

AMRITA SCHOOL OF AYURVEDA
DEPARTMENT OF POST GRADUATE STUDIES
LIST OF SYNOPSIS, GUIDE & CO-GUIDE

Department of Rashashastra & Bhaisajya Kalpana

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AMRITA SCHOOL OF AYURVEDA
AMRITA VISHWA VIDYAPEETHAM
(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

FOR

AYURVEDA VACHASPATI M.D (AYU) IN RASA SHASTRA AND BHAISHAJYA KALPANA

A PHARMACEUTICO - CLINICAL STUDY OF
KRIMIMUDGARA RASA IN UDARAKRIMI

BY

Dr. CHITHRA M.S
(1st YEAR P.G. SCHOLAR)

DEPT. OF P.G STUDIES IN RASA SHASTRA AND BHAISHAJYA KALPANA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

GUIDE

DR.K.UNNIKRISHNA PILLAI, M.D (Ayu.), Ph.D
PROFESSOR AND H.O.D.

DEPT. OF P.G STUDIES IN RASA SHASTRA AND BHAISHAJYA KALPANA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

CO-GUIDE

Dr. ABHAYAKUMAR MISHRA, M.D (Ayu).Ph.D
ASSOCIATE PROFESSOR,

DEPT. OF P.G STUDIES IN RASA SHASTRA AND BHAISHAJYA KALPANA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

SESSION: 2013-2014

FROM

CHITHRA.M.S,

Preliminary M.D (Ayu) Scholar,

Department of Post Graduate Studies in Rasashastra and BhaishajyaKalpana,

Amrita School of Ayurveda,

Vallikavu, Kollam- 690525.

TO

The Registrar,

Amrita VishwaVidyapeetham,

Ettimadai Post, Coimbatore – 641105.

THROUGH

The Principal and Head of the Dept. of Rasashastra and BhaishajyaKalpana,

Amrita School of Ayurveda,

Vallikavu, Kollam 690525.

Sub: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita University, for partial fulfillment of M.D. (Ayurveda) in Rasashastra and Bhaishajyakalpana.

THE TITLE OF DISSERTATION:

**“A PHARMACEUTICO - CLINICAL STUDY OF
KRIMIMUDGARARASA IN UDARAKRIMI.”**

Herewith I am enclosing a completed Proforma of synopsis for registration of the subject for dissertation.

Thanking you,

Yours faithfully,

Place: Vallikavu

Date:

(Dr.Chithra.M.S)

1. BRIEF RESUME OF THE INTENDED WORK:

I.NEED FOR THE STUDY:

Krimi roga especially udarakrimi (intestinal parasites) is one of the major global public health problem, in tropical countries. [WHO-1967, Waliden -1983, Mc Larne - 1984]. Besides the environmental conditions, poverty, illiteracy, lack of adequate sanitary facilities and lack of pure water supply make total eradication of this problem very difficult. It affects the children more frequently than adults¹ [CCRAS-1987].

Yet surprisingly, large numbers of case affected with Krimi roga are asymptomatic. Krimi's are the unsuspected and undetected villains responsible for malnutrition. No medical system in the world has an effective drug for total eradication of intestinal parasites. Through this present study, an effort is made with KRIMIMUDGARA RASA² to solve the problem of worm infestation.

II.REVIEW OF LITERATURE:

Proper screening of the literature from classical texts of Ayurveda, texts of allied science, and data from any other relevant source will be made use for the purpose of this study.

PREVIOUS RESEARCH WORKS:

1. 1968 Krimikudara rasa ka Krimi-roga par Adhyayan – Dandrial R. P., Rasashastra & Bhaishajya Kalpana Department (Jamnager).
2. 1970 Krimi Chikitsa Ka Tulanatmak Adhyayan – Sharma R. D., Kayachikitsa Department. (Jamnager).
3. 1971 Krimi Chikitsa ka Prayogik Adhyayan - Pathak M. J., Kayachikitsa Department. (Jamnager).
4. 1973 Krimi Prayogatmak Adhyayan – Lathi V. N., Kayachikitsa Department. (Jamnager).
5. 1979 Effect of Kampillaka and Vidanga an Giardiasis – Bhatt B. R. Kayachikitsa Department. (Jamnager).

6. 1980 A clinical study of effect of Ayurvedic yoga on intestinal parasite (UdaraKrimi) – Bajoria K. R., Kayachikitsa Department. (Jamnager).
7. 1983 Studies on Krimi Roga Samprapti and its management by Krimi KalamalRasa – Namboodiri, Kayachikitsa Department. (Jamnager).
8. 1984 A study on the effect of Katu taila basti in Purishaja Krimi in children below 12 years (W.S.R. to enterobious Vernicularis) Ramachandran S.K., Kaumarbhritya Department. (Jamnager).
9. 1986 Effect of certain indigenous drugs in Purishaja Krimi – Trivedi Y D. Kaumarbhritya Department. (Jamnager).
10. 1986-Krimi Roga Me Apakarshana Evam Prakriti Vighata Ka Mulyankan – Jani (Ms) V. H.,Kayachikitsa Department (Ahmedabad).
11. 2002 A comparative study of Krimighna vati and Palash beeja ghan vati on Udarkrimi in children – Dr. Seetal Parikha, KaumarbhrityaDepartment. (Jamnager).

LAIM AND OBJECTIVE OF THE STUDY:

- To assess the clinical effect of “KRIMIMUDGARA RASA” in UdaraKrimi.
- To do critical study on Krimiroga in Ayurvedic and modern literature.

2. MATERIALS AND METHODS

1.SOURCE OF DATA

Pharmaceutical source:

The drugs selected for the research work as mentioned in BhaishajyaRatnavali² will be prepared in the pharmacy attached to Amrita School of Ayurveda. Individual ingredients will be identified, validated by taking an expert opinion before subjecting them for the preparation.

Analytical study:

The finished products will be analyzed physico-chemically as per API³ in approved laboratory for;

- Organoleptic property.
- Moisture content
- Total ash
- Acid insoluble ash
- Water soluble ash
- Alcohol soluble ash
- Hardness
- Disintegration time.

Clinical Study.

Patients registered in the OP department of Amrita School of Ayurveda and medical camp conducted in nearby schools will be selected.

II.MATERIALS REQUIRED FOR THE STUDY:

i.METHOD OF COLLECTION OF DATA:

SAMPLE:

30 patients with clinical signs and symptoms ,fulfilling the inclusion criteria will be selected.

INCLUSION CRITERIA:

- Age group in between 6-12 years old children with classical symptomology of Krimi roga^{4, 5}.
- Stool examination – presence of ova/cyst in stool are included.

EXCLUSION CRITERIA:

- Children below 5year & above 12 years are excluded.
- Patients suffering from any other systemic illness.
- Stool examination – absence of ova/cyst in stool are excluded.

ii.PROCEDURE AND DESIGN OF THE STUDY:

1. MATERIALS AND METHODS:

Pharmaceutical preparation.

Name of the preparation Krimimudgara rasa			
Ingredients	Botanical name	Part used	Proportion
S .Parada	Purified mercury	As such	1 part
S .Gandaka	Purified sulphur	As such	2 part
Ajamoda	<i>Apium leptophyllum</i>	Dried fruits	3 part
Vidanga	<i>Embelia ribes</i>	Dried matured fruits	4 part
S.Vishamusthika	<i>Strychnos nux-vomica</i>	Dried fruits	5 part
Palasha	<i>Butea monosperma</i>	Dried stem bark	6 part

Preparation:

The drug Krimimudgara rasa will be prepared according to Bhaishajya Ratnavali² .

