD INDICES:

Packed cell volume (PCV) is the haematocrit value expressed as the percentage of cellular elements with that of whole blood.

BLOOD INDICES:

Blood indices are specifically meant for erythrocytes. Blood indices have got diagnostic value in determining the type of anaemia.

DIFFERENT BLOOD INDICES:

Following are the different blood indices

1. Mean Corpuscular Volume (MCV)

Mean Corpuscular Volume is the average volume of single red blood cells and it is expressed in cubic microns(cu.µ)

$$MCV = \frac{PCV \text{ in } 1000ml \text{ or } 100ml \times 10}{RBC \text{ in millions per cu.mm}}$$

2. Mean Corpuscular Haemoglobin (MCH)

Mean Corpuscular Haemoglobin is the quantity or amount of haemoglobin present in one red blood cell. It is expressed in micrograms or pictograms(pg)

$$MCH = \frac{\textit{Haemoglobin in gms per } 1000\textit{ml of blood} \times 100 \times 10}{\textit{RBC count in millions per cu.mm}}$$

3. Mean Corpuscular Haemoglobin Concentration (MCHC)

It is the amount of haemoglobin expressed in relation to volume of one blood cell. So the unit of expression is percentage.

$$MCHC = \frac{\textit{Haemoglobin in grams per 100ml of blood} \times 10}{\textit{PCV in 100 ml of blood}}$$

4. Colour Index:

This is the ratio between the percentage of the haemoglobin and the percentage of red blood cells in the blood.

$$\mathbf{CI} = \frac{\textit{Haemoglobin in } \%}{\textit{RBC in } \%}$$

All the above mentioned blood indices are reduced in iron deficiency anaemia.

NORMAL VALUES:

Packed Cell Volume (PCV):

3 month
$$-10$$
 years $-36.0\pm5.0\%$
 $11-15$ years $-39.0\pm5.0\%$

Mean Corpuscular Volume (MCV)

Mean Corpuscular Haemoglobin (MCH)

3months – 10years -27 picograms 11- 15 years -28 picograms

Mean Corpuscular Haemoglobin Concentration (MCHC)

3months to 10 years -34g/dl

11- 15 years -34g/dl

Reticulocytes:

6 months - 6 years -1.0%

7- 12 years -1.0%

IRON:

Iron is one of the most essential trace elements in the body. Heme is the most predominant iron containing substance. Iron is important for the formation of haemoglobin, myoglobin, cytochromes and other components of respiratory enzymes like cytochrome oxides, catalase and peroxidase.

NORMAL VALUE AND DISTRIBUTION OF IRON IN THE BODY:

The total quantity of iron in the body is about 4 grams. The approximate distribution of iron in the body is as follows:

In the haemoglobin -65 - 68%

In the muscle as myoglobin —4%

As intracellular oxidative heme compound -1%

In the plasma as transferrin -1%

Stored in the reticuloendothelial system -25 - 30%

BIOCHEMICAL FUNCTION:

- 1. Haemoglobin and myoglobin are required for the transport of O2and CO2.
- 2. Cytochromes and certain non heme proteins are necessary for electron transport chain and oxidative phosphorylation.
- 3. Peroxidase, the lysosomal enzyme, is required for phagocytosis and killing of bacteria by neutrophils.
- 4. Iron is associated with effective immunocompetence of the body.

Daily iron requirement in different age group.

Males 11 years to 17 years - 12mg/day.

Upto 10 years male and female - 10mg/day.

DIETARY IRON:

The dietary iron comes from two sourses, heme and non heme, the latter being the major source of iron in diet and is found in varying degrees in all foods of plant origin.

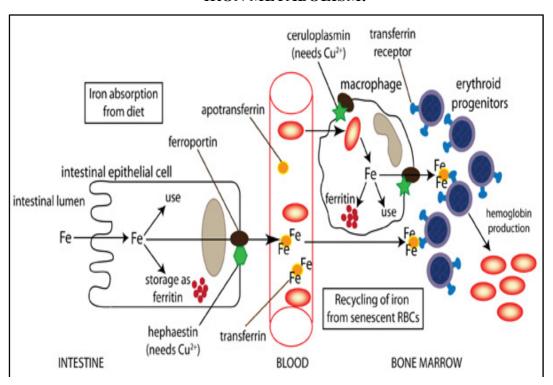
Heme iron is present in meet fish and poultry, but the intake of these product is generally low. Heme iron is better absorbed than non heme iron and is not influenced by dietary factors.

Breast milk even in spite of low levels of iron (0.5mg/lit) has a better absorption and bioavailability as compared to cow's milk. Good source of iron in diet include pulses, dhals, green leafy vegetables, dates, nuts, jaggery, meat and fish. Poor sources of iron in the diet include milk, wheat, polished rice. Administration of 50mg of vitamin C increases iron absorption by two folds.

FACTORS AFFECTING IRON ABSORPTION:

- 1. Acidity, ascorbic acid and cysteine promote iron absorption.
- 2. In iron deficiency anaemia, iron absorption is increased to 2- 10 times that of normal.
- 3. Small peptides and amino acids favour iron uptake
- 4. Phytates found in cereals and oxalates found in leafy vegetables interfere with iron absorption.
- 5. A diet with high phosphate content decreases iron absorption while too low phosphate promotes.
- 6. Impaired absorption of iron is absorbed in malabsorption syndrome such as steatorrhoea.
- 7. In patients with partial or total surgical removal of stomatch and or intestine, iron absorption is severely impaired.

IRON METABOLISM:



Absorption:

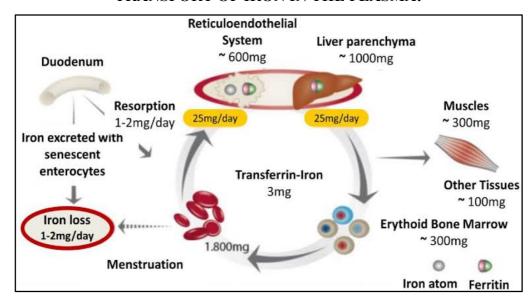
Iron is mainly absorbed in the stomach and duodenum. Iron is mostly found in foods in ferric form. Fe3+ bound to proteins or organic acids. In the acid medium provided by gastric hydrochloric acid the Fe3+is released from foods. Reducing substances such as ascorbic acid (vitamin c) and cysteine convert ferric iron (Fe3+) to ferrous form Fe2+.Iron in ferrous form is soluble and readily absorbed.

Iron in the mucosal cells:

The iron Fe2+entering the mucosal cells by absorption is oxidized to ferric (Fe3+) form by the enzyme ferroxidase.

Fe3+ then combine with apoferritin to form ferritin which is the temporary storage form of iron and is present in gastrointestinal mucosa, bone marrow, liver and spleen. From the mucosal cells, iron may enter the blood stream.

TRANSPORT OF IRON IN THE PLASMA:



The iron liberated from the ferritin of mucosal cells enters the plasma in ferrous state, it is plasma in ferrous state, it is plasma in ferrous state, it is oxidized to ferric form by a copper containing protein, ceruloplasmin. Another cuproprotein ferroxidase II also help for the conversion of Fe2+to Fe3+.

Ferric iron that binds with a specific iron binding proteins namely transferrin or siderophilin.

Each transferrin molecule can bind with two atoms of ferric ion Fe3+. The plasma transferrin can bind with 400mg of iron /dl plasma. This plasma is known as total iron binding capacity(TIBC) of plasma.

Hemosiderin is another iron storage protein, accumlate in the spleen and liver when the supply of iron is in excess of body demands.

IRON IS A ONE WAY SUBSTANCE

Iron is very efficiently utilized and reutilized by the body. Further, iron losses from the body are minimal which may occur through bile, sweat, hair loss etc. Iron is not excreted in urine.

ANAEMIA

DEFINITIONS:

Anaemia is present when the haemoglobin level in the blood is two standard deviations below the mean for the particular age and sex.

Physiological definition of anaemia is a condition in which tissue hypoxia occurs due to inadequate oxygen carrying capacity of blood.

WHO criteria for diagnosis of anaemia.

Children of 6 months- 6 years < 11

Children of 6 years -14 years <12

Grading of Anaemia:

WHO grades anaemia according to haemoglobin level as follows.

- Hb between 10gram and cut off point for age Mild
- Hb between 7-10gram Moderate
- Hb under 7gram Severe

CLASSIFICATION:

A. Based on the Morphology

Based on the red cell size haemoglobin content and red cell indices anaemia are classified as follows.

- 1. Microccytic hypochromic anaemia
- 2. Normocytic normochromic anaemia
- 3. Macrocytic normocytic anaemia
- 4. Macrocytic hypochromic anaemia

B .Based on Etiopathogenesis

- 1. Nutritional anaemia
- 2. Haemolytic anaemia
- 3. Haemorrage
- 4. Bone marrow suppression
- 5 Infections
- 6. Miscellaneous

I. <u>Disorders of impared RBC production</u>

A. Deficiency anemia

- I. Iron deficiency anaemia
- II. Nutritional megaloblastic anaemia (Vit B12 and folate deficiency)
- III. Mixed deficiency states (Dimorphic anaemia)

B. Bone marrow failure

- 1. Aplastic anaemia
 - Congenital and acquired
 - Acquired
- 2. Selective red cell aplasia:
 - Congenital
 - Diamond blacfan anaemia
 - Acquired

Eg. Transient erythroblastopenia of childhood.

- 3. Marrow replacement
 - Myelofibrosis
 - Osteopetrosis
 - Maligancies
- 4. Impaired erythropoiesis production
 - Chronic renal failure
 - Hypothyroidism and hypopituitarism
 - Chronic malnutrition
- 5. Miscellanaeous:
 - Congenital dyserythropoietc anaemia's
 - Erythropoietic porphyria

II. <u>Disorders of increased RBC production:</u>

A. RBC membrane defects

Eg. .Hereditary spherocytosis

- B. Defects of Haemoglobin synthesis
- i. Quantitative(Thalaseemia)
 - Alpha
 - Beta
 - Delta

ii. Qualitative (Haemoglobinopathesis)

Eg. Sickle cell disease HbE disease

iii. Combined –Quantitative and Qualitative defects

Hbs beta thalassemia

- C. Defects of RBC enzymes
 - G-6-PD deficiency
 - Pyruate kinase deficiency
- D. Acquired defects:
 - a) Immune haemolysis
 - Warm and cold antibody type
 - ABO and Rh incompactibility
 - b) Infections
 - Malaria
 - Kala azar
 - Acute bacterial infections

PATHOLOGICAL RED BLOOD CELLS IN ANAEMIA:

In anaemia, many kinds of abnormal red cells including nucleated forms are seen in the circulation. These abnormal cells are,

I. Anisocytosis(Variation in the size of RBC)

Macrocytosis, Microcytosis, Normocytosis

II. Poikilocytosis (Variation in shape of RBC)

Ovalocytosis, Spherocytosis, sickle cells

III. Polychromatophilia (Irregularity in stainig)

This indicates an increase in immature red cells in circirculation and occurs in the following forms Normoblasts, patchy staining of the cells, Punctate Basophilia (Basophilic stippling) and reticulocytes

IRON DEFICIENCY ANAEMIA

Iron Deficiency Anaemia is the most common and wide spread nutritional disorder present throughout the world, but its prevalence is higher in developing countries.

WHO estimates the number of anemic people worldwide to be a staggering two billion people and that approximately 50% of all anaemia can be attributed to iron deficiency.

Malaria, HIV/AIDS, hookworm infestations, schistomiasis and other infections such as tuberculosis are particularly important factors contributing to the high prevalence of anaemia in some areas.

40-50% of children and adult women were anaemic and that accounted for about 50% of anaemia in school children and women 80% in preschool children (2-5 years old)

According to third national family health survey (NFHS3)

79% of Indian children have anaemia including

7% of urban children and 84% of these in rural areas

STRUCTURE OF THE RED CORPUSCLES IN IRON DEFICIENCY ANAEMIA:

In iron deficiency anaemia the red blood corpuscles are decreased or normal in number and haemoglobin content of the red blood corpuscles is reduced. In blood smear, the red cells appear pale with a large central pale area and many of the red blood cells appear to be smaller than the normal.

This type of anaemia is called Hypochromic and microcytic anaemia.

ETIOLOGY:-

The Etiology varies with the age, sex and country of residence of the patients.

ETIOLOGICAL FACTORS IN IRON DEFICIENCY ANAEMIA:-

Increased physiological requirements:

Rapid growth during infancy and pre adolescence.

Decreased iron stores:

Premature babies and twins

Increased demand during:

Low birth weight, prematurity, adolescence, recovery from PEM.

Poor intake of dietary iron:

Exclusive milk diet, restriction of calories.

Poor absorption:

Celiac disease, giardiasis, drug intake

Excess loss of iron:

Blood loss during childbirth, gastrointestinal haemorrhage, faecal blood loss due to hookworm infestation, genitourinary bleed.

Iron malabsorption:

- > Starch and clay eating produce malabsorption of iron and iron deficiency anaemia.
- > PICA increases the risk of helminths
- > Delayed weaning, infection and lead poisioning
- > Sprue, non-tropical sprue, chronic diarrhea, mille induced enteropathy
- > Rarely errors in metabolism as
 - Sideroblastic anaemia
 - Idiopathic pulmonary hemosiderosis
 - Congenital transferrin deficiency where iron gets stored in the body rather than being utilized for erythropoiesis

Diminish absorption of iron:

Phytates, oxalates, phosphates, carbonates and tannates

Growth

Iron deficiency anaemia is more in children between the ages of 6 months to 2 years and from 11 to 16 years due to spurts of growth during these periods.

Pathophysiology

Diminished dietary absorption in proximal small intestine or excessive loss of body iron can result in iron deficiency

Iron deficiency anaemia develops when the supply of iron to the bone marrow is insufficient for the requirement of haemoglobin synthesis.

Iron is required for multiple metabolic process including,

- Oxygen transport
- DNA synthesis
- Electron transport
- ❖ In severe iron deficiency, the iron containing enzymes are low and this can affect immune and tissue function
- ❖ Iron deficiency anaemia can result in diminished growth /and learning and have serious consequences in children.
- ❖ Healthy new born infants have a total body iron of 250mg (Approximately 80 parts permillion ppm) this decreases to approximately 60 ppm in the first 6 months of the life.
- ❖ Body iron is regulated carefully by absorptive cells in the proximal small intestine, which alter iron absorption to match body losses of iron.
- ❖ Breast milk iron content is more bioavailable than cow's milk.
- ❖ Beside this fact, infants who consume cow's milk have more iron deficiency because bovine milk has a higher concentration of calcium which competes with iron for absorption and they may have gastrointestinal blood loss due to cow's milk allergy.

STAGES OF IRON DEFICIENCY ANAEMIA

On the basis of biochemical and haematological changes iron deficiency is graded into three stages

Stage I – Depletion of iron store

Ferritin is decreased, transferrin saturation, serum iron and haemoglobin are normal

Stage II- Depletion of transport

Iron transferrin saturation and serum iron also reduced. Haemoglobin is normal.

Stage III – State of IDA

Frank features of IDA

The flow of iron to erythroid marrow is impared to cause reduction in haemoglobin concentration with a progressive microcytic hypochromic anaemia associated with the reduced serum iron transferrin saturation and serum ferritin level.

CLINICAL FEATURES:-

Symptoms:

- Irritability
- Anorexia
- Easy fatigability
- Tiredness/ weakness
- Diarrhoea is often present
- Leg cramps
- Palpitations
- Inability to concentrate, somnolence, giddiness.
- Features of causative condition for example epigastric pain (Peptic ulcer)
- Constipation
- History of PICA
- Lack of memory

Signs:

- Eyes- Pallor in conjuntiva
- Nails- Pallor, Koilonychias (spoon shaped nails) and platynychia (flat nails)
- Hair- Dry, lusterless, excess loss of scalp hair
- Mouth- Bald, atrophy of tongue papillae glossitis, angular stomatitis
- Abdomen Mild hepatomegaly is common in children.

ROLE OF IRON DEFICIENCY ANAEMIA IN VARIOUS SYSTEMS

Cardiovascular system:-

Dyspnoea and palpitations are common symptoms but in very severe anaemia the patient may get congestive cardiac failure. Haemic murmurs are commonly heared in anaemic patients.

Respiratory system:-

Dyspnoea and respiratory infections

Central nervous system:-

Symptoms include faintness, giddiness, headache, lack of concentration and drowsiness with severe anaemia, clouding of consciousness, numbness and sometimes tingling of hands and feet.

Renal system:-

Slight protenuria may be present with severe anaemia

Gastrointestinal system:-

Anorexia is the commonest system nausea, flatulence and constipation may also occur slight to moderate smooth hepatomegaly is common in severe anaemia. Liver may become tender. In certain cases of iron deficiency anaemia, spleen may be enlarged.

DIFFERENTIAL DIAGNOSIS OF MICROCYTIC HYPOCHROMIC ANAEMIA

- Thalassaemia
- Pyridoxine deficiency
- **❖** Lead poisioning
- Chronic infection
- Sideroblastic anaemia
- Congenital atransferrinemia
- Copper deficiency
- **❖** G6PD deficiency

COMPLICATIONS:

- ❖ Infections are more common in iron deficiency anaemia, especially those of respiratory, gastrointestinal and urinary tracts.
- Chronic iron deficiency anaemia reduces the efficiency in work and study
- **CCF**

INVESTIGATIONS:

- Complete blood count with blood indexes
 - RBC count decreased, WBC count normal
 - Low –mean corpuscular volume (MCV), mean corpuscular haemoglobin(MCH) and mean corpuscular haemoglobin concentration (MCHC)
- Peripheral blood smear –RBCs are microcytic hypochromic and show anisocytic, poikilocytosis

- Normal reticulocyte count
- **❖** Serum iron level Less than 60 □ g/dl
- ❖ Total iron binding capacity(TIBC) >350 \(\text{g/dl} \)
- ❖ Transferrin saturation <16% (Normal range-25% -50%)
- ❖ Serum ferritin Low
- ❖ Free erythrocyte protoporphyrins(FEP)- increased
 - Normal $30 40\% \square g/dl$
 - 70□g/dl indicate IDA
- ❖ Stainable iron in marrow- low
- ❖ FEP/Haemoglobin ratio increases. Normal ratio 60 : 1
- ❖ Iron containing enzymes such as monoamine oxidase, catalase, cytochrome peroxidases will be − low
- Investigation to determine the cause of anaemia,
- ❖ Stool examination stools for occult blood, ova, cyst (hookworms).
- Gastrointestinal studies for bleeding, polyp, etc.-
- ❖ Barium meal examination, upper/ lower GI endoscopy, etc.