2. DESIGN OF THE STUDY:

1	Number of patients.	30 patients.
2	Medicine	Krimimudgara rasa.
3	Dose and time.	62.5mg divided dose after food.
4	Anupana	Honey
5	Route of administration	Oral
6	Duration of the study	1 month
7	Courses of medication	3 days
8	Follow up	4 th day, 7 th day, 1 month

3. ASSESSMENT CRITERIA:

Criteria for the assessment of the Udarakrimi will be taken by the lakshanas as said in the Ashtanga hridaya⁴ & Susrutha samhitha⁵, where each of the parameter will be scored by following a standard scoring pattern. Before and after treatment score detail of each parameter will be recorded in a specially prepared proforma.

4. STATISTICAL METHODS:

Change in the patient condition will be analyzed after completion of the study period by subjecting the scores of individual parameter for statistical analysis using paired 't' test.

3. Does the study require any investigations or interventions to be conducted on patients, Healthy volunteers, cadaver or animals? If so, please describe briefly:

Yes. During the study the following investigation will be done to check health status of patients.

Laboratory investigations:

- Blood Routine Examination.
- Stool Routine Examination.

4. Has ethical clearance been obtained from your institution in case of (3)?

Yes.

5. LIST OF REFERENCES:

1. R.S.Satoskar, Nirmala N Rege, S D Bhandarkar. Pharmacology and Pharmacotherapeutics, twenty second edition, Popular Prakashan, Mumbai, 2011 chapter 59 page 804.
2. Sri Govind dasa virachita Bhaishajya rathnavali, Chaukhambha prakashan, Varanasi, 9th ED. 2008, 11 chapter, page 366.
3. Sri Govind dasa virachita Bhaishajya rathnavali, Chaukhambha prakashan, Varanasi, 9th ED. 2008, 11 chapter, page 366.
4. Dr. Sreekantha Murthy, Vagbhata's Astanga hridayam, pub: Chowkamba Krishnadas academy, Varanasi. ED. 2008 page 145.
5. Vaidya Jadavji Trikamji Acharya, Susruta Samhitha of Susruta with the Nibandhasangraha Commentary of Sri Dalhanacharya and the Nayachandrika Panjika of Sri Gayadasacharya on nidanasthana, Chowkhamba krishnadas acadamey, Varanasi, reprint 2012, susruta utharathanthram, page 773.

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AMRITA VISWAVIDYAPEETHAM

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PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA VACHASPATI (M.D) IN RASA SHASTRA AND BHAISHAJYA KALPANA

**A COMPARATIVE PHARMACEUTICO-ANALYTICAL STUDY OF BALARISHTA
PREPARED WITH DHATAKI PUSHPA AND YEAST AS SANDHANA DRAVYAS**

BY

Dr.DIVYA RAVINDRAN

Ist YEAR P.G. SCHOLAR

DEPT. OF P.G STUDIES IN RASA SHASTRA & BHAISHAJYA KALPANA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, KOLLAM-690525

GUIDE

DR.ABHAYA KUMAR MISHRA, MD (Ayu.),Ph.D

ASSOCIATE PROFESSOR

DEPT. OF P.G STUDIES IN RASA SHASTRA & BHAISHAJYA KALPANA
AMRITA SCHOOL OF AYURVEDA

CO-GUIDE

Dr. ARUN MOHANAN,MD(Ayu.)

ASSISTANT PROFESSOR

DEPT. OF P.G STUDIES IN RASA SHASTRA & BHAISHAJYA KALPANA
AMRITA SCHOOL OF AYURVEDA

SESSION: 2013-2014

From,

DIVYA RAVINDRAN

Preliminary M.D (Ayu) Scholar,

Department of Post Graduate Studies in Rasashastra and Bhaishajya Kalpana,

Amrita School of Ayurveda, Vallikavu, Kollam- 690525.

To,

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THE TITLE OF DISSERTATION:

**A COMPARATIVE PHARMACEUTICO-ANALYTICAL STUDY OF BALARISHTA
PREPARED WITH DHATAKI PUSHPA AND YEAST AS SANDHANA DRAVYAS**

Herewith I am enclosing a completed Proforma of synopsis for registration of subject for Dissertation.

Thanking you,

Yours faithfully,

Place: Vallikavu

Date:

Divya Ravindran

1. BRIEF RESUME OF THE INTENDED WORK:

1.i. NEED FOR THE STUDY:

Asava and Arishta preparations have occupied unique place among the kalpanas mentioned in Ayurveda¹. These preparations are more popular and appreciated because of their good palatability, accelerated therapeutic action and long shelf life.²

Dhataki pushpa^{2,3} is mentioned by ancient Acharyas as a sandhana dravya in the preparation of Asavas and Arishtas. Now a days Yeast is also being used by many pharmaceutical companies as fermenting agent.⁴

Balarishta⁵ described in Sahasrayoga is taken for the present study. It is one among the Arishta kalpana which provides bala, pushti, improves agni and is indicated in severe vata rogas. The ingredients mentioned in the formulation are readily available.

Balarishta will be prepared by using sandhana dravyas such as Dhataki pushpa (as per its yoga) and with Yeast (market sample). A comparative study will be done to assess the efficacy of sandhana dravyas to yield a better Asava and Arishta.

1.ii. REVIEW OF LITERATURE:

With respect to the above hypothesis proper screening of the literature from classical texts of Ayurveda, related journals and data from any other relevant sources will be made use for the purpose of this study.

Balarishta comprises of Bala and Aswaganda as kashaya dravyas, Payasya, Eranda, Rasna, Ela, Prasarini, Devapushpa, Useera, Svadamshttra as prakshepa dravyas and Dhataki pushpa as sandhana dravya. Bhaishajya Ratnavali has also explained the same yoga with same ingredients.⁶

The method of preparation is as mentioned by Sahasrayoga and Ayurveda Formulary of India. Kashaya of Bala and Aswaganda is made, fine powder of other ingredients are added including Dhataki pushpa and kept for sandhana in mud pot. Another sample of Balarishta is also prepared with Yeast as fermenting agent instead of Dhataki pushpa.

Previous research works:

1. 1998, Dr. Raghunath – A study of Arishta kalpana wsr to its water soluble components & the factors influencing fermentation. Trivandrum, Trivandrum Ayurvedic College.
2. 2004, Vaidyaratnam Oushadhasala- The isolation, identification of microorganisms responsible for fermentation present in *Woodfordia fruticosa* and its application in fermenting Arishtasavas. Thrissur.
3. 2011, Dr. Sreelal. A. M – A comparative study of sandhana kalpana using dhataki pushpa, inoculum and yeast extract as sandhana dravyas for mustakarishtha, Rajiv Gandhi University of Health Sciences, Karnataka.

1.iii. AIM AND OBJECTIVE OF THE STUDY .

- Preparation of Balarishta using Dhataki pushpa and Yeast.
- Analytical study of Balarishta prepared using the two fermenting agents after 15 days, 30 days and 45 days.
- To assess the efficacy of sandhana dravyas, by comparing the analytical results.

2. MATERIALS & METHODS:

2.1. SOURCE OF DATA:

The raw materials required for this study will be collected and authenticated from reliable sources.

Pharmaceutical data:

Sl No	Drug Name	Latin Name	Parts Used	Proportion
1.	Bala	<i>Sida cordifolia</i>	Root	100 pala
2.	Aswaganda	<i>Withania somnifera</i>	Root	100 pala
3.	Guda	<i>Saccharum officinarum</i>	As such	3 tula
4	Payasya	<i>Holostemma ada-kodein</i>	Root	2 pala
5	Eranda	<i>Ricinus communis</i>	Root	2 pala
6	Rasna	<i>Alpinia galangal</i>	Rhizome	1 pala
7.	Ela	<i>Elettaria cardamomum</i>	Seed	1 pala
8.	Prasarini	<i>Merremia tridentate</i>	Whole plant	1 pala
9.	Lavanga	<i>Syzigium aromatic</i>	Dried flower bud	1 pala
10.	Useera	<i>Vetiveria zizanioides</i>	Roots	1 pala
11.	Gokshura	<i>Tribulus terrestris</i>	Fruit	1 pala
12.	a) Dhatakipushpa	<i>Woodfordia fruticosa</i>	Flower	16 pala
	b) Yeast	<i>Saccharomyces cerevisiae</i>		600mg/L

Analytical Data

The formulation will be assessed with the following analytical parameters.⁷

- 1.Organoleptic characters
- 2.pH
- 3.Total solids
- 4.Alcohol content
- 5.Reducing sugar
- 6.Non-reducing sugar
- 7.Total acidity
8. Specific Gravity
9. TLC

2.2.ii)PROCEDURE AND DESIGN OF THE STUDY:

i) MATERIALS AND METHODS.

METHOD OF PREPARATION:

Balarishta will be prepared as per the yoga mentioned in Sahasrayoga with sandhana dravyas Dhatakipushpa, and Yeast separately for each sample.

PLACE OF PREPARATION OF MEDICINE:

Thirty samples of Balarishta will be prepared at Dept.of Rasasastra and Bhaishajya kalpana, Amrita School of Ayurveda, Vallikavu.

ii) DESIGN OF THE STUDY.

a) Pharmaceutical study:

Balarishta will be prepared as per the reference and it will be kept in 30 fermenting vessels. 5 fermenting vessels are marked for one fermenting agent. Five vessels with Dhataki pushpa and 5 vessels with Yeast will be opened after 15 days, 30 days and 45 days respectively.

b) Analytical study:

The above mentioned analytical parameters will be assessed and compared from the Balarishta samples which are taken after 15 days, 30 days and 45 days from vessels with each fermenting agent.

iii) ASSESSMENT CRITERIA.

The assessment of efficacy of sandhana dravyas will be done according to the analytical parameters of samples and the results are compared.

iv) STATISTICAL METHODS.

Statistical analysis will be done by Student 't' test.

3. Does the study requires any investigations or interventions to be conducted on patients or other human or animal? If so, please describe briefly:

Not Applicable.

4 .Has ethical clearance been obtained from your institution in case (3)?

Not Applicable.

5. LIST OF REFERENCES

- 1 .Acharya Sharangadhara, Sharangadhara Samhita, Published by Chowkhamba Orientalia Varanasi, printed by Chowkhamba press Varanasi, Edition 2007,Chapter No:10, Sloka no.1-2.
2. Dr.Ravindra Angadi, A text book of Bhaishjya kalpana Vijnana,Chaukamba Surbharti Prakashan,Varanasi,2011.
3. Ayurvedic Pharmacopeia of India, Part. 1, Vol 1, The Controller of Publications Civil Lines; New Delhi,1st Edition,2008.
4. Anand Chaudhary, Neetu Singh, Madhuri Dalvi, Asmita Wele. A progressive review of Sandhana kalpana (Biomedical fermentation). AYU, 2011. Vol.32Issue.3.
- 5 S.Gopala pillai,K.V.Krishnan vaidyar,Sahasrayogam-Sujanapriya vyakhyanam,Arishta Yogas, Vidyarambham Publishers, 27th Edition,2007.
6. Das Govinda. Bhaishajya Ratnavali, Mishra Brahmashankar (ed.). Varanasi: Chaukamba Orientalia; ed:2012,Chapter no.26, Sloka no.607-610
7. Parameters for Quality Assessment of Ayurveda and Siddha Drugs, Part A, C.C.R.A.S, Dept. of AYUSH, New Delhi, 2005.

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**PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION
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**AYURVEDA VACHASPATI [M.D] IN RASA SHASTRA
AND BHAISHAJYA KALPANA**

**“PHYSICO-CHEMICAL ANALYSIS OF KASISA PURIFIED BY
DIFFERENT BHAVANA DRAVYAS AND
THEIR EFFECT IN HAEMOGLOBIN LEVEL - A COMPARATIVE STUDY.”**

BY

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(1st YEAR P.G. SCHOLAR)

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AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

CO-GUIDE

Dr. RAMESH N. V., M.D(Ayu)

ASSOCIATE PROFESSOR,

**DEPT. OF P.G STUDIES IN RASA SHASTRA AND
BHAISHAJYA KALPANA**

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

SESSION: 2013-2014

From

POOJA P,

Preliminary M.D (Ayu) Scholar,

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DIFFERENT BHAVANA DRAVYAS AND
THEIR EFFECT IN HAEMOGLOBIN LEVEL - A COMPARATIVE STUDY.”**

Here with I am enclosing a completed Proforma of synopsis for registration of the subject for dissertation.

Thanking you,

Place: Vallikavu

Your's faithfully,

Date:

(Dr.Pooja P)

1.BRIEF RESUME OF THE INTENDED WORK:

1. i.NEED FOR THE STUDY.

The problem of malnutrition is worldwide and it has assumed gigantic proportion in underdeveloped and developing countries and India is one among them. The percapita income in India is very low. An average individual, below poverty line, is generally deficient in essential minerals, vitamins, etc. Anemia is one of the most common disorder in clinical practice¹. It is characterized by decrease in the oxygen carrying capacity of the blood which is determined by the haemoglobin content of the erythrocytes¹. They contribute to malnutrition, diminished working capacity, pallor, slow cognitive development, etc. Along with iron deficiency anemia, at times affect other systems and even may prove fatal.

There are many medicines mentioned in other systems of medicine like iron tablets and injections. But these are having side effects on the body like nausea, diarrhoea, constipation, metallic taste etc.^[2] Ayurveda shows right path to overcome these effects and there are many drugs mentioned in Ayurveda which are very effective in increasing haemoglobin level.

Rasashastra is a science and a branch of Ayurveda dealing with metals, minerals & poisonous drugs. There are many references of usage of these metals, minerals, etc after Shodhana and/or Marana. Kasisa is mentioned in Rasa Shastra under the Uparasas and is used in the management of Pandu Roga after shodhana². It is very effective as compared to other drugs as it is fully absorbed and can expect the good results.

For the rational treatment of any disease, knowledge on the mode of action of a drug, its physico chemical analysis, its effect on various body systems and probable adverse effects is important.