DIAGNOSIS:

Following criteria are essential to diagnose iron deficiency anaemia

- History of inadequate intake of dietary iron and blood loss if any.
- Hypochromic and microcytic structure of red blood cells.
- Low serum iron, increased total iron binding capacity.
- Platelet count is either normal or raised.
- Haemoglobin estimation variably reduced
- Reduced mean cell volume
- Erythrocyte count may be normal or reduced less than haemoglobin level would suggest.
- Serum ferritin level is reduced
- Clinical features of anaemia.

MANAGEMENT:

- Treat the cause
- Increase the iron intake
- Increase iron absorption
 - Overall correction of nutrition with food articles rich in iron is most important. Meat, liver, green leafy vegetables, onion, grapes, and jaggery are good source of iron.
 - There are two forms of dietary iron heme and non heme.
 - Vitamin c help absorb the non heme iron. Food containing non heme iron and the vitamin C rich food are eaten at the same meal.

PREVENTION:

This is a condition which can be prevented easily by supplementing iron rich foods. This involves the following measures:

- ✓ Eating diet with a wide variety of iron containing food
- ✓ Fortification of articles of food such as bread, salt, wheat and flour
- ✓ Improvement of personal hygiene
- ✓ Avoiding open air defecation (ankylostomiasis)
- ✓ Wearing foot wear
- ✓ Frequent deworming
- ✓ Iron supplementation during pregnancy, lactation and childhood.

TRIAL MEDICINE PRINCIPLES AND PROPERTIES OF TRIAL DRUG KARISALANKANNI CHOORANAM



INGREDIENTS:

S. NO.	NAME	BOTANICAL NAME	PARTS USED	QUANTITY
1	Karisalankanni	Eclipta prostrata	Dried whole plant	4 thola
2	Mookirattai	Boerhaevia diffusa	Dried whole plant	1 thola
3	Chukku	Zingiber officinale	Dried rhizome	1 thola
4	Milagu	Piper nigrum	Dried seed	1 thola
5	Thippili	Piper longum	Dried fruit	1 thola
6	Kadukkaai	Terminalia chebula	Dried fruit coat	1 thola
7	Nellikkaai	Phyllanthus emblica	Dried fruit	1 thola
8	Thandrikkaai	Terminalia bellerica	Dried fruit coat	1 thola
9	Maramanjal	Coscinium fenestratum	Dried wood	1 thola
10	Thaniya	Coriandrum sativum	Dried fruit	1 thola
11	Athimathuram	Glycyrrhiza glabra	Dried root	1 thola
12	Karunseeragam	Nigella sativa	Dried seed	1 thola
13	Thalisapathiri	Abies spectabilis	Dried leaves	1 thola
14	Elam	Elettaria cardamomum	Dried seed	1 thola
15	Seeragam	Cuminum cyminum	Dried seed	1 thola

SOURCE OF RAW DRUGS

The above said raw drugs are purchased from a well reputed country shop. The raw drugs will be authenticated by the Head of the department of Medicinal Botany, at Govt. siddha medical college, chennai. The raw drugs are purified and the medicine is prepared in Gunapadam laborotary of GSMC, Chennai. The prepared medicine is again authenticated by the Head of the department of Gunapadam.

PURIFICATION OF THE RAW DRUGS:

- 1. **Karisalai:**Eclipta alba, Clean the leaves with pure cloth and remove the rotten leaves.
- 2. **Kadukai:**Terminalia chebulla, Soak the kadukai in rice water(kazhuneer) over night, remove the yellowish tint of the water and seed and dry it.
- 3. Nellikai: Phyllanthus emblica, Boil it with milk, remove the seed and dry it.
- 4. **Thaandrikai:**Terminalia bellarica, Soak it in Pandanus odoratissimus (Thaludhalai), juice for three hours (1Samam) remove the seed and dry it.
- 5. **Sukku:**Zingiber officinalis, Double the propotion of lime stone[calcium carbonate] solution is poured and boiled for three hours, then wash it, dry and remove the peel.
- 6. **Milagu:**Piper nigrum, Soak it in sour butter milk for three hours.
- 7. **Thippili:**Piper longum, Soak it in plumbago zeylanica, (Kodiveli) leaf juice for twenty four minutes (1 Nazhigai) and dry it sun.
- 8. **Mara manjal:**Coscinium fenestratum, Remove the peel cut it into pieces and dry it in sunlight.
- 9. **Karunjeragam:**Nigella sativa, Dry it in sunlight &fry it like as golden yellow colour.
- 10. **Seeragam:**Cuminum cyminum, Dry it in sunlight &fry it like as golden yellow colour.
- 11. **Athimathuram:**Glycrrhiza glabra, Wash with clean water and Remove the peel cut it into pieces.
- 12. **Mookkirattai:**Boerhaavia diffusa, Clean the leaves with pure cloth and remove the rotten leaves.
- 13. **Thalisa pathiri:** Abies spectabilis, Clean the leaves with pure cloth and remove the rotten leaves.
- 14. **Dhania:**Coriandrum sativum, Boil Kothumali seed with Hotwater & dry it in sunlight.
- 15. **Elam:** Elettaria cardamomum, Remove the peel & take the seeds.

INGREDIENTS OF KARISALANKANNI CHOORANAM



Eclipta prostate



Boerhavia diffusa



Glyzyrrhiza glabra



Zingiber officinale



Piper nigrum



Piper longum



Terminalia chebula



Phyllanthus emblica



Terminalia belarica







Cuminum cyminum



Nigella sativa



Abies spectabilis



Coscinium fenestratum

Elettaria cardamomum

Coriandrum sativum

METHOD OF PREPARATION

The above mentioned drugs are purified properly as said above and they are dried in shade & made into fine powder

DRUG STORAGE: The drug thus prepared is stored in a clean and dry glass bottles.

DOSE: 200mg – 500mg twice a day

ADJUVANT: Honey **DURATION:** 28 days

PROPERTIES OF THE DRUG

1. Karisaalai

Botanical name :Eclipta prostrata
English name :Trailing eclipta
Family :Compositae

Organoleptic characters

Taste :kaipu
Potency :veppam
Division :karpu

Parts used :leaves, flowers

Chemical constituents :Dithienylacetylene

Action :cholagogue, emetic, tonic, aphrodisiac, hepato

tonic

Uses :jaundice, pruritis, scabies, enlargement of

spleen, liver.

Pothu gunam

"குரற்கம்மற் காமாலை குட்டமொடு சோபை யுற்றபாண்டு பன்னோ யொழிய- நிரற்சொன்ன மெய்யாந் தகரையொத்த மீளிண்ணு நற்புலத்துக் கையாந் தகரையொத்தக் கால்."

2. Mookirattai

Botanical name : Boerhaavia diffusa
English name : Spreading hog-weed

Family : Nyctaginaceae

Organoleptic characters

Taste : Kaippu
Potency : Veppam
Division : Kaarppu
Parts used : Herb, root

Chemical constituents: Purine nucleoside (hypoxanthine-9-

arabinofuranoside), Rotenoids

(boeravinonesA and B), Punarnavoside.

Action : Stomachic, laxative, diuretic, diaphoretic,

expectorant.

Uses : Cures dropsy, ascities, asthma, heart disease,

renal calculi.

Pothu gunam

"சீத மகற்றுந் தினவடக்குங் காந்திதரும் வாத வினையை மடிக்குங்காண்- பேதி கொடுக்குமாதை உண்டாக்காற் கோமள்மே! பித்தம் அடுக்குமே மூக்குரட்டை யாய்."

3. Chukku

Botanical name : Zingiber officinale

English name : Dry ginger

Family : Zingiberaceae

Organoleptic characters

Taste : Kaarppu
Potency : Veppam
Division : Kaarppu
Parts used : Rizhome

Chemical constituents : β -Bisabolene, ar-curcumene, α -farnesene

Phellandrene and zingiberene.

Action : Carminative, aromatic, stimulant, increases

prostaglandins

Uses : Cures cold, cough, indigestion, peptic ulcer,

flatulence.

Pothu gunam

"தூலைமந்தம் நெஞ்செரிப்பு தோடமேப் பம்மழலை மூலம் இரைப்பிருமல் மூக்குநீர்- வாலகப தோடமதி சாரந் தொடர்வாத குன்மநீர்த் தோடம்ஆ மம்போக்குஞ் சுக்கு."

4. Milagu

Botanical name : Piper nigrum
English name : Black pepper
Family : Piperaceae

Organoleptic characters

Taste : Kaippu, kaarppu

Potency : Veppam
Division : Kaarppu

Parts used : Dried unripe fruit

Chemical constituents: Piperine, piperidine, clavicin.

Action : Carminative, antiperiodic, resolvent, anti-

pyretic

Uses : Cures dyspepsia, flatulence, colic, worms,

ascities, asthma, gonorrhoea.

Pothu gunam

"சீதசுரம் பாண்டு சிலேத்மங் கிராணிகுன்மம் வாதம் அருசிபித்தம் மாமூலம்- ஓதுசன்னி யாசமபஸ் மாரம் அடன்மேகம் காசமிவை நாசங் கறிமிளகினால் கோணுகின்ற பக்கவலி குய்யவுரோ கம்வாத சோணிதங்க ழுத்திற்குள் தோன்றுநோய்- காணரிய காதுநோய் மாதர்குன்மங் காமாலை மந்தமென்றீர்

5. Thippili

Botanical name : Piper longum

ஏதுநோய் காயிருக்கில் ஈங்கு."

English name : Dried catkins, long-pepper

Family : Piperaceae

Organoleptic characters

Taste: KaarppuPotency: VeppamDivision: Inippu

Parts used: Immature berries, stems, roots.

Chemical constituents : Piperine, piperolactam A and B, piperadione.Action : Stimulant, carminative, expectorant, diuretic

Uses : Cures cold, cough, asthma, hoarseness, hiccup,

colic, flatulence

Pothu gunam

"இருமல் குன்மம் இரைப்பு கயப்பிணி

ஈளை பாண்டு சந்யாசம் அரோசகம்

பொருமல் ஊதை சிரப்பிணி மூர்ச்சைநோய்

பூரிக் குஞ்சல தோடம் பீலிகமும்

வரும் லப்பெருக் கோடு மகோதரம்

வாதம் ஆதிமுத் தோடஞ் சுரங்குளிர்

பெருமாலைப்புரி மேகப் பிடகமும்

பேருந் திப்பிலிப் பேரங்குரைக்கவே."

6. Kadukkaai

Botanical name : Terminalia chebula

English name : Chebulic myrobalan, myrobalan

Family : Combretaceae

Organoleptic characters

Taste : Thuvarppu

Potency : Veppam

Division : Inippu

Parts used : Dried fruits, galls

Chemical constituents : Gallic acid

Action : Astringent, purgative, alterative, stomachic.

Uses : Cures worms, fever, cough, asthma, urinary

disease, piles, hiccup, vomiting.

Pothu gunam

"தாடை கழுத்தக்கி தாலுகுறி யிவிடப்

பீடைசி லிபதமுற் பேதிமுடம்- ஆடையெட்டாத்

தூலமிடி புண்வாத சோணிதங்கா மாலை

டாலமிடி போம்வரிக்கா யால்."

7. Nellikkaai

Botanical name : Emblica officinalis

English name : Emblicmyrobalan, Indian gooseberry

Family : Euphorbiaceae

Organoleptic characters

Taste : Pulippu, thurvarppu, inippu

Potency : thatpam

Division : inippu

Parts used : Dried fruit, nut or seed, leaves, rootbark,

flowers.

Chemical constituents: Procyanidin, prodelphinidin.

Action : Refrigerant, diuretic, laxative, astringent.

Uses : Cures jaundice, inflammation of lungs,

hiccup, dyspepsia, nausea, vomiting.

Pothu gunam

"பித்தமன லையம் பீநசம்வாய் நீர் வாந்தி மந்தமலக் காடும் மயக்கமுமில்- ஒத்தவுரு வில்லிக்கா யம்மருங்கா மென்னாட்கா லந்தேர்ந்தே நெல்லிகா யம்மருந் துணீ

நெல்லிக்காய்க் குப்பித்தம் நீங்கு மதன்புளிப்பால் செல்லுமே வாதமதிற் சேர்துவரால்- சொல்லுமையம் ஓடுமிதைச் சித்தத்தில் உன்ன அனலுடனே கூடுபிற மேகமும் பொங் கூறு."

8. Thandrikkaai

Botanical name : Terminalia bellarica
English name : Belericmyrobalans.

Family : Combretaceae

Organoleptic characters

Taste : Thuvarppu
Potency : Veppam
Division : Inippu
Parts used : Fruits

Chemical constituents: Punicalin, punicalagin, geraniin, granatin B.

Action : Astringent, tonic, laxative, expectorant.

Uses : Cures cough, hoarseness, sore throat, dropsy.

Pothu gunam

"சிலந்திவிடம் காமியப்புண் சீழான மேகங் கலந்துவரும் வாதபித்தங் காலோ- டலர்ந்துடலில் ஊன்றிக்காய் வெப்ப முதிரபித் துங்கரக்குந் தான்றிக்காய் கையிலெடுத் தால்

ஆணிப்பென் மேனிக் கழகும் ஒளியுமிகும் கோணிகொள்வாதபித்தக் கொள்கைபோம்-தானிக்காய் கொண்டவர்க்கு மேகமறும் கூற அனற்றணியும் கண்டவர்க்கு வாதம்போம் காண்".

9. Maramanjal

Botanical name : Coscinium fenestratum

English name : Tree turmeric
Family : Menispermaceae

Organoleptic characters

Taste : Kaippu
Potency : Veppam
Division : Kaarppu
Parts used : Stem

Chemical constituents: Berlambine, dihydroberlambine and

noroxyhydrastinine.

Action : Febrifuge, stomachic, tonic

Uses : Cures cold, cough, indigestion, peptic ulcer.

Pothu gunam

"அழன்றகண மூலம் அருசி யுடனே
உழன்ற கணசுரமும் ஒடுஞ்- சுழன்றுள்ளே
வீறுசுர முந்தணியும் வீசுமர மஞ்சளுக்குத்
தேறு மொழியன்மே! செப்பு".

10. Thaniya

Botanical name : Coriandrum sativum

English name : Coriander

Family : Umbelliferae

Organoleptic characters

Taste : Kaarppu

Potency : Seetha veppam

Division : Kaarppu

Parts used : Fruits, leaves.

Chemical constituents: Gnaphaloside A and B, quercetin,

isohamnetin, rutin and luteolin.

Action : Aromatic, stimulant, tonic, carminative,

anti- diabetic.

Uses : Cures diabetes, flatulence, colic, sore throat,

vertigo.

Pothu gunam

"கொத்துமல்லி வெப்பம் குளிர்காய்ச்சல் சர்த்திவிக்கல் தாகமொடு தாதுநட்டம்- கத்தியெழும் வாத விகார்மடர் வங்கர்த்த பிவிரணம் பூதலத்தில் லாதகற்றும் போற்று."

11. Athimadhuram

Botanical name : Glycyrrhiza glabra

English name : Liquorice
Family : Fabaceae

Organoleptic characters

Taste : Inippu
Potency : Thatpam
Division : Inippu

Parts used : Root and Rhizomes

Chemical constituents : Hexanoic acid, γ -nonalactone, cumic alcohol,

indole, anethole.

Action : Tonic, demulcent, expectorant, diuretic, mild

laxative, anti-arthritic.

Uses : Cures anemia, menorrhagia-metrorrhagia,

hematemesis.

Pothu gunam

"கத்தியரி முப்பிணியால் வருபுண் தாகங் கண்ணோய்உன் மாதம்விக்கல் வலிவெண்குட்டம் பித்தம்எலும் புருக்கி கிரிச்சரம் ஆவர்த்த பித்த மதமூர்ச்சை விடபாகம் வெப்பந் தத்திவரு வாதசோணிதங்கா மாலை சருவவிடங் காமியநோய் தாது நட்டங் குத்திருமல் ஆசியங்கம் இதழ்நோய் இந்து குயப்புணும்போம் மதூகமெனக் கூறூங்காலே".

12. Karunseeragam

Botanical name : Nigella sativa

English name : Small fennel or black cumin

Family : Ranunculaceae

Organoleptic characters

Taste: KaippuPotency: VeppamDivision: Kaarppu

Parts used : Dried fruits and seeds.

Chemical constituents : Nigellimine N-oxide, nigellicine, saponins.
 Action : Diuretic, stomachic, stimulant, carminative,

anthelmintic.

Uses : Cures obstinate hiccup, fever, diarrhea, skin

diseases.

Pothu gunam

"கருஞ்சீ ரகத்தான் கரப்பனொடு புண்ணும் வருஞ்சிராய்ப் பீநசமு மாற்றும்- அருந்தினால் காய்ச்சல் தலைவலியுங் கண்வலியும் போமுலகில் வாய்ச்ச மருந்தென்வே வை."

13. Thaalisapathiri

Botanical name : Abies spectabilis
English name : Himalayan yew

Family : Coniferae

Organoleptic characters

Taste: KaarppuPotency: VeppamDivision: Kaarppu

Parts used : Leaves, volatile oil

Chemical constituents: Betuloside, methyl betuloside, n-triacontanol, β -

sitosterol.

Action : Carminative, expectorant, stomachic, tonic,

antilithic.

Uses : Cures breast cancer, asthma, haemoptysis,

epilepsy.

Pothu gunam

"நாசி களப்பிணிகள் நாட்பட்ட காசஞ்சு வாசம் அருசி வனமங்கால்- வீசிவரு மேகமந்தம் அத்திசுரம் விட்டேகுந் தாளிச்சத்தால் ஆகுஞ் சுகப்பிரசவம்".

14. Elam

Botanical name : Elettaria cardamomum

English name : Cardamom

Family : Scitaminaceae

Organoleptic characters

Taste: KaarppuPotency: VeppamDivision: Kaarppu

Parts used : Dried ripe seeds, oil from fruits.

Chemical constituents : α-terpineol, myrcene, heptane, limonene,

menthone.

Action : Aromatic, stimulant, carminative,

stomachic, diuretic.

Uses : Cures stomach complaints, diarrhoea, atonic

dyspepsia.

Pothu gunam

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

15. Seeragam

Botanical name : Cuminum cyminum

English name : Cumin seed, caraway seed.

Family : Umbelliferae

Organoleptic characters

Taste: KaarppuPotency: ThatpamDivision: Inippu

Parts used : Fruit and seed.
Chemical constituents : Cuminaldehyde

Action : Carminative, aromatic, stomachic, stimulant,

astringent.