The ultimate objective of drug research is its success in terms of clinical trial. Pharmacological action may vary depending on the material used for purification. Hence in this study a comparative clinical trial of Kasisa purified by different Bhavanadravyas is included. By this an assessment of better effective Bhavanadravya for increasing haemoglobin level can be established.

1.ii. REVIEW OF LITERATURE:

With respect to the above hypothesis, proper screening of the literature from classical texts of Ayurveda and Rasasastra, texts of allied sciences, related journals, periodicals and data from any other relevant sources will be made use of in this study.

1. Properties of Kasisa² will be reviewed.
2. Kasisa shodhana² will be reviewed.
3. Relevant modern literature about Haemoglobin.^{3,4}

1.ii.i. Previous research works .Some research works have been carried out on the Kasisa at various research institutions all over India are-

- 1976-Chandrashekar Pandik Lingayat : Kasisabhasma vijgyaniyam[Jamnagar]
- 1977-Sharma P C : KasisaVivechana[Udaipur]
- 1985-VijayBala:Kasisabhasmaka nirmanaevampradara par adhyamana[Patiyala]
- 1987-Jacob H T:Preparation of different samples of Kasisabhasma and their analytical study and comparative evaluation of hematinic activity.[Banglore]
- 1992-Narmata: Study of Kasisabhasma w.s.r. to its diuretic activity.[Trivandrum]
- 1993-Tomar V V S:Comparative chemical study of KasisaBhasma prepared by different BhavanaDravyas and its physiological effects on general blood picture.[Haridwar]
- 1997-Rajashri B Nargunde: A comparative Pharmaco-clinical study of SuddhaKasisachoorna and KasisaBhasma on Pandu.[Jamnagar]
- 2000-Kurle L B: Preparation and Physico-chemical evaluation of KasisaBhasma and VardhamanaPippali Kalka and their comparative clinical study on PanduRoga w.s.r.to Iron deficiency anemia.[Bellary].
- 2002-Parvez Ahamed: Determination of number of Putas in the preparation of KasisaBhasma and its standardization [Haridwar].
- 2004-Jana RajibKishore:Comparative study of SuddhaKasisa and KasisaBhasma and hematinic effect w.s.r. to Panduroga .(iron deficiency anemia)[Puri].

- 2004-Khude Archana:Pharmaco analytical and experimental hematinic study on Kasisa and Mandur[Belgaum].
- 2011-Surinder Kumar:Study of preparation of KasisaBhasma,its Physico-chemical analysis and its clinical effect on general blood picture w.s.r. to PanduRoga.[Gadag,Karnataka.]

1.iii. AIM AND OBJECTIVE OF THE STUDY.

- To conduct chemical study on Kasisa,purified with different Bhavanadravyas.
- To compare the clinical efficacy of Kasisa, purified with different Bhavanadravyas on haemoglobin level.
- To establish a safe, cost effective drug in the management of low hemoglobin level.
- To compare the clinical efficacy of purified Kasisa and plane ferrous sulphate tablets on haemoglobin level.

2. MATERIALS & METHODS:

2.1. SOURCE OF DATA:

Literature: Will be collected from Ayurvedic and modern texts updated with recent Medical journals and internet.

Drugs:Individual ingredients will be identified, validated by taking an expert opinion before subjecting them for the preparation.

Pharmaceutical source:The drug selected for the research work “SuddhaKasisa” as mentioned in classics [BrihatRasaraSundara⁵ and Rasa Ratna Samucchaya⁶]will be prepared in the pharmacy attached to Amrita School of Ayurveda.Plane ferrous sulphate tablets will be collected from authentic source.

Analytical study: The finished products will be analyzed chemically as per Ayurveda Pharmacopoeia of India^{7,8} in an approved Laboratory.

Clinical study:Patients will be selected from the OP Department of Amrita School of Ayurveda.

2.2. MATERIALS REQUIRED FOR THE STUDY:

2.2.i. METHODS OF COLLECTION OF DATA:

A. SAMPLE:

It's a comparative clinical study with pre-test and post-test design, 60 patients of either sex fulfilling the inclusion criteria will be taken for study.

B.INCLUSION CRITERIA:

- Children between 6 -15 years of age, irrespective of sex, socio-economic status.
- Patients with hemoglobin percentage 10gm/dL and below.

C. EXCLUSION CRITERIA:

- Children under any specific medication will be excluded.
- Children having any congenital deformity and prolonged illness will be excluded.
- Patients having Hb% below 5gm/dL will be excluded.
- Girls who attained menarche will be excluded.

2.2. ii.PROCEDURE AND DESIGN OF THE STUDY.

1.MATERIALS AND METHODS.

PHARMACEUTICAL PREPARATION.

Features	NimbuswarasabhavitaKasisa	BhringarajaswarasabhavithaKasisa
Classical Reference	BrihatRasarajaSundara ⁵	Rasa RatnaSamucchaya ⁶
Ingredients	1.Kasisa. 2.Nimbuswarasa.	1.Kasisa. 2.Bhringarajaswarasa.
Procedure adopted	Bhavana.	Bhavana.

ANALATYCAL STUDY OF PREPARATION.

Organoleptic Characters:

- Appearance.
- Colour.
- Touch.
- Odour.
- Taste.

Physical Analysis:

- Loss on drying.
- Total ash.
- Water soluble ash.
- Determination of acid insoluble ash.

2. GROUPING AND TREATMENT

	Features	Group -1	Group -2	Group-3
1	Number of patients.	20 patients.	20 patients.	20 patients.
2	Drug.	NimbuSwarasaBhavita Kasisa.	BhringarajaSwarasaBhavitha Kasisa.	Plane ferrous sulphate tablet.
3	Dose	> 30kg body weight -1ratti. < 30kg body weight-1/2ratti.	> 30kg body weight -1ratti. < 30kg body weight-1/2ratti.	200mg.
4	Timing.	Twice daily -1/2 an hour before food.	Twice daily -1/2 an hour before food.	Once daily after food.
5	Duration of	42 days [7weeks].	42 days [7weeks].	42 days [7weeks].

	treatment.			
6	Route of administration.	Oral.	Oral.	Oral.
7	Anupana.	Water.	Water.	Water.
8	Follow up interval.	0 th , 21st and 42 nd day.	0 th , 21st and 42 nd day.	0 th , 21st and 42 nd day.

3. ASSESSMENT CRITERIA.

Assessment will be made through subjective and objective parameters, where each of the parameters will be scored by following a standard scoring pattern. After taking written consent from the parents/guardian, individual patient data will be collected through general history taking and physical examination. Before and after treatment score details of each parameter will be recorded in a specially prepared proforma.

4. STATISTICAL METHODS.

Change in the patient condition will be analyzed after completion of the study period by subjecting the scores of individual parameter for statistical analysis using paired 't' test.

3. Does the study require any investigations or interventions to be conducted on patients or other human or animal? If so, please describe briefly:

Yes, study will be conducted on patients having hemoglobin percentage below 10gm/dL.

Investigation:

Blood -Hb%

4. Has ethical clearance been obtained from your institution in case of (3)?

Yes

LIST OF REFERENCES.

- 1.R.S.Satoskar,Nirmala N Rege, S D Bhandarkar, Pharmacology and Pharmacotherapeutics,chapter-33,Twenty SecondEdition,Popular Prakashan,Mumbai,2011,pg.no.490.
- 2.Sharma S.N., Rasa Tarangini, ShastriK.N.,chapter21/231-233, Hindi Commentary, Delhi, MotilalBanarasidas, 2004, page 564.
- 3.Nicholas.A.Boonet all, Davidson's Principles and Practice Of Medicine, Chapter 11, Eighteenth Edition, London, Churchill Livingstone Harcourt, 2000, page 741.
- 4.Harsh Mohan, Textbook of Pathology, chapter 12, Fifth Edition, New Delhi, Jaypee Brothers Medical Publishers (P)Ltd.,2005, page 364.
- 5.DattaramaChaubae,Brihat Rasa Rajasundara,Third Edition,ChaukambaOrientalia,Varanasi,2000,page-162.
- 6.AcharyaSiddhiNandanMisra,RasaRattnSamucchaya,chapter3,verse53,first edition,ChaukambaOrientalia,Varanasi2011,page70.
- 7.Ayurveda Pharmacopoeia of India, Part-2,Volume-2,The controller of publications,civil lines New Delhi,1st edition ,2008.
- 8.Parameters for Quality Assessment of Ayurvedic and Siddha drugs, Part-A, Dept.of AYUSH, CCRAS ,New Delhi(2005).

TOP

AMRITA SCHOOL OF AYURVEDA

AMRITA VISWAVIDYAPEETHAM

(University under sec.3 UGC Act 1956)

**PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION
FOR**

AYURVEDA VACHASPATI (M.D) IN RASA SHASTRA AND BHAISHAJYA KALPANA

**PHARMACO-ANALYTICAL STUDY AND IN VITRO ANTIBACTERIAL EFFECT
OF SWASANANDA GULIKA IN SELECTED RESPIRATORY PATHOGENS.**

BY

DR. REMYA.A.

Ist YEAR P.G. SCHOLAR

**DEPT. OF P.G STUDIES IN RASASHASTRA & BHAISHAJYA KALPANA
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, KOLLAM- 690525.**

GUIDE:

**DR.ABHAYA KUMAR MISHRA, M.D (Ayu.), Ph.D
ASSOCIATE PROFESSOR.**

**DEPT. OF P.G STUDIES IN RASASHASTRA & BHAISHAJYAKALPANA.
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, KOLLAM- 690525.**

CO-GUIDE:

**Dr. ARUN MOHANAN; M.D (Ayu.)
ASSISTANT PROFESSOR.**

**DEPT. OF P.G STUDIES IN RASASHASTRA & BHAISHAJYA KALPANA.
AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, KOLLAM- 690525.
SESSION: 2013-2014.**

FROM

REMYA .A,

Preliminary M.D (Ayu) Scholar,

Department of Post Graduate Studies in Rasashastra and Bhaishajya Kalpana,

Amrita School of Ayurveda, Vallikavu, Kollam- 690525.

TO

The Registrar,

Amrita Vishwa Vidyapeetham, Ettimadai Post, Coimbatore – 641105.

THROUGH

The Principal and Head of the Dept. of Rasashastra and Bhaishajya Kalpana,

Amrita School of Ayurveda, Vallikavu, Kollam- 690525.

Sub: Submission of Completed Proforma for Registration of Synopsis of Dissertation.

Respected Sir,

I request you to kindly register the below mentioned subject against my name for the submission of the dissertation to Amrita University, for partial fulfillment of M.D.(Ayurveda) in Rasashastra and Bhaishajya kalpana.

THE TITLE OF DISSERTATION:

**PHARMACO ANALYTICAL STUDY AND IN VITRO ANTIBACTERIAL EFFECT
OF SWASANANDA GULIKA IN SELECTED RESPIRATORY PATHOGENS.**

Herewith I am enclosing a completed Proforma of synopsis for registration of subject for Dissertation.

Thanking you,

Yours faithfully,

Place: Vallikavu,

Date:

REMYA .A.

1.BRIEF RESUME OF THE INTENDED WORK:

1.i. NEED FOR THE STUDY:

According to the great Ayurveda Acharyas while describing the causes of extrinsic diseases, have considered “Bhoota” as a principal cause. The classical definition of diseases caused by microbes, infecting agents, toxins, wind, fire, injuries, mental effect etc. comes under extrinsic diseases. As per contemporary sciences this “Bhoota” can be taken as microorganisms causing infectious diseases¹.

Across the globe respiratory tract infections continue to be one of the most common causes of morbidity and mortality. Antibiotics which are presently using for infectious diseases are rapidly getting exhausted and day by day most of them are found to be resistant against lots of strains of bacteriae. Some of the rasaoushadhis are found to be effective in respiratory tract infections without side effects, if given in proper dose and conditions.

Swasananda gulika is mentioned in Arogya Raksha Kalpadruma 6th chapter, as remedy for kasa, swasa and hikka². No scientific study have been conducted yet about the antibacterial potential of Swasananda gulika. An effort is to be made to study the effect of **Swasananda gulika** against the bacteriae causing respiratory infections, like *Staphylococcus aureus*, *Klebsiella pneumonia* and *Streptococcus pneumonia*.³

1.ii. REVIEW OF LITERATURE:

Proper screening of the literature from classical texts of Ayurveda, related journals and data from any other relevant sources will be made use for the purpose of this study.

A) Drug review:

Swasananda gulika is mentioned in Arogya Raksha Kalpadruma 6th chapter, as remedy for kasa, swasa and hikka .The formulation Swasananda gulika consists of Hingula, Vatsanabha, Karpura and bhavana dravya is Triphala kashaya.The drug is considered to be effective in the treatment of respiratory infections.

B) Pharmaceutical review:

The method of preparation is as mentioned by Arogya Raksha Kalpadruma. Fine powder of sodhita Hingula, sodhita Vatsanabha⁴ and karpura each of equal quantity is made, triturated with triphala kashaya and tablets are made.

Previous research works:

1. 2007, Dr. Deepthi Desai- “ Preparation and Physico-chemical Analysis of Patra Haratala Bhasma and its Antimicrobial activity “ , Rajiv Gandhi University Of Health Sciences, Karnataka.
2. 2012, Dr. Yumnam Dhanesori Devi- “ Pharmaceutico-Analytical and Antifungal Study on Gandhaka Rasayana “ , Rajiv Gandhi University of Health Sciences, Karnataka.
3. 2012-2013, Dr. Rashin Chandrasekharan- “A Clinical Evaluation of Kanakasava and Swasananda Gulika in Tamaka Swasa w.s.r. to Bronchial Asthma” ,Rajiv Gandhi University Of Health Sciences, Karnataka.

1.iii. AIM AND OBJECTIVE OF THE STUDY:

- To evaluate the Physico-Chemical analysis of Swasananda gulika.
- To evaluate the Antibacterial effect of Swasananda gulika in respiratory infections caused by **Staphylococcus aureus, Klebsiella pneumonia and Streptococcus pneumonia**.

2. MATERIALS & METHODS:

A) Pharmaceutical study:

Pharmaceutical processing of the drug according to Arogya Raksha kalpadruma.

B) Analytical study:

Physico-chemical analysis will be carried out as per Ayurvedic Pharmacopoeia of India⁵ and Parameters for Quality Assessment of Ayurveda and Siddha Drugs by C.C.R.A.S⁶.

C) Antibacterial Study:

- Sample will be tested for antibacterial activity against standard strains of **Staphylococcus aureus, Klebsiella pneumonia and Streptococcus pneumonia**.