Uses : Cures hoarseness of voice, dyspepsia, chronic

diarrhea.

Pothu gunam

"பித்தமெனு மந்திரியைப் பின்னிப் படுத்தியவன் சத்துருவை யுந்துறந்து சாதித்து- மத்தனெனும் ராசனையு மீவென்று நண்பைப் பலபடுத்தி போசனகு டோரிசெயும் போர்".

PRECLINICAL SAFETY STUDIES BIO-CHEMICAL ANALYSIS

PREPARATION OF EXTRACT:

2 gm of the Karisalankaani chooranam is taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called extract. This fluid is taken for the Bio- Chemical analysis.

QUALITATIVE ANALYSIS:

S. NO	EXPERIMENT	OBSERVATION INFEREN					
I.	TEST FOR FREE RADICALS						
1.	Test for Chloride 2 ml of extract is added with dilute nitric acid till the effervescence ceases. Then 2 ml of silver nitrate solution is added	Presence of white precipitate	Present				
2.	Test for Phosphate: 2 ml of the extract is treated with 2ml of Ammonium molybdate solution and 2 ml of concentrated nitric acid	Absence of yellow precipitate	Absent				
3.	Test for Carbonate: 2 ml of the extract is treated with 2 ml of magnesium sulphate solution	Absence of white precipitate	Absent				
4.	Test for Sulphide: 1 gm of the substance is treated with 2 ml of concentrated Hydrochloric acid						
5.	Test for Sulphate: 2ml of the above prepared extract is taken in a test tube to this added 2ml of 4% preciptate Absent of white preciptate		Absent				
6.	Test for Nitrate 1 gm of the substance is heated with copper turnings and concentrated sulphuric acid and viewed the test tube vertically down	Absence of reddish brown gas	Absent				
7.	Test for Nitrite 3 drops of the extract is placed on a filter paper. On that, 2 drop of Acetic acid and 2 drops of Benzidine solution is placed	Absence of yellowis	sh Absent				
8.	Test for Borate 2 pinches of the substance is made into paste by using Sulphuric acid and Alcohol (95%) and introduced into the blue flame	Absence of green tinged flame	Absent				

	II. TEST FOR BASIC RADICALS						
9.	Test for copper One pinch of the 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	Absent				
10.	Test for iron To the 2 ml of extract, 2 ml of Ammonium thiocyanate solution is added	Presence of blood red colour	Present				
11.	Test for zinc To the 2 ml of extract Sodium hydroxide solution is added in drops to excess	Absence of white precipitate	Absent				
12.	Test for calcium 2 ml of the extract is added with 2 ml of 4 % Ammonium oxalate solution	Presence of white precipitate	Present				
13.	Test for magnesium 2ml of extract sodium hydroxide solution is added in drops to excess	Absence of white precipitate	Absent				
14.	Test for potassium A pinch of substance is treated with 2 ml of sodium nitrite solution and then treated with 2 ml of Cobalt nitrate in 30% glacial Acetic acid	Absence of yellow precipitate	Absent				
15.	Test for sodium 2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame	Absence of yellow colour flame	Absent				
16.	Test for starch 2 ml of extract is treated with weak iodine solution	Blue colour is obtained	Present				
17.	Test for reducing sugar 5 ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2 minutes. The colour changes are noted	Green colour is obtained	Present				
18.	Test for tannic acid The extract is treated with ferric chloride solution	Absence of Blue black precipitate	Absent				

RESULTS:

The trial drug Karisalankanni chooranam contains

Acid radical: Chloride

Basic radicals: Iron, calcium, starch and Reducing sugar.

PHYTOCHEMICAL ANALYSIS

Project Report

Project ID NRS/AS/0340/02/2019

Name and Address of the Researcher Dr. K.Karpagavalli

Government Siddha Medical College,

Chennai

Tamil Nadu, India

Sample –ID Karisalankanni Chooranam - KC

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°C. Formation of bluish green colour indicates the presence of anthocyanin.

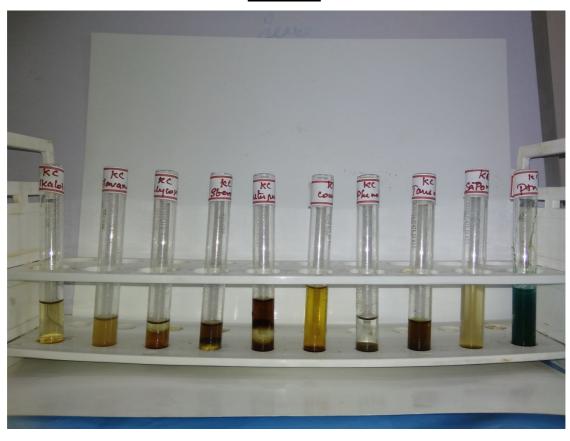
Test for Carbohydrates - Benedict's test:

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.

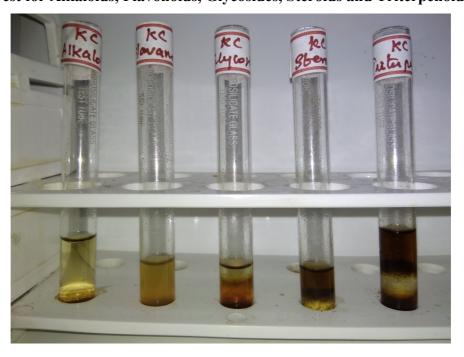
Proteins (Biuret Test)

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.

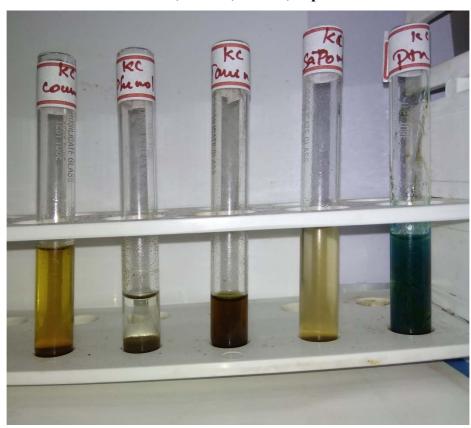
RESULTS



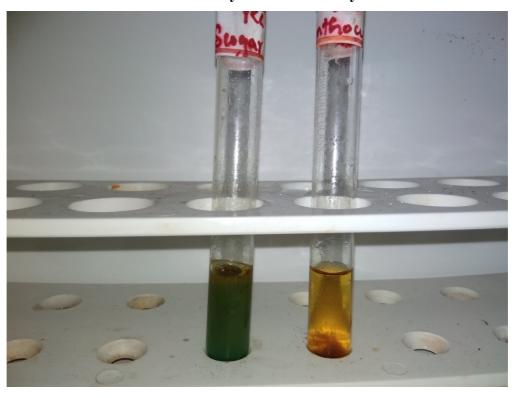
Test for Alkaloids, Flavonoids, Glycosides, Steroids and Triterpenoids



Test for Coumarins, Phenol, Tanins, Saponin and Protein



Test for Antho Cyanin and carbohydrates



PHYSICO-CHEMICAL ANALYSIS

Physicochemical Evaluation

Project ID NRS/AS/0340/02/2019

Name and Address of the Researcher Dr.Karpaga Valli

Government Siddha Medical College,

Chennai

Tamil Nadu, India

Sample –ID Karisalankanni Chooranam- KC

SAMPLE DESCRIPTION



State	Solid
Appearance	Brownish
Nature	fine powder
Odor	Strongly Aromatic
Flow Property	Non Free flowing

Solubility Profile of KC



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

Percentage Loss on Drying

Test drug was accurately weighed in evaporating dish . The sample was dried at 105° 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 °C 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 105°C, 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 chloroform 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 105°C, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

Final Test report KC

S.No	Parameter	Mean (n=3) SD
1.	Loss on Drying at 105 °C (%)	2.433 ± 0.30
2.	Total Ash (%)	17.6 ± 0.7
3.	Acid insoluble Ash (%)	0.26 ± 0.034
5.	Alcohol Soluble Extractive (%)	12 ± 1.55
6.	Water soluble Extractive (%)	26 ± 3.606

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

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.

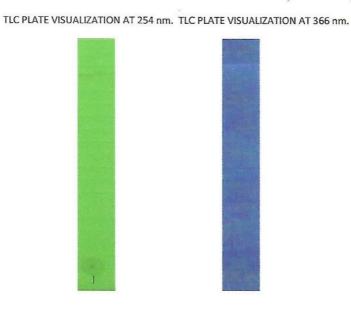
Scanning

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.

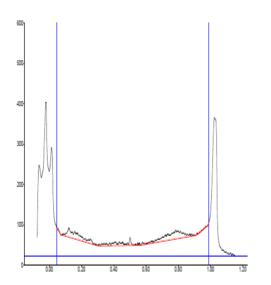
HPTLC ANALYSIS

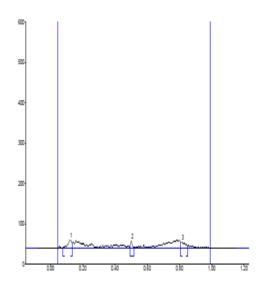
Project ID	NRS/AS/0340/02/2019
Name and Address of the Researcher	Dr.Karpagavalli Government Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested for Analysis	HPTLC Analysis
Sample Received	In Person
Sample –ID	Karisalankanni Chooranam- KC
Method of Analysis Instrument TLC Plate Mobile 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

TLC Analysis



HPTLC finger printing of SampleKC





Peak Table

Peak				Max Height				Area	Area %
1	0.08	0.5	0.12	21.9	37.64	0.14	12.5	378.9	44.89
2	0.49	2.8	0.50	19.6	33.56	0.52	1.2	136.6	16.18
3	0.81	13.2	0.82	16.8	28.80	0.85	3.8	328.5	38.92

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 0.08 to 0.81. Further the peak 1 and 3 occupies the major percentage of area of 44.89 and 38.92 %

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°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	PS	Cetrimide Agar
Aeruginosa		

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	
Salmonella	Absent	Absent	As per AYUSH
Staphylococcus Aureus	Absent	Absent	specification
Pseudomonas	Absent	Absent	
Aeruginosa			

Culture plate with E-coli (EC) specific medium



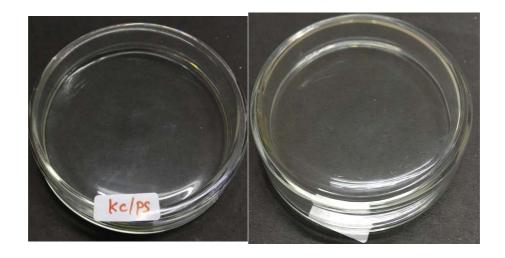
Culture plate with Salmonella (SA) specific medium



Culture plate with Staphylococcus Aureus (ST) specific mediu



Culture plate with Pseudomonas Aeruginosa (PS) specific medium



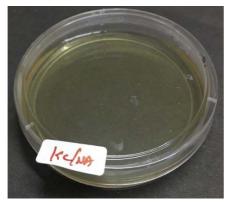
STERILITY TEST BY POUR PLATE METHOD

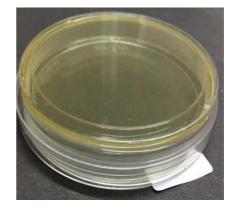
Objective

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°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° 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

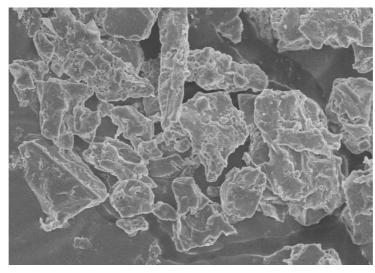
Result

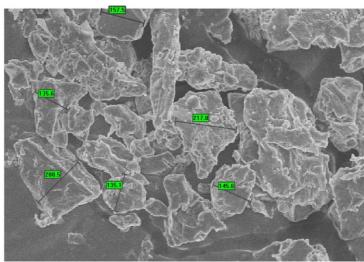
No growth / colonies were observed in any of the plates inoculates with the test sample.

Test	Result	Specification	As per AYUSH/WHO
Total Bacterial Count	Absent	NMT 10 ⁵ CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10 ³ CFU/g	1

PARTICLE SIZE

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





Mean	165.1
Std. Deviation	34.99
Std. Error	14.28

REPORT

Microscopic observation of the particle size analysis reveals that the average particle size of the sample was found to be 165.1 \pm 34.99 μm

AFLATOXIN

Project ID	NRS/AS/0340/02/2019
Name and Address of the Researcher	Dr.Karpaga Valli GovernmentSiddhaMedicalCollege,Chennai Tamil Nadu,India
Parameter Requested by the Customer for	Aflatoxin Assay By TLC (B1,B2,G1,G2)
Analysis	
Sample Received	In person
Sample –ID	Karasalankanni Chooranam- KC
Description of the Sample	Solid
Analysis Type	Third Party Analysis
Result of Analysis	Test Report Attached

Strandard

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 μ L, 5μ L, 7.5μ L and 10μ L. 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 KC	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.

HEAVY METAL ANALYSIS

Project ID	NRS/AS/0340/02/2019					
	Dr.Karpagavalli					
Name and Address of the Researcher	Government Siddha Medical College,					
	Chennai, Tamil Nadu, India					
Parameter Requested for Analysis	Heavy Metal analysis by AAS					
Sample Received	In Person					
Sample –ID	Karisalankanni Chooranam – KC					
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					

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 testitem.

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 HNO₃

Test Report

Name of the	Absorption	Result	Maximum
Heavy	Max	Analysis	Limit
Metal	Λ max		
Mercury	253.7 nm	0.3	1 ppm
Lead	217.0 nm	0.5	10 ppm
Arsenic	193.7 nm	0.25	3 ppm
Cadmium	228.8 nm	0.22	0.3 ppm

BDL- Below Detection Limit

Report and Inference

Results of the present investigation have clearly shows that the sample has traces of heavy metals Mercury, Arsenic, Cadmium andlead.

PESTICIDE ANALYSIS

Project ID	NRS/AS/0340/02/2019
	Dr.Karpaga Valli Government Siddha Medical College, Chennai Tamil Nadu, India
1 7	Organochlorine pesticides Organophosphorus pesticides Pyrethroids
Sample Received	In Person
Sample –ID	Karisalankanni Chooranam- KC
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 40°C 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

Test Result Analysis of the Sample KC

Pesticide Residue		
I.Organo Chlorine Pesticides	Sample KC	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.

ACUTE ORAL TOXICITY STUDY OF *KARISALANKANNI CHOORANAM*(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 22°C ± 3°C. 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 Kings institute, Guindy, 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 for Acute Toxicity Studies

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

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 No: LV/11/CLBMCP/2018

Test Substance : KARISALANKANNI CHOORANAM

Animal Source : Kings Institute, Guindy, 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,

Routeofadministration : 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 $22^{\circ}\text{C} + 3^{\circ}\text{C}$.

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:

KARISALANKANNI CHOORANAM was suspended in lukewarm 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 2000 mg/kg body weight was administered as single dose. 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 monitored 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.

${\bf Acute\ oral\ toxicity\ studyof KARISALANKANNI\ CHOORANAM}$

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	+	-	1	+	-	+	-	-	-	-	-	-	-	-	1	-	-	-	-	-
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
 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	244.1±65.70	246.3 ± 41.11	248.6 ±02.12						
HIGH DOSE	248.3± 4.64	250.7 ±3.22	252.2 ± 2.70						
P value (p)*	NS	NS	NS						

Table 4 (Water intake (ml/day) of Wistar albino rats group exposed to (KARISALANKANNI CHOORANAM):

DOSE	DAYS									
	1	6	14							
CONTROL	58.7 ± 1.22	59.2±2.16	60.2±3.14							
HIGH DOSE	58.2 ±1.30	60.6±2.70	61 ±2.64							
P value (p)*	NS	NS	NS							

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

Table 4: Food intake (gm/day) of Wistar albino rats group exposed to KARISALANKANNI CHOORANAM

DOSE	DAYS									
	1	7	14							
CONTROL	84.03±2.12	86.2±2.26	88.6±4.16							
High DOSE	90.2±2.44	92.4±3.20	94.4±2.34							

REPEATED DOSE 28-DAY ORAL TOXICITY (407) STUDY OFKARISALANKANNI CHOORANAM

Test Substance : KARISALANKANNI CHOORANAM

Animal Source : TANUVAS, Madhavaram, Chennai.

Animals : Wister Albino Rats (Male -24, and Female-24)

Age : 6-8 weeks

Body Weight : 50-200gm.

Acclimatization : Seven days prior to dose.

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

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 22°C + 3°C.

Relative humidity : between 30% and 70%,

Air changes : 10 to 15 per hour

Dark and light cycle : 12:12 hours.

Duration of the study : 28 Days.

Table 5

Groups	No of Rats			
Group I Vehicle control (Water)	12(6male,6 female)			
Group II KCM- low dose X (50mg)	12 (6male,6 female)			
Group III KCM- Mid dose 4X (200mg)	12 (6male,6female)			
Group IV KCM- High dose 8X(400 mg)	12(6male,6female)			

KCM - KARISALANKANNI CHOORANAM

Methodology

Randomization, Numbering and Grouping of Animals:

48 Wistar Albino Rats (24M + 24F) were selected and divided into 4 groups. Each group consist of 12 animals (Male -6, and Female-6). First group treated as a control and other three group were treated with test drug (low, mid, high) for 28 days. Animals were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal was marked with picric acid. The females were nulliparous and non-pregnant.

Justification for Dose Selection:

As per OECD guideline three dose levels were selected for the study. They are low dose (X), mid dose (4X), high dose (8X). X is calculated by multiplying the therapeutic dose (500 mg) and the body surface area of the rat (0.018). i.e X dose is (50mg/kg), 4X dose is (200mg/kg), 8X dose is (400mg/kg).

Preparation and Administration of Dose:

Karisalankanni chooranam suspended in with water, It was administered to animals at the dose levels of X, 4X, 8X. The test substance suspensions were freshly prepared every two days once for 28 days. The control animals were administered vehicle only. The drug was administered orally by using oral gavage once daily for 28 consecutive days.

Observations:

Experimental animals were kept under observation throughout the course of study for the following

Body Weight:

Weight of each rat was recorded on day 0, at weekly intervals throughout the course of study.

Food and water Consumption:

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

Clinical signs:

All animals were observed daily for clinical signs. The time of onset, intensity and duration of these symptoms, if any, were recorded.