- Culture medium: -As per the organisms.
- Solvents :- As per sample.
- Method :-Disc diffusion method.

2.1. SOURCE OF DATA:

Pharmaceutical source:

The drug sample will be collected from authentic and reliable sources and will be prepared in the Department of Rasasastra and Bhaishajya kalpana, Amrita School of Ayurveda, Kollam.

Analytical source:

The finished products will be analyzed Physico-chemically in approved lab.

2.2. MATERIALS REQUIRED FOR THE STUDY:

METHOD OF COLLECTION OF DATA:

A.SAMPLE:

Total 30 samples.5 samples each of aqueous extract and alcoholic extract of Swasananda Gulika is taken and these 10 samples are cultured in 3 pathogens, **Staphylococcus aureus**, **Klebsiella pneumonia** and **Streptococcus pneumonia**.

B.INCLUSION CRITERIA:

Stock culture of selected standard bacterial strains causing respiratory tract infections.

C.EXCLUSION CRITERIA:

Excluding the pathogens, other than **Staphylococcus aureus**, **Klebsiella pneumonia** and **Streptococcus pneumonia**.

2.2.ii. PROCEDURE AND DESIGN OF THE STUDY:

1. MATERIALS AND METHODS:

PHARMACEUTICAL PREPARATION:

Classical Reference	Arogya Raksha Kalpadruma
Ingredients	Sodhita Hingula, Sodhita Vatsanabha & Karpura each 1part.

Quantity	500 tablets.
Procedure adopted	All the ingredients will be triturated with Triphala kwatha, and tablets will be made.

ANALYTICAL STUDY OF THE PREPARATION:

Physico-chemical analysis:-

- Uniformity of the tablet (wt. variation).
- Tablet Disintegration Time.
- Tablet hardness.
- Loss on drying (Moisture content).
- Total Ash.
- Acid insoluble Ash.
- Water soluble extractives.
- Alcohol soluble extractives.
- Petroleum Ether soluble extractives.
- pH value.

2. DESIGN OF THE STUDY:

Antibacterial study of Swasananda gulika against selected respiratory pathogens.

Antibacterial activity using Disc diffusion method:

- **The agar diffusion test or “Kirby-Bauer disc diffusion method”** ^{7,8} is a mean of measuring the effect of an antibacterial agent against bacteria grown in culture.
- The bacteria is swabbed uniformly across a culture plate.
- A filter paper disc impregnated with the compound to be tested is then placed on the surface of the agar.

- The compound diffuses from the filter paper into the agar medium, killing some of the disease agents where the antibacterial agent is inoculated, depending on how susceptible the disease agent is to the antibacterial agent.
- The concentration of the compound will be highest next to the disc & will decrease as distance from the disc increases.
- If the compound is effective against bacteria at a certain concentration, no colonies will grow where the concentration in the agar is greater than or equal to the effective concentration. This is the zone of inhibition.
- Thus the size of the zone of inhibition is a measure of the compound's effectiveness.
- The larger the clear area around the filter disc, more effective will be the compound.

3. ASSESSMENT CRITERIA:

The assessment of antibacterial activity will be done according to microbiological parameters and the result will be analyzed.

4. STATISTICAL METHODS:

The Statistical analysis will be done by Student 't' test.

3) Does the study require any investigations or interventions to be conducted on patients or other human or animal? If so, please describe briefly:

Not applicable.

4) Has ethical clearance been obtained from your institution in case (3)?

Not applicable.

5) LIST OF REFERENCES:

1. Dr. Sreekantha Murthy, Vagbhata's Ashtanga Hridayam, Pub: Chaukambha Krishnadas academy, Varanasi, Edition 2008.

2. Dr.Lal Krishnan, Arogya Raksha Kalpadrumah, Chaukamba publications, Varanasi, 1st Edition, 2006.
3. Harsh Mohan, Text Book of Pathology, Jaypee Brothers Medical Publishers, New Delhi, 5th Edition, 2005.
4. Pandit Kashinath Shastri, Rasa Tarangini, Motilal banarasidas, Varanasi, 2004.
5. The Ayurvedic Pharmacopoeia of India ,Part II, Volume II, The controller of Publications, Civil Lines, New Delhi, 1st Edition, 2008.
6. Parameters for Quality Assessment of Ayurveda and Siddha Drugs, Part A, C.C.R.A.S, Dept. of AYUSH, New Delhi, 2005.
7. P.C.Trivedi, Text Book Of Microbiology, Aavishkar Publisher Distributors, 1st Edition, 2010.
8. Willey Sherwood & Woolverton, Prestott , Harley & Klein's Microbiology, Mc Graw Hill Medical Publishers, 7th Edition.

TOP

AMRITA SCHOOL OF AYURVEDA

AMRITA VISWAVIDYAPEETHAM

(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

FOR

**AYURVEDA VACHASPATI M.D(AYU) IN RASA SHASTRA AND BHAISHAJYA
KALPANA**

**“ COMPARATIVE PHYSICO - CHEMICAL ANALYSIS OF
KSHEERABALA TAILA W.S.R TO AVARTANA (FORTIFICATION)”**

BY

Dr. PRAJEESH NATH E N.

(Ist YEAR P.G. SCHOLAR)

DEPT. OF P.G STUDIES IN RASA SHASTRA & BHAISHAJYA KALPANA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

GUIDE

Dr. RAMESH N. V. MD(Ayu)

ASSOCIATE PROFESSOR,

DEPT. OF P.G STUDIES IN RASA SHASTRA AND BHAISHAJYA KALPANA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

CO-GUIDE

Dr. ARUN MOHANAN. MD(Ayu)

ASSISTANT PROFESSOR,

DEPT. OF P.G STUDIES IN RASA SHASTRA AND BHAISHAJYA KALPANA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

SESSION: 2013-2014

FROM

PRAJEESH NATH E N,

Preliminary M.D (Ayu) Scholar,

Department of Post Graduate Studies in Rasashastra and Bhaishajya Kalpana,

Amrita School of Ayurveda,

Vallikavu, Kollam- 690525.

TO

The Registrar,

Amrita Vishwa Vidyapeetham,

Ettimadai Post, Coimbatore - 641105.

THROUGH

The Principal and Head of the Dept. of Rasashastra and Bhaishajya Kalpana,

Amrita School of Ayurveda,

Vallikavu, Kollam - 690525.

Sub: Submission of Completed Proforma for Registration of Synopsis of Dissertation

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THE TITLE OF DISSERTATION:

**“ COMPARATIVE PHYSICO - CHEMICAL ANALYSIS OF KSHEERABALA TAILA
W.S.R TO AVARTANA (FORTIFICATION)”**

Herewith I am enclosing a completed Performa of synopsis for registration of subject for Dissertation.

Thanking you,

Yours faithfully,

Place: Vallikavu

Date:

(Prajeesh Nath E N)

1. BRIEF RESUME OF THE INTENDED WORK:

1.1. NEED FOR THE STUDY:

Sneha kalpana⁽¹⁾ is a formulation which can be administered both internally and externally such as *pana*, *abhyanga*, *nasya*, *basti* etc. *Ksheerabala Taila*⁽²⁾ is one of the most popular oil preparation in Ayurveda and recognized as a very effective remedy for *Vatarogas*. The name *Ksheerabala taila* is mentioned in Sahasra Yoga, an authentic Ayurvedic formulary of Kerala. The similar preparation has been mentioned by almost all ancient Ayurvedic texts but with different names. Charaka mentioned as *Shatasahasra Pakabala Taila*, Sushruta mentioned as *Shatapakabala taila* and Ashtanga hridaya mentioned as *Shatapaka-sahasrapakabala Taila*.

In this modern era, people expect quicker relief from ailments. To meet this expectation we should have highly potent formulations. By doing *Avaratana*(repeated processing) of *Ksheerabala Taila*⁽³⁾, It helps the physicians to minimize the dose and easy to administer.

The current work will be an effort to study the changes that occurs in avartana of Ksheerabala taila.

2.2. REVIEW OF LITERATURE:

Review of Literature includes thorough screening of classical literature regarding the drug and the pharmaceutical preparation.

A. Drug review:

Drug review of the ingredients used in the preparation of the *Ksheerabala Taila* and its *Avartana*.

The various ingredients of *Ksheerabala taila* are listed here under:

Sl.No	Name of the drug	Botanical name	Family	Parts used
1	<i>Bala</i> ⁽⁴⁾	<i>Sida cordifolia Linn.</i>	MALVACEAE	Root
2	<i>Ksheera</i>	Cow's Milk		
3	<i>Taila</i>	TilaTaila		

B. Method of preparation of the *Ksheerabala Taila*

The pharmaceutical process involved in this study are *Taila kalpana* and its *Avartana*; referred from the classic Ayurvedic texts like Ashantanga Hridaya, Charaka Samhita and Sarangadhara Samhita. *Ksheerabala taila* and its *Avartana* is explained in *Pharmacopoeia*(Government Ayurveda college, Thiruvananthapuram).

The *Ksheerabala taila* is prepared by taking all ingredients in proper proportion for *sneha paka*. Then it is boiled till it attains *Sneha paka lakshanas*⁽⁵⁾ and its *Avartana* is done for 21 times.

Previous research works illustrating the preparation of *Ksheerabala taila* and *Avartana* are as follows:

- A comparative pharmaco-chemical study of 1-7-50 *Avartita Ksheera Bala Taila* prepared by *Atibala* (*Abutilon indicum Linn*) and their clinical efficacy in the management of *Sandhigata vata* by Dr.Krishnamurthy. M.S-Jamnagar, 2002.
- Comparative pharmaceutico-analytical study of *sahacharadi taila* with its 7 and 14 *avarti* by Dr.Rohitkrishna G. B, Bangalore, 2012.

1.3. AIM AND OBJECTIVE OF THE STUDY:

- Analytical study of all the ingredients will be done.
- The product will be chemically analysed at 1st, 7th, 14th, and 21st processing.

- The results will be compiled and compared for the expected changes in advance processing and product.

2. MATERIALS & METHODS:

2.1. SOURCE OF DATA:

Literary source:

All the relevant classical texts, modern text books, recent medical journals and internet sources will be used.

Pharmaceutical source:

- Collection of the raw drugs from Wayanad after looking its grahyalakshana as explained in texts.
- Raw drugs will be identified, validated by taking an expert opinion before subjecting them for preparation.
- *Ksheerabala taila* and its 21 *Avartana* will be prepared as per classical text and traditional practices and it will be prepared in the PG Department Laboratory of Rasa Sashttra and Bhaishajya Kalpana, Amrita School of Ayurveda.

2.2. MATERIALS REQUIRED FOR THE STUDY:

2.2.i. METHODS OF COLLECTION OF DATA:

Sample

- 20 samples of Ksheerabala taila(5 samples each of 1st , 7th , 14th , and 21st avartana)

2.2.ii. DESIGN OF THE STUDY:

Pharmaceutical study

- Snehasidhi lakshnas mentioned in the texts and organoleptic characters of each avartana of Ksheerabala taila will be studied.

Analytical study

The following analytical study will be done at 1st, 7th, 14th, and 21st avartana of Ksheerabala taila.

- Specific gravity
- Viscosity
- Refractive Index
- pH
- Loss on drying at 110⁰C
- Acid value
- Iodine value
- Peroxide value
- Ash value
- Saponification value
- Unsaponifiable matter
- TLC

Statistical Methods

- Results will be analysed statistically by Student 't' Test.

3. Does the study requires any investigations or interventions to be conducted on patients or other human or animal? If so, please describe briefly:

Experimental and clinical trials will not be carried out.

4. Has ethical clearance been obtained from your institution in case (3)?

Not Applicable

5. LIST OF REFERENCES:

1. Acharya Sharangadhara, Sharangadhara Samhita, Published by Chowkhamba Orientalia Varanasi, printed by Chowkhamba press Varanasi, Edition 2007, Chapter No:9, Page No:212-213.
2. Acharya Vagbhata, Ashtangahrdayam, Published by Krishnadas Academy Varanasi, Printed by Chowkhamba press, Varanasi, Cikitsita Sthana, Chapter No: 22, Sloka No:45-45, Page No:732.
3. Pharmacopoeia, Trivandrum Government Ayurvedic College, 1996, Page No:178
4. Sastry J.L.N, DravyagunaVijnana, Chaukamba publications 2005, Page No.87.
5. Acharya Sharangadhara, Sharangadhara Samhita, Published by Chowkhamba Orientalia Varanasi, printed by Chowkhamba press Varanasi, Edition 2007, Chapter No:9, Page No:212-213

TOP

AMRITA SCHOOL OF AYURVEDA

AMRITA VISWAVIDYAPEETHAM

(University under sec.3 UGC Act 1956)

PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

FOR

AYURVEDA VACHASPATI [M.D] IN RASA SHASTRA

AND BHAISHAJYA KALPANA

**“A PHARMACEUTICO-ANALYTICAL STUDY OF PRAVALA PISHTI AND ITS
CLINICAL EFFICACY ON HYPOCALCAEMIA IN MENOPAUSAL WOMEN.”**

BY

PRIYA RAGHUNATHAN

(1st YEAR P.G. SCHOLAR)

DEPT. OF P.G STUDIES IN RASA SHASTRA AND

BHAISHAJYA KALPANA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

GUIDE

DR.K.UNNIKRISHNA PILLAI, M.D (Ayu.), Ph.D

PROFESSOR AND H.O.D.

DEPT. OF P.G STUDIES IN RASA SHASTRA AND

BHAISHAJYA KALPANA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

CO-GUIDE

DR. ABHAYA KUMAR MISHRA., M.D (Ayu),Ph.D

ASSOCIATE PROFESSOR,

DEPT. OF P.G STUDIES IN RASA SHASTRA AND

BHAISHAJYA KALPANA

AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA POST, KOLLAM

SESSION: 2013-2014

FROM

PRIYA RAGHUNATHAN

Preliminary M.D (Ayu) Scholar,

Department of Post Graduate Studies in Rasashastra and Bhaishajya Kalpana,

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**“A PHARMACEUTICO-ANALYTICAL STUDY OF PRAVALA PISHTI AND ITS
CLINICAL EFFICACY ON HYPOCALCAEMIA IN MENOPAUSAL WOMEN.”**

Herewith I am enclosing a completed Proforma of synopsis for registration of subject for Dissertation.