Mortality:

All animals were observed twice daily for mortality during entire course of study.

Necropsy:

All the animals were sacrificed by excessive anesthesia on day 29. Necropsy of all animals was carried out.

Laboratory Investigations:

Following laboratory investigations were carried out on day 29 in animals fasted over- night. Blood samples were collected from orbital sinus using sodium heparin (200IU/ml) for Bio chemistry and potassium EDTA (1.5 mg/ml) for Hematology as anticoagulant. Blood samples were centrifuged at 3000 r.p.m. for 10 minutes.

Haematological Investigations:

Haematological parameters were determined using Haematology analyzer.

Biochemical Investigations:

Biochemical parameters were determined using auto-analyzer.

Histopathology:

Control and highest dose group animals will be initially subjected to histopathological investigations. If any abnormality found in the highest dose group than the low, then the mid dose group will also be examined. Organs will be collected from all animals and preserved in 10% buffered neutral formalin for 24 h and washed in running water for 24 h. The organ sliced 5 or 6µm sections and were dehydrated in an auto technicon and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" moulds. It was followed by microtome and the slides were stained with Haematoxylin-eosin red.

Statistical analysis:

Findings such as body weight changes, water and food consumption, hematology and blood chemistry were subjected to One-way ANOVA followed by dunnet t test using a computer software programme – Graph pad version 7. All data were summarized in tabular form, (Table-6 to 12)

RESULTS

Repeated Dose 28- day oral toxic study of KARISALANKANNI CHOORANAM

Table 6: Body weight of wistar albino rats group exposed to KARISALANKANNI CHOORANAM

DOSE	1	DAYS											
DOSE	1	7	14	21	28								
CONTROL	235.2±18.46	236.5 ± 35.10	236.6 ± 45.60	238.7±56.16	238.4 ± 66.15								
LOW DOSE	248.2 ± 65.24	250.7 ± 66.28	254.6± 55.34	256 ±56.34	256.8± 35.36								
MID DOSE	252.4± 18.34	253.3 ± 16.24	253.4 ± 14.12	255.2 ±15.20	256.4 ± 54.10								
HIGH DOSE	261.6± 62.24	261.4±42.22	262.4 ± 52.24	263 ± 54.28	264 ± 74.60								
P value (p)*	NS	NS	NS	NS	NS								

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

Table 7: Water intake (ml/day) of Wistar albino rats group exposed to KARISALANKANNI CHOORANAM

DOSE	DAYS								
	1	6	14	21	28				
CONTROL	60.1 ± 8.72	60±1.52	60.2±1.40	61±1.32	61.4±1.62				
LOW DOSE	65.1±1.21	65.6±4.22	66.6±1.02	65.2±2.06	66.4±1.20				
MID DOSE	62.1±1.02	62.3±1.21	62.1±2.62	63.4±4.32	63.4±1.64				
HIGH DOSE	64.1±1.81	64.2±1.32	64.4±1.14	64.6±1.62	65.8±2.02				
P value (p)*	NS	NS	NS	NS	NS				

N.SNotSignificant,**(p>0.01),*(p>0.05),n=10valuesaremean±S.D(OnewayANOV A followedbyDunnett'stest)

Table 8: Food intake (gm/day) of Wistar albino rats group exposed to KARISALANKANNI CHOORANAM

DOSE	DAYS					
	2	7	23	22	28	
CONTROL	34±4.14	34.2±6.12	34.3±2.18	34.2±1.14	34±5.62	
LOW DOSE	36.3±1.64	36.3±1.51	36.2±1.51	36.5±1.62	36.5±1.22	
MID DOSE	34.1±2.12	34.2±3.50	34.2±2.14	34.2±2.16	35.2±1.64	
HIGH DOSE	32.4±1.62	32.1±1.64	32.6±2.36	32.6±1.20	36.4±2.32	
P value (p)*	NS	NS	NS	NS	NS	

. NS- NotSignificant,**(p>0.01),*(p>0.05),n=10valuesaremean \pm S.D(Oneway ANOVA followedbyDunnett's test

Table 9: Haematological parameters of Wistar albino rats group exposed to KARISALANKANNI CHOORANAM

Category	Control	Low dose	Mid dose	High dose	P value
Category	Control	Low dose		ingii dosc	(p)*
Haemoglobin (g/dl)	13.4±0.71	13.30±0.14	13.4±0.13	13.72±0.13	N.S
Total WBC (×10 ³)	09.41±0.22	09.32±0.22	09.34±0.22	09.30±1.10	N.S
Neutrophils (%)	21.13±0.60	21.02±0.52	22.11±1.42	22.02±2.71	N.S
lymphocyte (%)	82.10±1.26	82.12±1.42	83.10±2.44	83.20±2.54	N.S
Monocyte (%)	1.1±0.03	1.1±0.01	1.2±0.04	1.1±0.03	N.S
Eosinophil (%)	0.8±0.03	0.8±0.04	0.9±0.05	0.9±0.08	N.S
Platelets cells10³/μl	900.17±3.18	902.11±4.62	902.11±2.20	902.22±2.64	N.S
Total RBC 10 ⁶ / μl	9.32±0.11	9.47±0.33	9.50±0.64	9.60±0.46	N.S
PCV%	48.10±0.2	48.62±5.30	48.8±4.70	48.4±.71	N.S
MCHC g/dL	36.5±1.61	36.2±1.51	36.8±1.30	36.13±1.60	N.S
MCV fL(μm³)	58.2±2.02	58.2±1.80	58.7±1.10	59.7±1.30	N.S

 $N.S- NotSignificant, **(p>0.01), *(p>0.05), n=10 values are mean \pm S.D (One way ANOVA followed by Dunnett's test)$

Table 10: Biochemical Parameters of of Wistar albino rats group exposed toKARISALANKANNI CHOORANAM

BIOCHEMICAL PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
GLUCOSE (R) (mg/dl)	138.10±2.02	138.12±2.10	138.9±12.06	138.12±5.25	N.S
T.CHOLESTEROL(mg/dl)	140.14±5.10	140.15±5.20	142.40±1.68	143.21±1.10	N.S
TRIGLY(mg/dl)	74.15±1.82	74.11±1.32	74.15±1.22	76.16±1.21	N.S
LDL	78.6±2.13	78.7±2.05	78.10±1.03	78.40±01.32	NS
VLDL	14.2±1.52	14.20±2.41	14.02±1.32	14.04±12.15	NS
HDL	28.12±4.32	28.32±2.50	28.46±1.20	28.51±1.23	NS
Ratio 1(T.CHO/HDL)	3.73±1.16	3.72±1.80	3.73±1.32	3.74±2.33	NS
Ratio 2(LDL/HDL)	1.92±1.22	1.92±1.20	1.93±2.20	1.94±06.02	NS
Albumin (g/dL)	6.21±0.22	6.22±0.52	6.4±7.20	6.55±6.48	NS

 $NS-NotSignificant, **(p>0.01), *(p>0.05), n=10 values are mean \pm S.D (One way ANOVA followed by Dunnett's test)$

Table 11: Renal function test of of Wistar albino rats group exposed to

KARISALANKANNI CHOORANAM

					P Value
PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	(p)*
UREA (mg/dl)	14.50±0.29	14.50±0.29	14.46±1.18	14.42±1.22	N.S
CREATININE(mg/dl)	0.42±0.02	0.41±0.04	0.43±0.03	0.44±0.09	N.S
BUN(mg/dL)	19.1±0.02	19.10±0.34	19.6±0.42	19.26±1.02	NS
URIC ACID(mg/dl)	4.02±0.04	4.06±0.21	4.4±0.12	4.20±0.10	N.S

 $NS-NotSignificant, **(p>0.01), *(p>0.05), n=10 values are mean \pm S.D (One way ANOVA followed by Dunnett's test)$

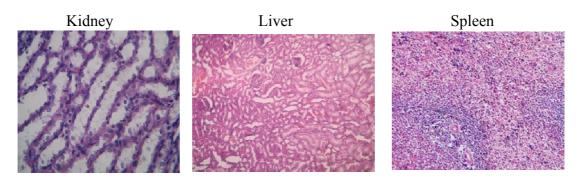
Table 12: Liver Function Test of of Wistar albino rats group exposed to

KARISALANKANNI CHOORANAM

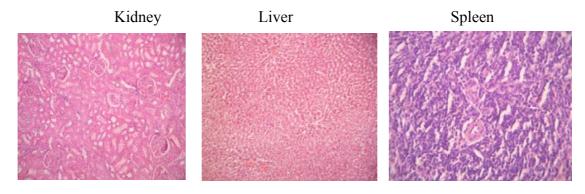
PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
T BILIRUBIN(mg/dl).	0.08±0.01	0.08±0.03	0.08±0.03	0.08±0.01	N.S
SGOT/AST(U/L)	64.11±1.53	64.12±0.22	64.24±1.54	65.74±1.53	N.S
SGPT/ALT(U/L)	79.21±1.02	79.34±1.04	79.44±1.16	79.38±0.21	N.S
ALP(U/L)	137.11±2.21	137±2.20	139±1.24	140.03±6.02	N.S
T.PROTEIN(g/dL)	7.2.40±0.14	7.2±0.41	7.2±0.60	7.3±0.61	N.S

 $NS-NotSignificant, **(p>0.01), *(p>0.05), n=10 values are mean \pm S.D (One way ANOVA followed by Dunnett's test$

HISTO PATHOLOGY CONTROL GROUP



High dose



PHARMACOLOGICAL ACTIVITY (HEMATINIC ACTIVITY)

MATERIAL AND METHODS

Animals

Albino rats (Wistar strain) were obtained from C.L.Baid metha college of pharmacy, chennai India. The rats were housed in an animal house with temperature and humidity control. Water and rat pellets (Biogen Bangalore Industries, India) were provided to the animals ad libitum. The animals were daily monitored for their behaviour and health.

Acclimatization

Prior to any experimentation, the animals were allowed to adapt to the animal house environment for 15 days. During this period, no experiments were performed on the animals. The males and females were separated and kept in clean cages. Suitable temperature, humidity and lighting conditions were maintained and feed and water were supplied ad libitum. Cleanliness and hygienic conditions were maintained as required. The animals were monitored regularly for signs of infection or injury.

Grouping of the animals

The acclimatized animals were subsequently divided into five groups each consisting of five rats (2 males and three females) and tails/ears were marked accordingly. Group I constituted the control animals that were not induced for anaemia and did not receive any treatment for anaemia. Anaemia was experimentally induced in animals of group II, group III and group IV. The group II animals served as the anaemic control (negative control) animals that did not receive any treatment with the test formulations. Group III animals received Karisalankanni Chooranam 100mg/kg and group IV received Karisalankanni Chooranam 200mg/kg group IV animals received conventional chemotherapy, i.e. allopathic treatment (positive control).

Induction of anaemia

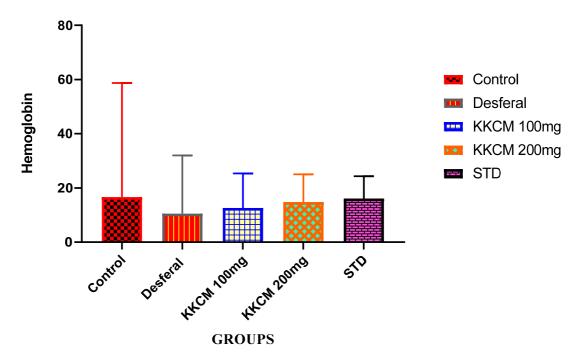
Desferrioxamine (Desferal, Novartis, Switzerland), a chemically treated form of ferrioxamine was used as an iron chelator for induction of anaemia in Wistar rats. Based on LD50 value of desferal, 1/10th of the dose was calculated and accordingly, 15 mg of desferal powder dissolved in 0.7 ml of injection grade distilled water (injection grade, pyrogen free) was administered in the rats via intramuscular route for 15 days. During this period, the rats were fed wheat flour along with the feed. The animals were observed for any toxicity symptoms, general behaviour and body weight. Hemoglobin content of group II rats (% Hb) was estimated by Sahli's hemoglobinometer on the 16th day.



Hemoglobin level of Karisalankanni Chooranam

S.no	Groups	Hemoglobin Hb (g/dl)
1	Control	16.6±42.1
2	Desferal Treated	10.5±21.5
3	Desferal +Karisalankanni Chooranam 100mg	12.6±12.74
4	Desferal + Karisalankanni Chooranam 200mg	14.8±10.22
5	Desferal + ferrous succinate +folic acid	16.1±8.24

Hemoglobin level of Karisalankanni Chooranam



MATERIALS AND METHODS

STUDY DESIGN:

An open clinical trial on paandu noi was carried out in the OP of P.G Kuzhanthai Maruthuvam Department attached to Aringnar Anna Hospital of Indian Medicine, Chennai-106.

The study was approved by Institutional Ethical Committee(IEC) and approval number is **GSMC-CH-ME-2/01/20182017**

POPULATION AND SAMPLE:

The population consists of all patients satisfying the inclusion and exclusion criteria mentioned below. Sample consists of paandu noi patients who were attending the OP of Aringnar Anna Hospital, Arumbakkam, Chennai- 106.

SAMPLE SIZE:

The study is considered in 40 selected patients of both genders between age groups of 3-12 years.

INCLUSION CRITERIA:

- Age: 3-12 years
- ➤ Hb level between 7-12 gms
- ➤ Worm infestation
- > Angular stomatitis
- Pallor of the skin, mucous membrane, nail bed and conjunctiva.
- Lack of concentration and poor school performance
- > Fatigue
- Constipation

EXCLUSION CRITERIA:

- ➤ Known H/O of Metabolic disorder
- ➤ Known H/O of Haemolytic anaemia
- > Patient with previous blood transfusion
- > Patient with any other serious illness.

WITHDRAWAL CRITERIA:

> Exacerbation of symptoms.

The subject develops adverse drug reactions and adverse event they will be

withdrawn from the trial.

Patient turned unwilling to continue in the course of clinical trial.

EVALUATION OF CLINICAL PARAMETERS:

Patients are clinically evaluated by using the following parameters

History taking:

Age, occupation, Socio economic status, complaints and duration, past illness,

family history, and personal habits were recorded in the case sheets for every patients

during his / her first visit to OP.

INVESTIGATIONS:

Blood: TC, DC, ESR, Hb

Urine: Albumin, Sugar, Deposit

SPECIFIC IVESTIGATIONS:

Blood: PCV, MCV, MCH, MCHC, Total RBC

Motion: Ova, Cyst, Occult blood

CLINICAL DIAGNOSIS BASED ON SIDDHA SYSTEM:

The parameters used to diagnose the disease paandu Noi in siddha system are

as follows,

Poriyal aridhal

Pulanaal aridhal

Vinaadhal

Uyirthathukkal

• Udalthadhukkal

Envagaithervu

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METHODOLOGY OF TREATMENT:

Study Enrollment:

Patient reporting at the OPD associated with clinical features of Pallor in conjuctivia & mucous membrane, Headache, Fatigue, Loss of appetite, worm infestation, dyspnoea on exertion, constipation are chosen for enrolment based on the inclusion criteria. The patients who are enrolled are informed about the study trial drug Karisalankanni chooranam, 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/patients parent using consent/Assent form.

Conduct of the Study:

On the first day onwards the trial drug "Karisalankanni chooranam" (Internal) will be given. The trial drug will be given in the OPD department of Kuzhanthai Maruthuvam, GSMC, Chennai. The patients will be asked to have a regular follow up in the OPD department once in 7days. In each and every visit the clinical assessment will be recorded in the prescribed proforma. The laboratory investigation 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 reduction in clinical symptoms and by Raising Hb above 3 g/dl and comparing the following parameters 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 the investigator will give the proper management 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 refer to OPD.

RESULTS AND OBSERVATION:

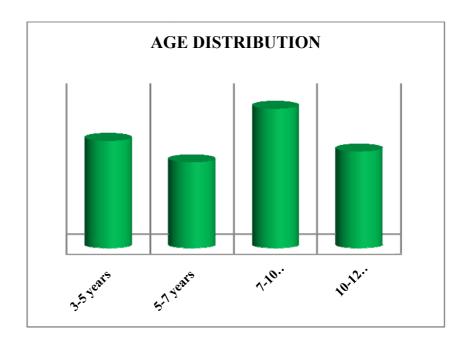
A total number of 40 child patients with signs and symptoms of Paandu Noi attending P.G-IV, KuzhanthaiMaruthuvam, Out Patient Department in Govt. Siddha Medical College attached to Aringnar Anna Hospital during 2016- 2019 were observed in the present study. The observations were made and tabulated with regards to the following features:

- 1. Age Distribution
- 2. Gender Distribution
- 3. Socio-Economic status
- 4. Aetiological factor
- 5. Dietary habits
- 6. Seasonal reference
- 7. Reference to Thinai
- 8. UyirThathukkal
- 9. Udarthathukkal
- 10. Envagaithervugal
- 11. Neikkuri
- 12. Clinical prognosis
- 13. Results after treatment

The observation recorded are given below in tabular form

1. AGE DISTRIBUTION

S. No	Age(years)	No. Of Cases	Percentage
1	3-5 years	10	25%
2	5-7 years	8	20%
3	7-10 years	13	32.50%
4	10-12 years	9	22.50%



Inference:

The above table indicates that children coming under 3-5 years of age group were 10(25%), 5-7 years were 8(20%), 7-10 years were 13(32.5%), 10-12 years were 9(22.5%) respectively.

2. GENDER DISTRIBUTION

S. No.	SEX	No. OF CASES	PERCENTAGE
1	Male	21	52.50%
2	Female	19	47.50%

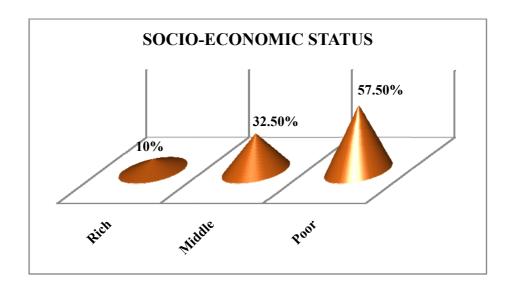


Inference:

Among the 40 cases for this present study, (52%) children were male and (48%) children were female. According to modern theory there is no apparent sex prediction.

3. SOCIO-ECONOMIC STATUS

S. No.	Socio-economic status	No. Of Cases	Percentage
1	Rich	4	10%
2	Middle	13	32.50%
3	Poor	23	57.50%

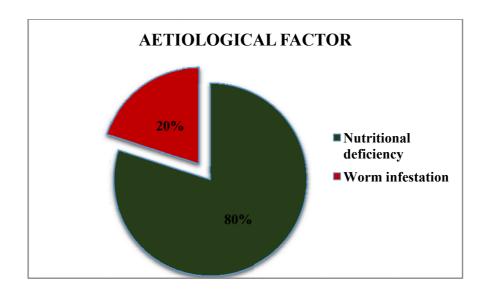


Inference:

Regarding socio-economic status, 23(57.50%) cases were belong to poor status, 13(32.50%) cases were belong to middle class and 4(10%) cases belong to high class.

4. AETIOLOGICAL FACTOR

S. No	Etiology	No. Of Cases	Percentage
1	Nutritional deficiency	32	80%
2	Worm infestation	8	20%

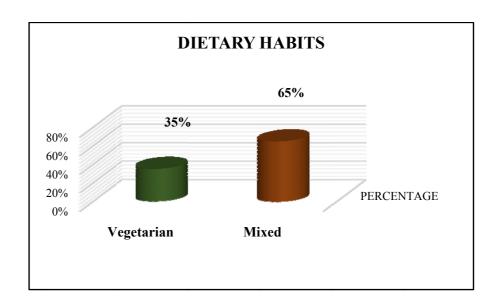


Inference:

Among 40 cases, 8(20%) cases were due to worm infestation and 32(80%) cases were due to Nutritional deficiency.

5. DIETARY HABITS

S. No	DIET	No. OF CASES	PERCENTAGE
1	Vegetarian	14	35%
2	Mixed	26	65%

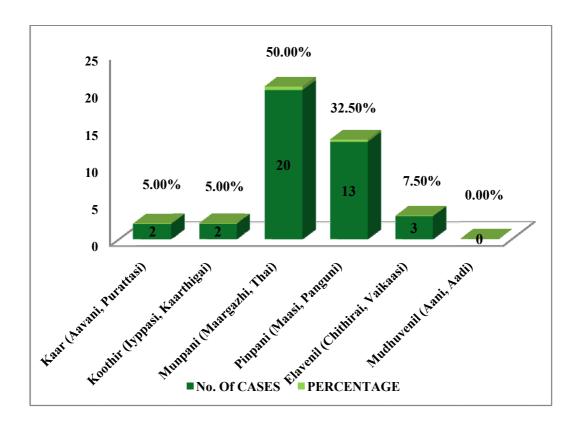


Inference:

Among 40 cases, 35% belong to vegetarian diet and 65% belongs to mixed diet habit.

6. SEASONAL REFERENCE

S. NO.	KAALAM	No. Of CASES	PERCENTAGE
1	Kaar (Aavani, Purattasi)	2	5.00%
2	Koothir (Iyppasi, Kaarthigai)	2	5.00%
3	Munpani (Maargazhi, Thai)	20	50.00%
4	Pinpani (Maasi, Panguni)	13	32.50%
5	Elavenil (Chithirai, Vaikaasi)	3	7.50%
6	Mudhuvenil (Aani, Aadi)	0	0.00%

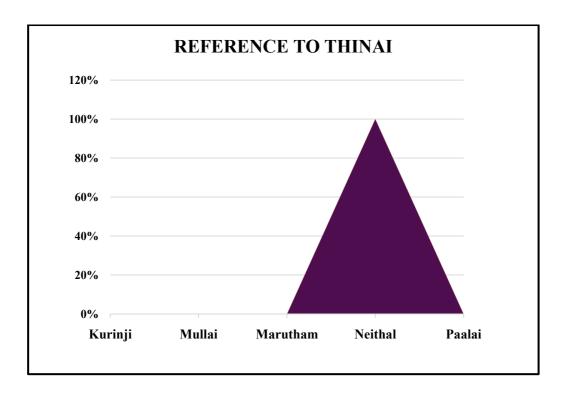


Inference:

Regarding to paruvakalangal among 40 cases, 2(5%) cases were reported in kaarkaalam, 2(5%) cases were reported in koothirkaalam, 20(50%) cases were reported in munpani kaalam, 13(32.5%) cases were reported in elavenil kaalam and no cases were reported in mudhuvenil kaalam respectively.

7. REFERENCE TO THINAI

S. NO.	NILAM	NO. OF CASES	PERCENTAGE
1	Kurinji	0	0%
2	Mullai	0	0%
3	Marutham	0	0%
4	Neithal	40	100%
5	Paalai	0	0%



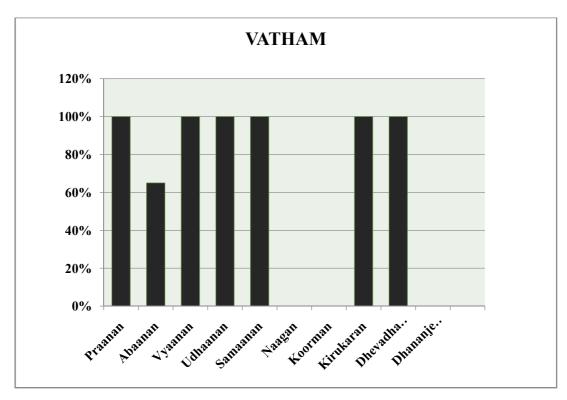
Inference:

Among the 40 cases reported were from the surroundings of Chennai which belongs to Neithal nilam. It cause increase in piththam.

8. UYIR THATHUKKAL

i. Vatham:

S. NO.	VAATHAM	NO. OF CASES	PERCENTAGE
1	Praanan	40	100%
2	Abaanan	26	65%
3	Vyaanan	40	100%
4	Udhaanan	40	100%
5	Samaanan	40	100%
6	Naagan	0	0%
7	Koorman	0	0%
8	Kirukaran	40	100%
9	Dhevadhaththan	40	100%
10	Dhananjeyan	0	0%

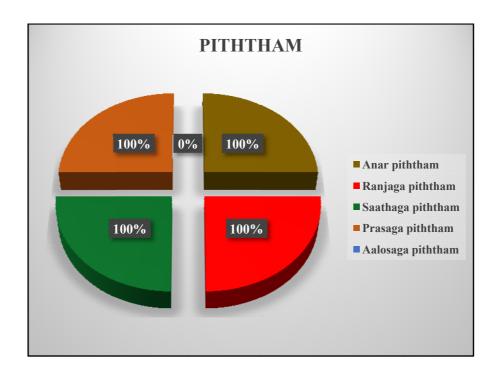


Inference:

In 40 cases, among 10 types of vaatham, praanan, viyaanan, udhaanan, samaanan, kirukaran and devathaththan were affected in all 40 cases (100%), abaanan was affected in 26cases (65%) respectively.

ii. PITHTHAM:

S. NO.	PITHTHAM	No. OF CASES	PERCENTAGE
1	Anar piththam	40	100%
2	Ranjaga piththam	40	100%
3	Saathaga piththam	40	100%
4	Prasaga piththam	40	100%
5	Aalosaga piththam	0	0%

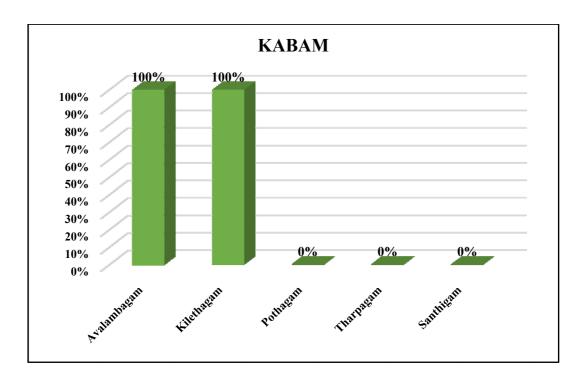


Piththam:

Among 5 types of piththam, except aalosagam all other types were affected.

iii. KABAM:

S. NO.	KABAM	NO. OF CASES	PERCANTAGE
1	Avalambagam	40	100%
2	Kilethagam	40	100%
3	Pothagam	0	0%
4	Tharpagam	0	0%
5	Santhigam	0	0%

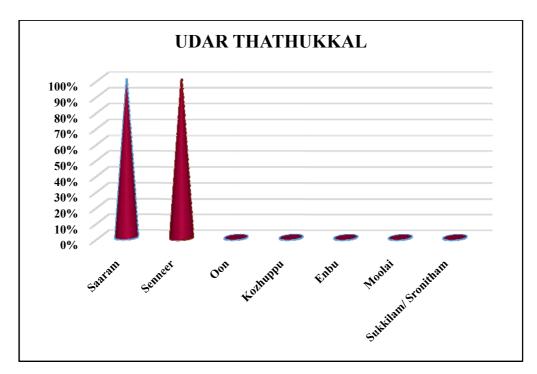


Inference:

Among 40 cases, avalambagam and kilethagam were affected in all the cases.

9. UDAR THATHUKKAL

S. NO.	UDARTHATHUKKAL	NO. OF CASES	PERCENTAGE
1	Saaram	40	100%
2	Senneer	40	100%
3	Oon	0	0%
4	Kozhuppu	0	0%
5	Enbu	0	0%
6	Moolai	0	0%
7	Sukkilam/ Sronitham	0	0%

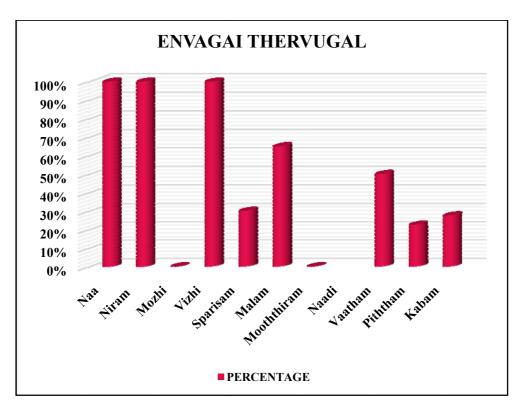


Inference:

In 7 udar thathukkal, saaram and senneer were affected in all the 40(100%) cases.

10. ENVAGAI THERUVUGAL:

S. NO.	ENVAGAI THERVUGAL	NO. OF CASES	PERCENTAGE
1	Naa	40	100%
2	Niram	40	100%
3	Mozhi	0	0%
4	Vizhi	40	100%
5	Sparisam	12	30%
6	Malam	26	65%
7	Mooththiram	0	0%
8		Naadi	
	i. Piththavaatham	20	50%
	ii. vaathakabam	9	22.50%
	iii. Kabapiththam	11	27.50%

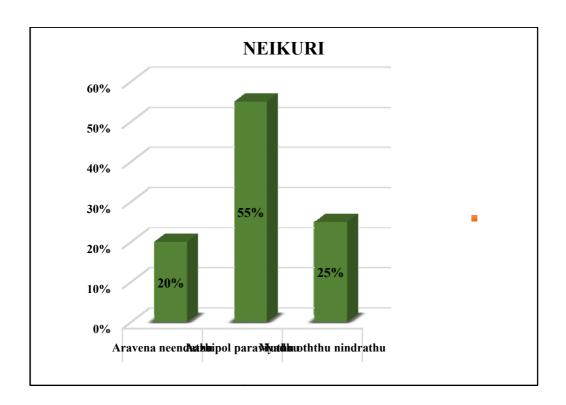


Inference:

Among the Envagaithervugal, naa, niram and vizhi were affected in all 40 cases(100%). In 26 cases(65%) malam and in 12 cases (30%) sparisam were affected and in naadi 20 cases(50%) piththavaatham, in 10 cases(22.5%) vaathakabam and 11 cases(27.5%) were seen.

11. NEIKKURI

S. NO.	TYPES OF NEER	CHARACTER	NO. OF CASES	PERCENTAGE
1	Vaatha neer	Aravena neendathu	8	20%
2	Piththa neer	Aazhipol paraviyadhu	22	55%
3	Kabha neer	Muthu oththu nindrathu	10	25%

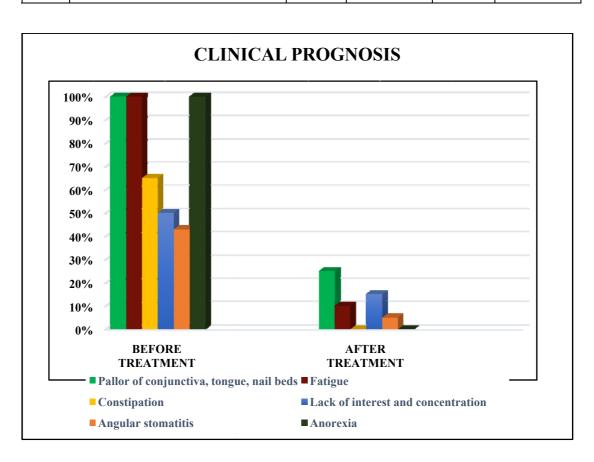


Inference:

Among 40 cases, vaatha neer was observed in 8 (20%) cases, piththa neer was observed in 22(55%) cases, kabaneer was observed in 10(25%) cases.

12. CLINICAL PROGNOSIS:

S.		BE	FORE	Al	FTER			
NO.	CLINICAL FEATURES	TREA	ATMENT	TREATMENT				
	CERVICAL FEATURES	No. Of	Percentage	No. Of	Percentage			
		cases	i or conounge	cases	- 01 001.0mg			
1	Pallor of conjunctiva, tongue,							
	nail beds	40	100%	10	25%			
2	Fatigue	40	100%	4	10%			
3	Constipation	26	65%	0	0%			
4	Lack of interest and							
	concentration	20	50%	6	15%			
5	Angular stomatitis	17	43%	2	5%			
6	Anorexia	40	100%	0	0%			



Inference:

The above table reveals that, among all the 40 cases Anorexia was reduced, pallor of conjunctivae, tongue nail beds was reduced in 30 cases among 40, fatigue was reduced in 36 cases among 40, constipation was reduced in all cases, lack of interest / concentration was reduced in 14 cases among 20, angular stomatitis was reduced in 15 cases among 17.

13. RESULTS AFTER TREATMENT

Results were observed on the basis of two main criteria. One on the basis of clinical improvement and the other on the results derived from the blood picture.

a. Results from clinical improvement

Good, Moderate, Mild improvements were assessed on the basis of relieved signs and symptoms as follows.

Good improvement

- ➤ Anorexia nil
- ➤ Fatigue nil
- ➤ Pallor of conjunctiva and nail beds nil
- > constipation nil
- ➤ Lack of interest / concentration improved

Moderate improvement

- ➤ Anorexia nil
- ➤ Fatigue nil
- ➤ Pallor of conjunctiva and nail beds improved
- constipation moderately improved
- ➤ Lack of interest / concentration slightly improved

Mild improvement

- ➤ Anorexia nil
- Fatigue present or absent
- ➤ Pallor of conjunctiva and nail beds present
- ➤ Constipation present
- ➤ Lack of interest / concentration present
- Among the 40 cases, 27 cases assessed as good improvement, 8 cases assessed as moderate improvement, and 5 cases assessed as mild improvement.

b. Results derived from the blood picture

Good:Increase in Hb level between 3gms/dl and above after treatment .

Moderate: Increase in Hb level between 2gms/dl to 2.9 gms/dl after treatment

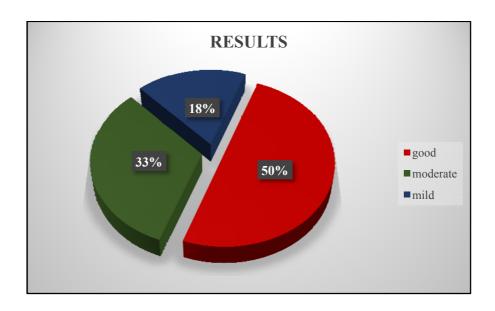
Mild:Increase in Hb level between 0.5gms/dl to 1.5gm/dl after treatment

Among the 40 cases studies the result were observed as follows:

S. NO.	RESULTS	NO. OF CASES	PERCENTAGE
1	Good	20	50%
2	Moderate	13	32.5%
3	Mild	7	17.5%

Inference:

Among the 40 cases treated, 20 cases (50%) showed good result, 13 cases (32.5%) showed moderate result and 7 cases (15%) showed mild result. The results were based on clinical improvement and results derived from the blood picture.