Thanking you,

Yours faithfully,

Place: Vallikavu

Date:

(Priya Raghunathan)

1. BRIEF RESUME OF THE INTENDED WORK:

1.1. NEED FOR THE STUDY

The Rasashastra is a unique branch of Ayurveda which includes metals, minerals and gems¹. Praval comes under Ratna varga. Its chemical name is Calcium carbonate (CaCO_3) and has origin from the sea animal Anthozoan polyps². Due to predominance of commercial attitude of some manufacturers, in the brand name of standard medicine, adulterated and spurious medicines are also used. Here Praval is chosen which is very commonly used in practice. But facing lack of credibility in terms of final product. It is not sure that the Praval Pishti are made by an acceptable form of Praval. So, it is decided to work on standard parameters of pharmaceutical processing of Praval Pishti, supported by its analytical study.

Calcium is one of the most essential mineral of body and almost 99% of the calcium is stored in the bones³.

In women, normal values of estrogen help the bones to absorb calcium to impart strength to the body³. Following menopause, there is loss of bone mass by about 3-5% per year, due to deficiency of estrogen³. Long term effects of estrogen lack are Osteoporosis and Artherosclerosis⁴. According to Sushruta, 50 years is mentioned as the Rajonivritti kala⁵.

This study has been undertaken in order to find out an effective medicament without creating any adverse effect for the management of hypocalcaemia in menopausal women.

1.2. REVIEW OF LITERATURE:

Review of Literature includes literature regarding the pharmaceutical preparation of drug and disease; so it will be dealt under two headings:

A. Pharmaceutical review:

- Method of shodhana of Praval as explained in the classical text⁶.
- Method of preparation of Praval pishti from an authentic text⁷.

B. Disease review

- Review of the disease Hypocalcaemia in Menopausal women³.

Previous research works.

Some research works have been carried out on Pravala at various research institutions all over India which are-

- 1981 – Dr. Gupta B.M. : A study of Pravala. [Jamnagar]
- 1983 – Dr. Lakshmi.P. : Comparative study of Pravala pishti and Bhasma. [Trivendrum]
- 1988 – Dr. Khandelwal. N.K.: Pravala pishti ka nirmanatmaka evam Prabhavatmaka adhyayan. [Jaipur]
- 1989 - Dr. Joshi Chetana. : Pravala pishti evam Bhasma ka Amlapitta mein tulanatmaka adhyayana.[Jamnagar]
- 1997 – Dr. Bakhare Sunil E: Manufacture of Pravala pishti and Pravala Bhasma according to Ayurveda text, comparative study of its use with chemical analysis. [Pune Tilak Ayurveda college]
- 2003 – Dr. Bhatt Apoorva M.: A comparative Pharmaceutico-clinical study of Praval pishti and Pravala Bhasma w.s.r to management of Hyperacidity. [Jamnagar].

1.3. AIM AND OBJECTIVE OF THE STUDY.

- To establish a standard operative procedure for preparation of Pravala Pishti.
- To analyze sample of raw material, in-process material and end products by employing physical and chemical parameters. .
- To clinically evaluate the effect of Pravala Pishti on hypocalcaemia in Menopausal women.

2. MATERIALS & METHODS

2.1. SOURCE OF DATA:

Literary source:

Literary source will be collected from Ayurvedic classical text books, modern texts, and relevant research literatures.

Pharmaceutical source

Basic raw material will be collected from the market looking at the grahya-agrahya lakshana as explained in the classical texts⁸ and will be prepared in the pharmacy attached to Amrita school of Ayurveda, Vallikavu, Kollam.

Analytical source:

Basic analytical studies as per “Ayurvedic Pharmacopoeia of India”⁹ and “The Parameters for Quality Assessment of Ayurveda and Siddha Drugs by CCRAS”¹⁰ will be carried out in an approved laboratory.

2.2. MATERIALS REQUIRED FOR THE STUDY:

2.2 (i) METHODS OF COLLECTION OF DATA:

A. SAMPLE: 40 patients fulfilling the inclusion criteria will be selected for the study.

B. INCLUSION CRITERIA:

- Females of age above 50 years who have attained menopause.
- Patients having serum calcium level less than 8.5 mg/dl on examination.

C. EXCLUSION CRITERIA:

- Patients with evidence of malignancy.
- Patients with serum calcium level more than 8.5 mg/dl.
- Patients suffering from other severe systemic diseases.

2.2. (ii). PROCEDURE AND DESIGN OF THE STUDY:

1) MATERIALS AND METHODS.

PHARMACEUTICAL PREPARATION.

Features	Gulab Arka	Pravala pishti
Ingredients	Rose petals, water. (1:10)	Shuddha Pravala,
Bhavana		Gulab arka
Number of days	2 days	2-3 days
Procedure adopted	Distillation process	Trituration process

2) DESIGN OF THE STUDY:

I. Pharmaceutical study:

- Pravala shodhana will be according to the procedure given in “Rasa tarangini”.
- Pravala pishti nirmana will be according to the procedure given in “The Ayurvedic Formulary of India (Ayurveda sara samgraha page 119)”.
- Preparation of Gulab arka will be according to procedure given in “Arka Prakash”.

II. Analytical study:

- Organoleptic analysis
 - a) Colour
 - b) Taste
 - c) Odour
 - d) Appearance
- Physical tests
 - a) pH
 - b) Loss on drying
 - c) Ash content
 - d) Acid insoluble ash content
- Chemical tests
 - a) Qualitative analysis – Calcium and other components.
 - b) Quantitative analysis --Estimation of total quantity of Calcium in the sample.

III. Clinical study:

- 40 female patients fulfilling the inclusion criteria will be selected from the Hospital attached to Amrita school of Ayurveda.

3) GROUPING AND TREATMENT/PROCEDURE :

- 2 groups will be taken - a trial group and a standard group.

S.no	Features	Trial group	Standard group
1.	Number of patients	20	20
2.	Drug	Pravala pishti	Shelcal
3.	Dose	Capsule of 250 mg.	Capsule of 500 mg.
4.	Timing	Twice daily ½ an hour before food.	Once daily after food.
5.	Duration of treatment	3 months	3 months
6.	Route of administration	Oral	Oral
7.	Anupana	Dugdha	Water
7.	Follow up interval.	Monthly	Monthly

4) ASSESSMENT CRITERIA.

Normal range for serum calcium level in blood is in between 8.5-10.5 mg/dl¹¹.

Assessment will be carried out through subjective and objective parameters, where each of the parameters will be scored by following a standard scoring pattern. After taking written consent from the patients, individual patient data will be collected through general history taking and physical examination. Score details of each parameter will be recorded after 30 days, 60 days and 90 days of the treatment in a specially prepared proforma.

5) STATISTICAL METHODS.

- Statistical methods will be carried out by paired 't' test¹².

3. Does the study require any investigations or interventions to be conducted on patients or other human or animal? If so, please describe briefly:

- Yes.
- The Pravala Pishti will be administered orally to 20 patients and Shelcal as a standard group will be administered orally to another group of 20 patients suffering from hypocalcaemia in Menopausal stage. Duration of treatment will be 3 months. Assessment will be carried out according to the serum calcium level recorded after 30 days, 60 days and 90 days of the treatment.

4. Has ethical clearance been obtained from your institution in case (3)?

- Yes

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