CASE SUMMARY OF THE PATIENTS:

S.NO.	OP NO.	NAME	AGE(YEARS)/SEX	REMARKS			
1	9733	Melvin	10/mc	Moderate			
2	750	Janani sridevi	7/fc	Mild			
3	2724	Mitheshwaran	3/mc	Moderate			
4	822	Vasanthi	7/fc	Moderate			
5	797	Kagan	5/mc	Mild			
6	2941	Aravindh	4/mc	Moderate			
7	3637	Kousalya	5/fc	Good			
8	3688	Logeshwaran	7/mc	Moderate			
9	3079	Monika	8/fc	Good			
10	494	Tharshini	3/fc	Moderate			
11	493	Vignesh	8/mc	Good			
12	1007	Tharshini	8/fc	Good			
13	2959	Ketson	4/mc	Good			
14	2958	Nithya	7/fc	Good			
15	4937	Deniyal	7/mc	Moderate			
16	4936	Mikayal	9/mc	Good			
17	7575	Sundar	8/mc	Good			
18	7318	Hariharan	10/mc	Moderate			
19	5681	Monesh	11/mc	Good			
20	8452	Nisha	12/fc	Mild			
21	1638	Sandhiya	5/mc	Good			
22	5191	Sakthi	4/fc	Good			
23	2288	Rajesh	5/mc	Mild			
24	2558	Roshan	3/mc	Good			
25	1416	Sai krish	5/mc	Mild			
26	3304	Oviyasri	3/fc	Moderate			
27	8981	Aswin kumar	10/mc	Moderate			
28	540	Elakkiya	8/fc	Good			

29	7576	Sam rakshan	6/mc	Good
30	5612	Nikkilesh	3/mc	Mild
31	613	Nikkitha	3/fc	Mild
32	2760	Joswa	4/fc	Moderate
33	4177	Shakila	6/fc	Good
34	4343	Abijith Krishna	5/mc	Good
35	5552	Sarika	12/fc	Moderate
36	7419	Yogeshwaran	12/mc	Good
37	2272	Hariharasudhan	7/mc	Good
38	3940	Hemala	7/fc	Moderate
39	3836	Manith	12/mc	Good
40	4810	Sagana	10/fc	Good

LABORATORY INVESTIGATION REPORT OF THE PATENTS

		AGE(years	BEFOR	E TRE	ATMI	ENT	AFTER	TREA	TME	NT		ES	SR		URINE ANALYSIS					
S.NO.	OP NO.))	TC		DC		TC		DC		ВТ		AT			BT			AT	
		/SEX	TC	P	L	E	TC -	P	L	E	1/2 HR	1 HR	1/2 HR	1 HR	Alb	Sug	Dep	Alb	Sug	Dep
1	9733	10/mc	6000	45	49	6	6500	47	51	2	7	18	7	14	N	N	N	N	N	N
2	750	7/fc	8100	51	42	7	8500	50	45	5	12	25	9	18	N	N	N	N	N	N
3	2724	3/mc	10700	64	32	4	10000	58	40	2	14	22	10	20	N	N	N	N	N	N
4	822	7/fc	7300	61	33	6	7600	55	40	5	9	21	7	14	N	N	N	N	N	N
5	797	5/mc	12500	77	17	6	12000	65	33	2	3	5	6	12	N	N	N	N	N	N
6	2941	4/mc	7200	52	43	5	8000	51	44	5	7	12	7	12	N	N	N	N	N	N
7	3637	5/fc	7800	56	34	10	7900	58	36	6	15	25	10	20	N	N	N	N	N	N
8	3688	7/mc	6800	43	48	9	7000	45	49	6	8	15	7	14	N	N	N	N	N	N
9	3079	8/fc	8200	52	42	6	8100	52	44	4	5	12	6	12	N	N	N	N	N	N
10	494	3/fc	11300	26	63	8	11200	40	45	5	10	26	8	16	N	N	N	N	N	N
11	493	8/mc	5300	72	28	6	6800	52	43	5	3	8	5	10	N	N	N	N	N	N
12	1007	8/fc	10600	58	36	6	9400	50	44	6	2	6	7	14	N	N	N	N	N	N
13	2959	4/mc	8900	45	47	8	8500	50	43	7	22	42	10	20	N	N	N	N	N	N
14	2958	7/fc	6000	56	39	5	7300	53	43	4	8	15	6	12	N	N	N	N	N	N
15	4937	7/mc	7500	48	45	7	8000	49	45	6	14	20	10	20	N	N	N	N	N	N
16	4936	9/mc	6800	73	24	3	6800	58	38	4	21	38	11	24	N	N	N	N	N	N
17	7575	8/mc	7200	64	30	6	7100	54	42	4	5	12	7	14	N	N	N	N	N	N
18	7318	10/mc	5300	45	49	6	6900	50	45	5	7	12	7	12	N	N	N	N	N	N
19	5681	11/mc	6100	45	49	6	7200	49	48	3	10	25	8	16	N	N	N	N	N	N
20	8452	12/fc	9500	68	26	6	8300	58	35	7	10	22	7	14	N	N	N	N	N	N

BT- Before Treatment, AT- After Treatment, N-Nil, TC-Total Blood Count, DC-Differential Blood Count, P-Polymorphs, L-Leucocytes, EEosinophils, ESR-Erythocyte Sedimentation Rate, mm-Milimeter, Hb-Hemoglobin, Alb-Albumin, Sug-Sugar, Dep-Deposits.

		A CECHEA PON	BEFORE T	REA	TMF	ENT	AFTER T	REA	TMF	ENT		ES	SR		URINE ANALYSIS						
S. NO.	OP NO.	AGE(YEARS)/ SEX	TC		DC		TC		DC		ВТ	BT AT				BT			AT		
		SEX	ic	P	L	E	ic	P	L	E	½ HR	1 Hr	½ Hr	1Hr	Alb	Sug	Dep	Alb	Sug	Dep	
21	1638	5/mc	5700	60	31	9	6500	54	40	6	9	20	5	10	N	N	N	N	N	N	
22	5191	4/fc	7200	69	30	1	7200	60	36	4	5	11	11	22	N	N	N	N	N	N	
23	2288	5/mc	5800	58	35	7	6300	55	40	5	7	15	9	18	N	N	N	N	N	N	
24	2558	3/mc	8400	52	41	7	8100	54	42	4	4	10	7	14	N	N	N	N	N	N	
25	1416	5/mc	11200	37	56	7	10800	48	45	7	2	10	5	10	N	N	N	N	N	N	
26	3304	3/fc	7600	56	39	5	8000	53	42	5	5	15	10	20	N	N	N	N	N	N	
27	8981	10/mc	7800	44	50	6	7500	48	46	6	10	25	7	16	N	N	N	N	N	N	
28	540	8/fc	8600	47	46	7	9200	50	45	7	7	14	7	14	N	N	N	N	N	N	
29	7576	6/mc	3500	53	38	9	5000	55	41	4	3	8	6	14	N	N	N	N	N	N	
30	612	3/mc	7100	48	42	10	7600	50	43	7	14	22	11	22	N	N	N	N	N	N	
31	613	3/fc	11900	50	43	7	10900	52	42	6	7	15	9	18	N	N	N	N	N	N	
32	2760	4/fc	8400	47	47	6	8800	49	43	8	5	10	6	14	N	N	N	N	N	N	
33	4177	6/fc	7700	53	42	5	8000	55	42	3	28	40	12	24	N	N	N	N	N	N	
34	4343	5/mc	6800	54	42	4	7100	50	45	5	13	26	9	18	N	N	N	N	N	N	
35	5552	12/fc	7200	58	38	4	8100	55	41	4	14	28	10	20	N	N	N	N	N	N	
36	7419	12/mc	5400	43	48	9	6800	50	42	8	15	28	9	18	N	N	N	N	N	N	
37	2272	7/mc	9800	52	42	6	9700	48	45	7	15	30	11	22	N	N	N	N	N	N	
38	3940	7/fc	6600	50	40	10	7100	52	43	5	14	28	7	14	N	N	N	N	N	N	
39	3836	12/mc	7200	49	45	6	7600	50	45	5	7	14	3	6	N	N	N	N	N	N	
40	4810	10/fc	8900	53	43	4	8800	54	42	4	8	16	5	10	N	N	N	N	N	N	

BT- Before Treatment, AT- After Treatment, N-Nil, TC-Total Blood Count, DC-Differential Blood Count, P-Polymorphs, L-Leucocytes, EEosinophils, ESR-Erythocyte Sedimentation Rate, mm-Milimeter, Hb-Hemoglobin, Alb-Albumin, Sug-Sugar, Dep-Deposits.

BIO CHEMICAL AND HEMATOLOGICAL REPORTS

C NO	OD NO	NIAME	ACE(waara)/SEV	Hb (g	ms/dl)	RBC (N	Tillions/dl)	PCV	/ (%)	MC	V (fl)	MCH	(Pg)	MCHC	(gm/dl)
5. NO.	OP NO.	NAME	AGE(years)/ SEX	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	9733	Melvin	10/mc	11.5	13	3.4	3.6	36	40	70	75	26	29	32	34
2	750	Janani sridevi	7/fc	11.5	13	3.5	3.8	35	36	85	88	27.5	30	32.4	35
3	2724	Mitheshwaran	3/mc	10	12.5	3.1	3.3	30	35	72	76	22	25	30	34
4	822	Vasanthi	7/fc	10.8	12.5	3.5	3.8	32	35	73	77	26	28	32	33
5	797	Kagan	5/mc	11.6	12.8	3.3	3.7	30	34	72	76	23	25	31	33
6	2941	Aravindh	4/mc	10.2	12	3.1	3.4	31	35	69.8	74	23	25	31	33
7	3637	Kousalya	5/fc	9.7	11.8	3.2	3.8	32	33	72.3	73.5	22.2	23	30.8	32
8	3688	Logeshwaran	7/mc	11.1	12.8	3.7	3.9	32	34	72	80	26	38	32	33
9	3079	Monika	8/fc	9.3	12.6	3.4	3.6	34	35	76	80	26	38	32	33
10	494	Tharshini	3/fc	9.9	12.6	4	4.2	22	25	73	86	24	26	27	33
11	493	Vignesh	8/mc	9	12.8	3.2	3.4	29	31	69	78	23	27	28	33
12	1007	Tharshini	8/fc	8.6	11.9	2.8	3.2	17	20	68	80	27	30	28	34
13	2959	Ketson	4/mc	8	11	3.2	3.7	21	23.2	75	85	27	32	31.2	33
14	2958	Nithya	7/fc	10.5	13.6	3.4	3.6	28	32	70	83	23	27	24	29
15	4937	Deniyal	7/mc	11	12.7	4	4.2	32	34	72.3	78	22.2	25	30.8	32
16	4936	Mikayal	9/mc	10.7	13.8	3.2	3.3	32	34	71	87	22	29	32	34
17	7575	Sundar	8/mc	10.2	13.3	3.2	3.4	23	30	51.3	69	26.6	29	22.1	30
18	7318	Hariharan	10/mc	11.6	13.4	3.6	3.8	37	37	80	82	26.9	28	33.7	35
19	5681	Monesh	11/mc	10.8	13.9	3.6	3.6	40	42	82.3	85	26.3	30	32	34
20	8452	Nisha	12/fc	11	12.2	3.5	3.8	32	35	76	90	24	27	32	34

BT- Before Treatment, AT- After Treatment, PCV-Packed Cell Volume, MCV-Mean Corpuscular Volume, RBC-Red Blood Cells MCH-Mean Corpuscular Hemoglobin, MCHC- Mean Corpuscular Hemoglobin Concentration.

S.NO.	OP NO.	NAME	AGE(years) /SEX	HB(GMS/DL)		RBC(MILLIONS/DL)		PCV (%)		MCV (fl)		MCH (Pg)		MCHC (gm/dl)	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	1638	Sandhiya	5/fc	8.6	11.8	3.4	3.3	34	38	74	89	25	28	32	35
22	5191	Sakthi	4/fc	7.7	10.8	3.9	3.9	25	30	55	68	17	25	30.6	34
23	2288	Rajesh	5/mc	11.6	12.9	2.8	3.3	36	40	85	88	26	29	32	33
24	2558	Roshan	3/mc	8.4	11.5	3.5	3.9	25	29	57	71	17	22	29.7	33
25	1416	Sai krish	5/mc	11.4	12.6	3.7	3.9	34	36	78	80	24.5	28	31.6	34
26	3304	Oviyasri	3/fc	10	12.3	3.3	3	35	38	77	82	26	30	33.8	34
27	8981	Aswin kumar	10/mc	11.5	12.7	3.5	3.9	35	38	81	84	26.6	30	33	36
28	540	Elakkiya	8/fc	10	13.2	3.3	3.5	35	40	80	84	26	32	32.5	34
29	7576	Sam rakshan	6/mc	6.5	9.6	3.1	3.3	28	34	75	88	24.2	28	32	34
30	5612	Nikkilesh	3/mc	11.6	12.4	3.6	3.4	37	42	82	86	25.5	30	31.2	32
31	613	Nikkitha	3/fc	11.8	12.7	3.7	3.8	37	41.2	78	80.4	23.7	26	31.4	33
32	2760	Joswa	4/fc	11.1	13.5	3.4	3.5	20	26	72	83	30	34	28.3	33
33	4177	Shakila	6/fc	10.8	13.9	3.7	3.7	20	27	68	82	28	32	31.5	34
34	4343	Abijith krishna	5/mc	8.2	11.3	3.2	3.7	26	34	71	83	28	29	27	29
35	5552	Sarika	12/fc	9.3	12.4	2.9	3.2	28	32	70	81	28	30	22	25
36	7419	Yogeshwaran	12/mc	7.8	10.9	3.2	3.4	23	28	73	88	23.2	28	27	30
37	2272	Hariharasudhan	7/mc	10	13.2	3.5	3.8	28	32	63	77	25	29	28.5	31.5
38	3940	Hemala	7/fc	9.9	12.8	3.2	3.5	22	25	71	79	24	31	27.2	30.2
39	3836	Manith	12/mc	9.8	12.9	3.8	3.8	20	24	70	80	30.2	33	29	32.5
40	4810	Sagana	10/fc	8.8	12	3	3.4	30	32	72	87	30	34	32	33

BT- Before Treatment, AT- After Treatment, PCV-Packed Cell Volume, MCV-Mean Corpuscular Volume, RBC-Red Blood Cells MCH-Mean Corpuscular Hemoglobin, MCHC- Mean Corpuscular Hemoglobin Concentration.

DISCUSSION

PaanduNoi is a clinical entity described by Siddhars and having symptoms such as loss of appetite, lassitude, pallor of skin and mucous membrane, conjunctivae, tongue, and nail beds, angular stomatitis. These symptoms are identical with Iron Deficiency Anaemia (Microcytic hypochromic anaemia) a clinical entity described in modern medical literature.

Iron deficiency anaemia is one of the most common and widespread nutritional disorder present throughout the world and its prevalence is higher in children, but they are not completely relieved from their symptoms by other system of medicine. Hence with the help of trial medicine from Siddha system, results and observation are noted for the study.

The patients were examined based on Siddha as well as modern aspects.

All the necessary investigation were made during the study. The results obtained from their studies were discussed below for better conclusion.

Trial medicine administered was Karisalankannichooranam 200- 500mg with honey, 2 times a day after food for 28 days.

In this study, 40 cases were selected according to the proforma with investigations and treated with the trial drug Karisalankannichooranam for 28days. The treatment and investigation was done in the OPD of PG-Dept. of KuzhanthaiMaruthuvam, Govt.Siddha Medical College attached to Arignar Anna Hospital of Indian Medicine Chennai-106, during the period 2017-2019. All the necessary investigations were carried out to all patients and trial drug were given. Weekly follow up were done. All the patients were strictly advised to follow diet and peaceful lifestyle to normalize the immune mechanism.

Drug Authetication:

All the ingredients of the trial drug Karisalankannichooranamwere procured from indigenous drug shop, Park town, Chennai.

Microscopic and Macroscopic examination was conducted, identified and authenticated by the concerned pharmacognosist, GSMC, Chennai.

Pre clinical screenings:

Biochemical Analysis:

Qualitative Analysis of the trial drug revealed the presence of iron, chloride, calcium, starch, reducing sugar.

Phytochemical Analysis:

The phytochemical analysis of the trial drug shows that the drug contains Glycosides, Carbohydrates, Coumarins, Phenols.

Physico chemical Analysis:

Loss on drying at 105° C - 2.43%

Total ash - 17.6%

PH - 5

Acid insoluble ash - 0.26%

Water soluble extractive -26%

Alcohol soluble extractive - 12%

TOXICITY STUDY OF THE DRUG:

IAEC NO: LV/11/CLBMCP/2018

Acute toxicity:

Acute and sub acute toxicity studies were conducted on experimental rats at C.L.BaidMetha College of Pharmacy, Chennai, Tamilnadu.

Acute toxicity study of the drug k was carried out as the OECD guideline-423 (Organisation to Econamic Co-operation and Development).

The acute toxicity study of $\,$ my trial drug was studied and the drug was proved safer for long term administration, as it did not exhibit any significant toxicity at 2000 mg / kg body weight.

Sub acute toxicity:

Sub acute toxicity study as per the guideline of -407. Under the dosage of trial drug 200mg / kg (Low dose), 400mg / kg (High dose) it did not exhibit any significant.

Histo pathology:

At the end of toxicity studies the animal were sacrified and they were subjected to hematological parameters (TC, DC &Hb) chemical parameters (LFT, RFT) and histopathology of vital organs like Liver, Kidney, Spleen, Lungs were carried out. The studied did not exhibit the evidence of remarkable pathological lesions in the tissues.

Pharmacological activity:

The pharmacological studies of trial medicine Karisalankannichooranam showed significant Haematinic action wistar albino rats.

Haematinic action of Karisalankannichooranamwas carried out by producing anemia by administrating a single intramuscular injection ofdesferrioxamine at a dose of 15mg/kg b.w. Drop out period of four days was awaited until the sufficient drop in Hb level was noticed in animals. Rats were considered as anaemic model if haemoglobin concentration was less than 14g/dl. Then the trial drug was administered show a potent haematinic action during the studies.

The result of preclinical screening, the result of chemical analysis, Toxicological studies, Pharmacological studies were shown in pre-clinical.

Age Distribution:

Among the 40 cases, 25% of patients were in the age group of 3 to 5 years, 20% were in the age group of 5 to 7 years, 32.5% were in the age group of 7 to 10 years and 22.5% were in the age group of 10 to 12 years.

Sex Distribution:

Among the 40 cases for this present study, 21 (52.5%) children were male and 19 (47.5%) children were female. According to modern theory there is no apparent gender prediction.

Socio Economic status:

Among the 40 cases, maximum numbers of patients 57.50% were in poor status, 32.50% were in middle class and 10% were in rich class. The highest incidence was observed in poor class children due to low nutritional diet, so the poor children are more prone to the disease.

Aetiological factor:

Among 40 cases, 20% cases were due to worm infestation, 80% cases were due to nutrional deficiency because of poor intake of food respectively.

Dietary Habits:

Among 40 cases was reported, 65% belonged to mixed diet and 35% belonged to vegetarian diet habit respectively.

According to Paruvakaalam:

Regarding Paruvakaalam among 40 cases, 5% cases were reported in Kaarkaalam, 5% cases were reported in Koothirkaalam, 7.5% cases were reported in ElavenilKaalam, 50% cases were reported in Munpanikaalam, 32.5% cases were reported in Pinpanikaalam and no cases were reported in Muduvenilkaalam respectively

Thinai:

Among the 40 cases reported were from surroundings of Chennai which belongs to Neithalnilam.It cause increase in pitham.

UyirThathukkal:

Disturbance of Vatham:

In 40 cases, among 10 types of Vaatham, Praanan was affected in a 100% of cases because of dyspnoea on exertion, Abanan was affected in a 65% of cases due to constipation, Viyaanan was affected in a 100% of cases because of pallor of skin, Samaanan and Kirukaran were affected in a 100% of cases due to loss of appetite, Devathathan was affected in a 100% of cases due to tiredness respectively.

Disturbance of Pitham:

Among 5 types of Pitham, except Aalosagam all types of pitham were affected. Sathagam was affected due to inability to do work, Ranjagam was affected which causes discolouration of blood, Anal pitham which causes loss of appetite, Prasagam was affected because of pallor of skin respectively.

Disturbance of Kabam:

Among 40 cases, Aavalamgam was affected in 40 cases(100%) due to dyspnea and Kilathagam was affected in 40 cases (100%) due to loss of appetite respectively.

UdalKattukal:

In this, Saaram and Senneer were affected in 100% of the cases. Saaram was affected because of anorexia, Senneer was affected because of pallor of skin.

EnnvagaiThervugal:

Among the Ennvagaithervukal, Naa, Niram and Vizhi were affected in all cases (100%). In 26 cases (65%) Malam, and in Naadi 20 cases (50%) Pithavaatham, in 9 cases (22.5%) vathakabam and in 12 cases (27.5%) Kabapitham were seen.

Neikuri:

Among 40 cases, Pithaneer was observed in 55% cases, vathaneer was observed in 20% cases, Kabaneer was observed in 25% cases.

Clinical presentation:

Out of 40 patients, before treatment all the 40 patients had 100% of pallor of conjunctivae, tongue, nail beds, Anorexia, fatigue, 65% of cases had constipation, 50% of cases had Lack of interest and concentration, 43% of cases had angular stomatitis. After treatment most of the patients were relieved from the symptoms of anorexia and constipation. Pallor of conjunctivae, tongue, nail buds was present in 25%, fatigue in 10%, lack of interest and dyspnoea on excertion in 15%, angular stomatitis in 5% were observed in this study.

Lab investigation:

Routine blood and urine examination were done before and after the treatment. In most of the cases, Total RBC count, PCV, MCV, MCH, MCHC were observed to be reduced. After treatment there is a tremendous increase in the haemoglobin level, Total RBC count, PCV, MCV, MCH, MCHC.

Haemoglobin range was Good (50%) in 20 cases, Moderate (32.5%) in 13 cases, Poor (17.5%) in 7 cases in prognosis.

Bio statistical study:

By statistical analysis, since the p value is significant in Hb level i.e., null hypothesis is rejected and alternate hypothesis is accepted. And by age wise analysis, the mean difference is high in 8 years children and by sex wise analysis, the mean difference is high in male children. Thus concluding that there is difference in the means of before and after treatment.

Result observed from Hb level:

Since the p value is significant (0.04). So the treatment was significantly improving the Hb level among the patients for the treatment of *PaanduNoi*.

Treatment:

In this study all 40 cases were treated with Karisalankannichooranam. The trial medicine having the properties of neutralizing pitham was given to the patients to set right the deranged pitham on the basis of Arusuvai and Panchabootham.

So the selected trial drug is in the form of powder, is found to be normalize the increased pitham. Intake of powder with honey in therapeutic doses increase appetite and gives relief from abdominal discomfort and constipation.

The trial medicine contain iron in the form of ferrous state that are easily absorbed. The efficacy was established throughout the treatment. During the treatment the study subject were strictly advised to have Iron rich diet.

SUMMARY

To study the efficacy of Siddha trail drug *Karisalankanni chooranam* as internal medicine for the treatment of PaanduNoi in children. This disease mostly resembles Iron deficiency anaemia in modern system. Literature evidences of both Siddha and Modern system were collected and also the ingredients of the trial drug was reviewed as well. For the clinical study, 40 patients were selected based on protocol. This study is conducted after the drug being screened by the Screening committee and approved by the Institutional Ethical Committee (IEC) of Govt. siddha medical college Chennai.

Selected patients with PaanduNoi diagnosed clinically treated in outpatient department of Govt. siddha medical college attached with Arignar Anna Hospital of Indian Medicine, Chennai-106. They were undergone laboratory investigation and treated with trial drug, observed for clinical improvement and any adverse reaction.

Qualitative analysis of the *Karisalankanni chooranam* presence of iron, calcium, starch, chloride and Reducing sugar. Phytochemical analysis of the trial drug shows that presence of Glycosides, carbohydrates, coumarins, phenol.

Physico chemical analysis of the trail drug shows the pH 5, Total ash value 17.6% shows the safe and effectiveness of the trial drug.

Toxicological studies shows that, it has no significant toxic effect. From the preclinical pharmacological study shows that the drug has got a significant haematinic activity.

Among the 40 patient's good improvement was observed in 20 cases (50%), moderate improvement in 13 cases (32.5%) and mild improvement in 7 cases (17.5%).

CONCLUSION

Paandunoi is mainly caused by the derangement of Pithamfollowed by vatham and kabam. The deranged kuttram is settled down by the kaippusuvai in the trial drug there by medicine act effective in cure the disease.

In physico chemical Analysis iron was found to be present as effective ingredients in treating anaemia.

The Karisalankannichooranam reveal no toxicity in the preclinical studies and hence proven to be safe for human administration.

From the pre- clinical pharmacological study it is evident that the trial medicine has significant Haematinic action.

Also Karisalankannichooranam has been proved clinically. Since as it raises the haemoglobin level in a marked level to the patients given regularly for not less than 30 days along with supplementary diets. Both symptomatic and qualitative improvement were absorbed. For prognosis, routine haematological investigation was taken. During the treatment no adverse events were observed.

Statistically it has been proved that it shows significant raise in the haemoglobin level.

Hence I concluded that the trial drug Karisalankannichooranam will be a better drug that can be used in the treatment of PaanduNoi.

BIO STATISTICAL ANALYSIS

	DIODITION	ICAL ANALISI	,
AGE	BEFORE	AFTER	DIFFERENCE
11/Fc	11.5	12	0.5
10/Fc	10.3	12.2	1.9
08/Mc	11.5	11.8	0.3
06/Mc	11.1	11.5	0.4
09/Mc	9.2	10.5	1.3
08/Fc	12	11.5	-0.5
08/Fc	12.9	12.5	-0.4
12/Fc	11.7	11.9	0.2
09/Fc	10.4	11.2	0.8
10/Fc	11.6	12	0.4
12/Fc	9.9	11	1.1
08/Fc	7.1	10.2	3.1
6 ^{1/2} /Fc	12.1	12.5	0.4
08/Fc	13.1	12.8	-0.3
07/Fc	12.4	12.1	-0.3
09/Mc	12.9	12.8	-0.1
08/Mc	8.6	10.2	1.6
06/Fc	8.8	10.8	2
06/Mc	13.4	13.4	0
09/Fc	11.9	12	0.1
06/Fc	12.1	12	-0.1
07/Fc	8	10.2	2.2
11/Mc	13.1	13.2	0.1
06/Mc	12.2	12.4	0.2
08/Mc	12.3	12.5	0.2
08/Mc	12.2	12.8	0.6
10/Fc	14.3	14	-0.3
07/Fc	12.4	12.6	0.2
$6^{1/2}/Mc$	13.4	13	-0.4
12/Fc	12.7	12.6	-0.1
06/Mc	11.3	11.2	-0.1
12/Mc	11.8	11.5	-0.3
08/Fc	11.6	11.2	-0.4
8 ^{1/2} /Mc	13	15	2
06/Mc	11.2	12	0.8
10/Mc	12	12.4	0.4
07/Fc	9	10.2	1.2
11/Fc	11.2	12	0.8
08/Fc	11.8	12.2	0.4
08/Fc	12	12.5	0.5
MEAN	11.5	12.01	0.51
St.dev	1.579841	1.035473	0.840269

- Mean value of HB before treatment: 11.5 ± 1.57
- Mean value of Hb after treatment 12.01 ± 1.03

To analyse the significance, Paired T- Test is chosen

Results:

T- Test of Paired sample			
	Variable 1	Variable 2	
Mean	11.5	12.01	
Variance	2.495897436	1.072205128	
Observations	40	40	
Pooled Variance	1.784051282		
Hypothesized Mean Difference	0		
df	78		
t Stat	-1.707581759		
P(T<=t) one-tail	0.045845808		
t Critical one-tail	1.664624645		

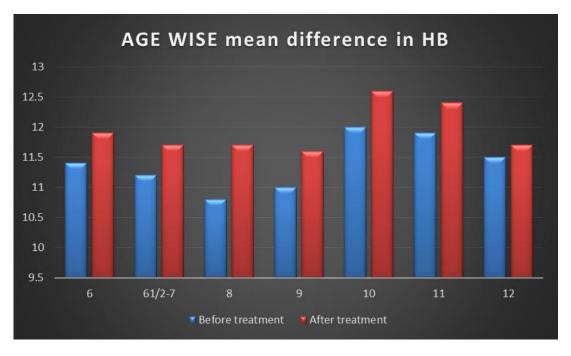
- Null Hypothesis: There is no difference between means
- Alternate Hypothesis: There is absolute difference between two means

- If the P-Value is less than 0.05, then the null hypothesis is rejected
- As the P-Value of this study is 0.04, Null Hypothesis is rejected and Alternate hypothesis is accepted. Thus concluding that there is difference in the means of before and after treatment.
- To signify the difference, Pearson correlation between two variables taken which shows the result of **0.87** (**87%**)

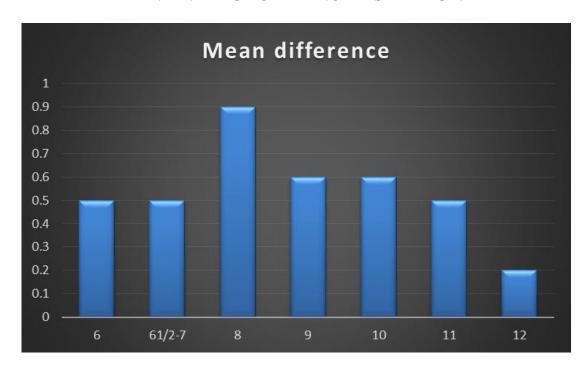
coefficient of Correlation		
Value of r	Strength of relationship	
-1.0 to -0.5 or 1.0 to 0.5	Strong	
-0.5 to -0.3 or 0.3 to 0.5	Moderate	
-0.3 to -0.1 or 0.1 to 0.3	Weak	
-0.1 to 0.1	None or very weak	

- As the r value of this study is 0.87, it shows that the result has Strong Positive correlation
- i.e statistical correlation is measured by what is called the coefficient of correlation (r). Its numerical value ranges from +1.0 to -1.0. It gives us an indication of both the strength and direction of the relationship between variables.

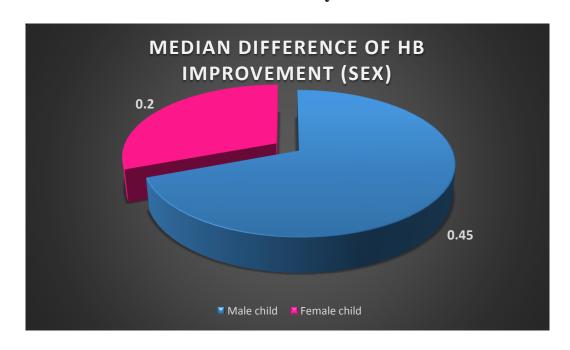
1. AGE WISE MEAN DIFFERENCE:



2. AVERAGE OF HB INCREASE BY AGE:



3. Mean difference By sex:



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GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI - 600 106

CLINICAL STUDY ON "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF "PAANDU NOI" (IRON DEFICIENCY ANAEMIA) IN CHILDREN

FORM 1 - SCREENING AND SELECTION PROFORMA

1.	OP NO	:	
2.	NAME	:	
3.	AGE	:	
4.	GENDER	:	
5.	F.OCCUPATION	:	
6.	F.INCOME	:	
7.	ADDRESS	:	
8.	CONTACT NO	:	
INCI	LUSION CRITERIA	A :	
>	Age: 3-12 Yrs		Yes/ No
>	Hb 7-11 gm		Yes/No
>	Patient having sign of	f pallor in conjunctivae, tongue, Nail bud	Yes/No
>	Patient having sympton	oms of fatigue, Anorexia, dyspnoea on exer	tionYes / No
>	Loss of memory/ lack	c of concentration	Yes/No
>	Patient suffering from	n worm infestation	Yes/No
>	Patients who are willi	ing to undergo laboratory investigation.	Yes/No
>	Patients who are willi	ing to sign the informed consent stating that	she will
	continuously stick to	the treatment during 28days but can opt out	of the trial of
	her own conscious dis	scretion.	Yes/No

EXCLUSION CRITERIA

(Clinical history)

- History of Metabolic disorder
- History of Haemolytic anaemia
- Patient with previous blood transfusion
- Patient with any other serious illness

ΔΤ	MI	TTEL	TO	TRI	ΔΤ	

YES	NO	
If yes,	OPD/IPD	
Date : Station:		
Signature of the G	uide	Signature of the Investigator

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE, CHENNAI – 600 106

CLINICAL STUDY ON "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF "PANNDU NOI" (IRON DEFICIENCY ANAEMA) IN CHILDREN

FORM II -HISTORY TAKING PROFORMA

1. S. NO. OF THE CASE	:
2. OP/IP NO	:
3. NAME	:
4. AGE	:
5. GENDER	:
6. F.OCCUPATION	:
7. F. INCOME	:
8. COMPLAINTS& DURATION	ON :
9. PERSONAL HISTORY	:
10. HISTORY OF PREVIOUS I	LLNESS:
11. BIRTH HISTORY	:
12. DIETARY HABIT	:
 Vegetarian 	
 Non-vegetarian 	
13. FAMILY HISTORY	:
Whether this problem runs in	n family?
1. Yes 2.1	No
If yes, mention the relations	hip 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 "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF

"PAANDU NOI" (IRON DEFICIENCY ANAEMIA)IN CHILDREN

FORM III ASSESSMENT PROFORMA

1. SERIAL NO	:
2. OP / IP NO	:
3. NAME	:
4. AGE	:
5. GENDER	:
GENERAL EXA	MINATION:
Height (cms)	:
Weight (kg)	:
Temperature(°F)	:
Pulse rate(/min)	:
Heart rate(/min)	:
Respiratory rate(/n	nin) :
Blood pressure(mr	m/Hg) :
Present Absent	
Pallor	
Jaundice	
Cyanosis	
Lymphadenopathy	
Pedal edema	
Clubbing	
Jugular vein pulsation	

SYSTEMIC EXAMINATION	
CardioVascularSystem :	
Respiratory system :	
Gastro-intestinal system :	
Central Nervous System :	
Urogenital system :	
Endocrine System :	
SIDDHA SYSTEM OF EXAMINA	ATIONS:
I. THEGI: [BODY CONSTIT	TUTION]
i. Vathaudal :	
ii. Pithaudal :	
iii. Kabaudal :	
iv. Thonthaudal:	
II. NILAM: [LAND WHERE	PATIENT LIVED MOST]
a) Kurinji(Hilly terrain)	:
b) Mullai(Forest range)	:
c) Marutham(Plains)	:
d) Neithal(Coastal belt)	:
e) Paalai (Arid regions)	:
III. KAALAM:	
a. Kaarkaalam	:
b. Pinpanikaalam	:
c. Koothirkaalam	:
d. Ilavenilkaalam	:
e. Munpanikaalam	:
f. Muthuvenilkaalam	:
IV. GUNAM:	
1. Sathuvam :	
2. Raasatham :	

3. Thaamatham:

V.	IMPORIG A	AL (SENSORY	ORGANS	5):		
	Normal/Affe	ected				
	Mei	:				
	Vaai	:				
	Kann	:				
	Mookku	:		_		
	Sevi	:				
VI.	KANMENI	OHIRIYAM (M	OTOR O	RGANS):		
	Kai	:				
	Kal	:				
	Vaai	:				
	Eruvai	:				
	Karuvaai	:				
VII.	KOSANGA	L (SHEATH):				
	Ann	amayakosam	:			
	Prar	namayakosam	:			
	Mar	nomayakosam	:			
	Vig	nanamayakosam	:			
	Ana	ndamayakosam	:			
VIII.	UYIR THA	ATHUKKAL:	THREE	HUMORS] ((VALI, AZHAL, IYA	M)
	A. VA	LI				
	Praa	nan	:			
	Aba	anan	:			
	Sam	naanan	:			
	Utha	aanan	:			
	Vya	anan	:			
	Naa	gan	:			
	Koo	orman	:			
	Kiru	ıkaran	:			
	Dev	athaththan	:			
	Dha	nanjayan	:			

	В.	. AZHAL		
		Analakam	:	
		Ranjakam	:	
		Sathakam	:	
		Prasakam	:	
		Alosakam	:	
	C	. IYAM		
		Avalambagan	n:	
		Kilethagam	:	
		Pothagam	:	
		Tharpagam	:	
		Santhigam	:	
IX.	SEVE	N UDAL THA	ATHUKKAL: (SEVEN SOMATIC COMPONENTS	3)
		Saram	:	
		Senneer	:	
		Oon	:	
		Koluppu	:	
		Enbu	:	
		Moolai	:	
		Sronitham	:	
X.	ENVA	GAI THERV	U:	
	1.	NAADI	: [PULSE PERCEPTION]	
	2.	SPARISAM	: [PALPATION]	
	3.	NAA	: [TONGUE]	
	4.	NIRAM	: [COMPLEXION]	
		a. Vadh	nam	
		b. Pitha	m	
		c. Kaba	nm	
	5.	MOZHI	: [VOICE]	
		i. Hig	h Pitched	
		ii. Lov	v Pitched	
		iii. Med	dium Pitched	

6. VIZHI : [EYES]

MALAM	: [BOWEL HABITS / S	TOOLS
	Niram	
	Irugal	
	Ilagal	
	Others	
7.	MOOTHIRAM: [URIN	E EXAMINATION]
NEERKKUR	I:	
Niram	l	
Manai	m	
Edai		
Nurai		
Enjal		
NEIKKURI:		
Date :		
Station:		
Signature of t	he 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 "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF "PAANDU NOI" (IRON DEFICIENCY ANAEMIA)IN CHILDREN

FORM IV: LABORATORY INVESTIGATIONS PROFORMA

SERIAL NO. OF THE CASE:
 OP / IP NO :
 NAME :
 AGE :
 GENDER :

A) BLOOD INVESTIGATIONS:

BLC INVESTIC	OOD GATIONS	BEFORE TREATMENT	AFTER TREATMENT
Hb(gms/dl)			
T.RBC (million cells/ Cu.mm)			
ESR(mm)	½ hour		
	1 hour		
T. WBC (ce	ells/cu.mm)		
Differential co	ount(%)		
Polym	norphs		
Lymph	nocytes		
Monocytes			
Esinophils			
Baso	phils		

BLOOD INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
PCV		
MCV		
MCH		
MCHC		
SERUM IRON		
SERUM FERRITIN		
TIBC		

INVESTIGA	TIONS	BEFORE TREATMENT	AFTER TREATMENT
MOTION	OVA		
TEST	CYST		

B) URINE INVESTIGATIONS:

URINE INVESTIGATION	BEFORE	AFTER
	TREATMENT	TREATMENT
Albumin		
Sugar		
Deposit		

Date	:									
Station	1:									

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 "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF "PAANDU NOI" (IRON DEFICIENCY ANAEMIA)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".

affecting my child further medical care".	
"I have received a copy of the infor	mation sheet/consent form".
Date:	
Signature of the participant:	
In case of illiterate participant	
"I have witnessed the accurate reads participant, and the individual has the oppo- individual has given consent freely."	ing of the consent form to the potential ortunity to ask questions. I confirm that the
Date:	
Signature of a witness	Left thumb Impression of the Participant
(Selected by the participant bearing no con-	nection with the survey team)
Date :	
Station:	
Signature of participant:	
Signature of the Guide	Signature of the Investigator:

அரசச் த்தமருத்தவக்கல்லூர், சன்னை-106

அறி ஞர் அண்ணா மருத்து வமனரை, சன்னை

பாண்டு ந பேய்க்கான சேத்த மருந்தேன் (கரிசலங்கண்ணி சூரணம்) பரிகரிப்புத் தேறனகை கண்டறியம் மருத்துவ ஆய்விற்கான தகவல் படிவம் ஒப்புதல் படிவம் ஆய்வாளரால் சான்றவிக்கப்பட்டது.

நான் இந்த ஆய்வகை சுறித்த அனதைது விபரங்களமைம் ந போ விக்கு பூரியம் வக டையில் எடுத்துரதைதனே என உறுதியவிக்கிறனே.

த தே :	
கயை பெப்பம் :	
இடம் :	பயெர் :

ந ரேயா வென் படுற்ற ரேர் ஒப்புதல் படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தடைம், மருந்தின் தன்மமை மற்றும் மருத்துவ வழிமுறை பற்றிடிம், தடெர்ந்து எனது உடல் இயக்கத்தடைகண்காணிக்கவம், அதனை பாதுகாக்கவம் பயன்படும் மருத்துவ ஆய்வக் கூட பரிச நேனைகள் பற்றி திருப்தி அளிக்கும் வகமையில் ஆய்வ மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் எனது சுழந்தடையின் இந்த மருத்துவ ஆய்வின் ப நே காரணம் எதுவம் கூறாமல், எப்ப பெழுது வணேடுமானாலம் இந்த ஆய்வில் ருந்து எனது சுழந்தயை வெடுவித்து க பெள்ளம் உரிமயை தெடிந்திருக்கேறனே. நான் என்னடையை சுதந்திரமாக தரேவ செய்யம் உரிமயைகை க பெண்டு ந பேய்க்கான கரிசலாங்கண்ணி சூரணம் மருந்தின் பரிகரிப்புதேறனகை கண்டறியம் மருத்துவ ஆய்விற்சு என் சுழந்தயை உட்படுத்த ஒப்புதல் அவிக்கேறனே.

БСВ :	கயை பெப்பம் :
இடம் :	பயெர் :
563 :	சாட்சக்காரர் கடைபடைபட்ட
இடம் :	பயெர் :
உறவமுறை :	

து ற தைதலவைர்க யை பெப்பம்: ஆராய்ச்சே யா ளர்க யை பெப்பம்:

GOVERNMENT SIDDHA MEDICAL COLLEGE, CHENNAI

CLINICAL STUDY ON "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF "PAANDU NOI" (IRON DEFICIENCY ANAEMIA) IN CHILDREN

FORM VI - WITHDRAWAL FORM

S. 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 reaction 	ıs	:	Yes/No
Date :			
Station:			
Signature of the Guide	Siona	ture c	of the Investigator

GOVERNMENT SIDDHA MEDICAL COLLEGE ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF "PAANDU NOI" (IRON DEFICIENCY ANAEMIA) IN CHILDREN

FORM VII – PATIENT INFORMATION SHEET

Name of Co- Investigator: K. Karpagavalli

Name of the college: Govt. Siddha Medical College, Arumbakkam, Chennai-106.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, K. Karpagavalli, studying M.D(Siddha) at Govt.Siddha Medical College, Chennai, is doing a clinical trial on "PaanduNoi" –Iron Deficiency Anaemia 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 "Karisalankannichooranam" (Internal medicine) 800mg – 1000mg (B.D) for 28 days.

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 K. Karpagavalli, PG Scholar cum Co-investigator of this study, attached to Govt. Siddha Medical College, Chennai-106. You can also contact the Member-secretary of Ethics committee, Govt. Siddha Medical College, Chennai.

அரசுச்த்த மருத்தவக் கல்லூர், சன்னை-106 அறிஞர் அண்ணா மருத்துவமன், சன்னை

பாண்டு ந பேய்க்கான சேத்த மருந்தின் (கரிசலங்கண்ணி சூரணம்) பரிகரிப்புத் துறனகை கண்டறியம் மருத்துவ ஆய்விற்க்கான தகவல்படிவம்

ஆராய்ச்சேயாளர் பயெர்: க.கற்பகவள்ளி

நேறுவனத்தன் பயெர்: அரச செத்த மருத்துவக் கல்லூரி, அரும்பாக்கம், சன்னை-106.

அரச இத்த மருத்துவக் கல்லூரியில் பட்டமறேபடப்பு பயின்று வரும் நான் மருத்துவர் க. கற்பகவள்ளே பாண்டு என்னும் நமியில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளனே.

இந்த ந டேய் உட்டச்சத்து சுறவைனால் ஏற்படு கேன்றன. இது பரவக் கூடிய ந டேயல்ல.

இந்த ஆராய்ச்சி சம்பந்தமாக சில களேவி களகை கடேகவம், தவேயை வ ஆய்வகப் பிரச நேனகைசு தங்கள் சுழந்தயை உட்படித்தவம் உள்ளனே.

இந்த ஆராய்ச்செக்கு தங்கள் விருப்பத்தின் பரேல் உட்படும் பட்சத்தில் உள்மருந்தாக கரிசலங்கண்ணி சூரணம் 200மி.கி - 500மி.கி 2 வளே ைகாலை, மாலை) உணவக்கு பின் 28 நாட்கள் உட்க டுள்ள வணேடும். வடுள் நாட்கள் 7 நாட்களுக்கு ஒருமுறைவைரவணேடும்.

இந்த மருந்து சேறப்பாக பாண்டூ நபேய்க்காக அங்கீகரிக்கப்பட்ட சேத்தமருத்துவ நூலில் கூறப்பட்டுள்ளது.

இந்த ஆராய்ச்சேயில் தங்களை அண மதித்த பிறசு உங்களுக்கு விருப்பம் இல்லயைனெல் எப்ப சூற வணெடுமானாலும் ஆராய்ச்செயில் இருந்து விலகிக்க ொள்ள உரிம உள்ளது.

இந்த ஆராய்ச்சேக்கு சம்பந்தமாக நமேயன் தன்ன பற்றி டீம் மற்ற வே பரங்களுக்கும் ஆராய்ச்செயாளர் மருத்துவர் க.கற்பகவள்ளி (பட்ட மறேபடிப்பாளர், குழந்த மைருத்துவத்துறரை) அவர்களரை எந்த நரேத்தேலும் தொடர்பு க ெள்ளலாம். கடைப்பசே எண்: 7373127490. மலே ம் இந்த ஆராய்ச்சுக்கு தக்கஅன மதுச் சான்று பறெப்பட்டுள்ளது.

இந்த மருந்து முற்றிலம் பாதுகாப்பான மூலிகை பொருட்களகை க பெண்டு தயாரிக்கப்பட்டுள்ளது. பக்க வௌனைகளை ஏற்படுத்தூது. மலேம் உணனமுறமையல் மருத்துவரால் கூறப்படும் பத்தியம்காக்குமாற அறினறுத்தப்படுகேறது.

இது சம்பந்தமான தங்களது அனதைது விவரங்களும் ரகசெயமாக வகைகப்படும் என உறு இ அளிக்கேறனே.

இதில் பயணப்பட முதலிய எந்த உதவித் தளிகணும் வழங்கப்படமாட்டாது.

இந்த ஆராய்ச்சேயின் ப ோேது உடலுக்கு வேறே பாதிப்பு ஏற்படும் பட்சத்தில் அறிஞர் அண்ணா மருத்துவமனமையில், தக்க சேகிச்ச அைவி க்கப்படும்.

GOVERNMENT SIDDHA MEDICAL COLLEGE ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

CLINICAL STUDY ON "KARISALANKANNI CHOORANAM" IN THE TREATMENT OF "PAANDU NOI" (IRON DEFICIENCY ANAEMIA)IN CHILDREN

FORM X - ADVERSE REACTION REPORTING FORM

SERIAL NO	:			
OP/IP NO	:			
NAME	:			
AGE	:	GENDER	:	
DATE OF TH	RIAL COM	MENCEMENT	:	
DATE OF O	CCURREN	CE OF THE AD	VERSE REACT	TION:
TIME	:			
DESCRIPTION	ON OF ADV	VERSE REACTI	ON :	
MANAGEMI	ENT :			
Date :				
Station:				

Signature of the Investigator

Signature of the Guide

DEPARTMENT OF KUZHANTHAI MARUTHUVAM

DISSERTATION STUDY ON "KARISALANKANNI CHOORANAM" IN PAANDU NOI (IRON DEFICIENCY ANAEMIA)

INVESTIGATOR – Dr. K. KARPAGAVALLI

ANNA HOSPITAL OPD- CHENNAI-106

RS

OP.NO	:		DATE	:
NAME	:			
AGE / SEX	:			
PARENT NAME	:			
ADDRESS	:			
PHONE NO	:			
COMPLAINTS &	& DURA	ATION		
Loss of app	petite			
> Fatigue				
Worm infe	station			
Pallor of sl	cin and 1	mucous	membrane	
Lack of co	ncentrat	ion		
ECONOMIC STA	ATE	:	POOR / MIDDLE / RICH	
DIET		:	VEG / MIXED	
H/O PICA		:		
FAMILY HISTOR	RY	:		
PAST HISTORY		:		
ON EXAMINAT	ION			
HT :				
WT :				
PALLOR :				
CVS :				

ENVAGAI THERVU:

NAA : MALAM:

NIRAM : MOOTHIRAM :

MOZHI : NAADI :

VIZHI : SPARISM :

INVESTIGATION:

	BEFORE	AFTER		BEFORE	AFTER
BLOOD			S. FERRITIN		
TC			TIBC		
DC			URINE		
ESR			Alb		
Hb			Sugar		
RBC			Deposit		
PCV			MOTION		
MCV			Ova		
МСН			Cyst		
MCHC					

TREATMENT:

WEEK S/ DATE	PALLO R	WORM INFESTATIO N	LOSS OF APPETIT E	FATIGU E	LACK OF CONCENTRATI ON
I.					
II.					
III.					
IV.					
V.					

GOVT SIDDHA MEDICAL COLLEGE AND HOSPITAL

CHENNAI

Branch -IV KUZHANTHAI MARUTHUVAM

PROFORMA OF CASE SHEET FOR PAANDU NOI

IP. No :		Nationality	:
Name :		Religion	:
Age :		Date of Admission	:
Sex :		Date of Discharge	:
Address :		Diagnosis	:
Informant :		Medical Officer	:
1. Complaints and duration	:		
2. History of present illness	:		
3. History of Past illness	:		
4. Antenatal history	:		
5. Birth history	:		
6. Neonatal history	:		
7. Developmental history	:		
8. Nutritional history	:		
9. Immunization history	:		
10. Family history	:		
11. Socio economic status	:		
General examination:			
1. Appearance and posture	:		
2. Nutritional status	:		
3. Anaemia	:		
4. Cyanosis	:		
5. Clubbing	:		

6. Jaundice

7. Lymphadenopathy :8. Abdominal distension :9. Pedal oedema :

Vital Signs:

Temperature :
 Pulse rate :
 Respiratory rate :
 Heart rate :
 Blood pressure :

Anthropometry

a. Height :b. Weight :c. Chest circumference :

SIDDHA ASPECTS

Nilam

Kurinji :
 Mullai :
 Marutham :
 Neithal :
 Paalai :

Paruvakalam

Kaar :
 Koothir :
 Munpani :
 Pinpani :
 Elavenil :
 Muthuvenil :

Poripulangal

- 1. Mei :
- 2. Vai :
- 3. Kan :
- 4. Mooku :
- 5. Sevi :

Kanmenthiriyam

- 1. Kai :
- 2. Kaal :
- 3. Vaai :
- 4. Eruvai :
- 5. Karuvai :

Uyirthathukkal

Vadham

- 1. Praanan
- 2. Abaanan :
- 3. Viyaanan :
- 4. Uthaanan :
- 5. Samaanan :
- 6. Naagan :
- 7. Koorman :
- 8. Kirukaran :
- 9. Devathathan:
- 10. Dhananjeyan:

Pitham

- 1. Analpitham:
- 2. Ranjagam
- 3. Saadhagam
- 4. Praasagam :
- 5. Aalosagam

Kabam

- 1. Avalambagam:
- 2. Kiletham:
- 3. Pothagam:
- 4. Tharpagam:
- 5. Santhigam

UdalKattugal

- 1. Saaram
- 2. Senneer :
- 3. Oon :
- 4. Kozhuppu :
- 5. Enbu :
- 6. Moolai :
- 7. Sukkilam/Suronitham:

EnvagaiThervugal

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

MODERN ASPECTS

- 1. Respiratory System
- 2. Cardiovascular system :
- 3. Gastro intestinal system :
- 4. Central nervous system :
- 5. Excretory system :

Laboratory investigations

TC	:			
DC	:			
ESR				
1/2 hr	:			
1 hr	:			
Hb%	:			
Urine	;			
Album	nin	:		
Sugar		:		
Depos	its	:		
Stools				
Ova	:			
Cyst	:			
Other Investigations				
PCV	:			
MCV	:			
MCH	:			
MCHO	C:			

Blood

Investigation - Siddha aspect

1. Neerkuri

Niram :

Edai :

Manam :

Nurai :

Enjal :

2. Neikuri

3. Daily progress

DATE	SYMPTOMS	MEDICINE

GOVERNMENT SIDDHA MEDICAL COLLEGE

Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-2/018/2017

Protocol title:					
AN OPEN CLINICAL STUDY ON PAANDU NOI (IRON DEFIENCY ANEMIA) IN CHILDREN WITH THE EVALUATION OF SIDDHA TRIAL DRUG KARISALANKANNI CHOORANAM					
Principal Investigator: Dr. K.KARPAGAVALLI					
Name & Address ofInstitution:					
Government Siddha Medical College,					
Arumbakkam, Chennai-106					
New Review 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.Change Dosage :200-500mg.Remove Thirigadi alavu. 2.Add Adjuvant Honey. 3.HB level add in inclusion criteria. 4.Remove patient with chronic disease and add previous blood transfusion. 5.Remove pheripheral blood smear in investigation. 6.Change duration 48 days.					
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.K.Kanakavalli Chairman Manchan See					
Chairman Member Secretary					

INSTITUTIONAL ETHICS COMMITTEE

Date: 06.04.2017

Sub : IEC Review of research proposals

Ref : Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
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Dr. K. KANAKAVALLI., MD(S)., Member secretary		2. h. h. 2. 6-13
Dr.SATHYA RAJESWARAN M.D(S), Clinician - Siddha		Show In
Dr.KABILAN M.D(S), Clinician - Siddha		Second 1
Dr.R.VASUDEVAN, M.D(S)., PG.DIP (Clinical research), Msc (Medical sociology), Sociologist		D. d. bluss
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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. K. Karpagavalli 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	KARISALAI	ECLIPTA PROSTATE	ASTERACEAE
2	CHUKKU	ZINGIBER OFFICINALE	ZINGIBERACEAE
3	MILAGU	PIPER NIGRUM	PIPERACEAE
4	THIPPILI	PIPER LONGUM	PIPERACEAE
5	KADUKKAI	TERMINALIA CHEBULA	COMBRETACEAE
6	NELLIKKAI	PHYLLANTHUS	EUPHORBIACEAE
		EMBLICA	
7	THANDRIKKAI	TERMINALIA BELARICA	COMBRETACEAE
8	MARAMANJAL	COSCINIUM	MENISPERMACEAE
		FENESTRATUM	
9	THANIYA	CORIANDRUM SATIVUM	APIACEAE
10	MUKKIRATTAI	BOERHAVIA DIFFUSA	NYCTAGINACEAE
11	KARUNSEERAKAM	NIGELLA SATIVA	RANUNCULACEAE
12	THALISAPATHTHIRI	ABIES SPECTABILIS	PINNACEAE
13	ELLAM	ELLATTERIA	ZINGIBERACEAE
		CORDAMONUM	
14	SEERAKAM	CUMINUM CYMINUM	APIACEAE
15	ATHIMATHURAM!	GLYZYRRHIZA GLABRA	FABACEAE

References: Flora of Presidency, Gamble, J. S.

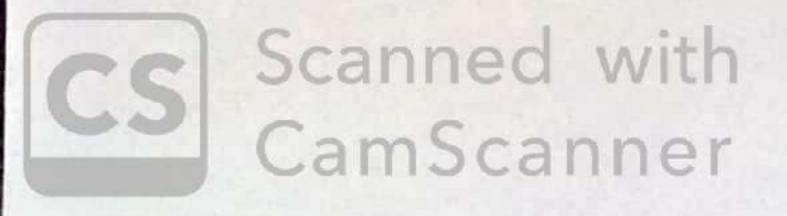
Date: 05.04.2018

Place: Chennai

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.



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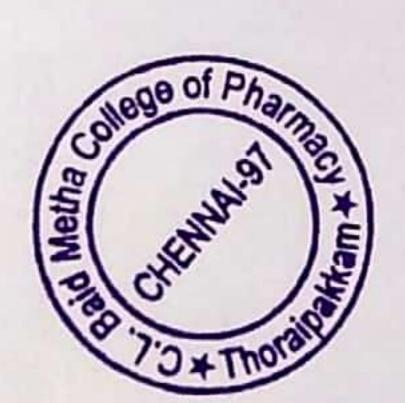


Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai.
Approved by Pharmacy Council of India, New Delhi, and
All India Council for Technical Education, New Delhi

CERTIFICATE

This is to certify that the project title "An open clinical study on PAANDU NOI (IRON DEFICIENCY ANEMIA) in children with the Evaluation of Siddha trial drug KARISALANKANNI CHOORANAM for its toxicological and HEMETINIC activity in Wistar albino rats" has been approved by IAEC

IAEC No: LV/11/CLBMCP/2018



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. K. KARPAGAVALLI

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.

FROF & HEAD DEPT.OF SIDDHA

Prof. Dr. T. BALASUBRAMANIAN, M.D., D.L, O., Prof. Dr. S. GEETHALAKSHMI, M.D., Ph.D., REGISTRAR

VICE CHANCELLOR







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	k. KARPAGA	VALLI, GSMC	
has participated/Chaired a session in t			
Development wing, Sree Balaji Medical Co	llege & Hospital, Cl	hromepet, 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