

**AMRITA SCHOOL OF AYURVEDA**  
**DEPARTMENT OF POST GRADUATE STUDIES**  
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**Department of KAYACHIKITSA**

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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) KAYACHIKITSA

**OPEN LABEL SINGLE ARM CLINICAL STUDY TO ASSESS THE EFFICACY OF  
RAJANNYADI CHOORNA & VYAGHRADI KASHAYA IN TAMAKA SWASA  
(BRONCHIAL ASTHMA)**

BY

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AMRITA SCHOOL OF AYURVEDA,  
VALLIKAVU, CLAPPANA P.O. KOLLAM

GUIDE

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AMRITA SCHOOL OF AYURVEDA

SESSION 2013-14

## **1. BRIEF RESUME OF THE INTENDED WORK:**

### **I .NEED FOR THE STUDY:**

Tamaka swasa is a disease which have been elaborately mentioned by Acharyas in Ayurveda classics . <sup>3/1</sup>swasa krichrata (difficulty in breathing) peenasa (coryza) , kasa (cough) , kapha nishteeva (expectoration) , ghurghuratvam (wheezing) , krichra bhashana (difficulty in speaking) , assene labdhe sukham (feel comfort in sitting) , lalata sweda (perspiration on fore head),sleshmakala vardhana (attacks in morning & evening) are the symptoms seen .Disease characterized by obstruction of prana vata by kapha leading to further vitiation of vata resulting in upward movement or vimarga gamana of vata resulting in difficulty in breathing and associated symptoms.

This disease have similarity in clinical presentation with Bronchial Asthma characterized by intermittent airflow obstruction , airway inflammation and bronchial hyper responsiveness and the disease manifests with difficulty in breathing ,cough ,wheezing tightness of chest. Irrespective of age & gender it affects all categories of people and is seem to cause serious impairment in the quality of life of the patients.

The World Health <sup>13</sup> organization estimated in 1998 that Asthma affect 155 million people world wide ,based on the data collected in epidemiological studies in more than 80 countries . Asthma rates has sharply increased significantly in recent decade which is increasing 50% every decade world wide .Deaths from this condition have reached over 180,000 annually.It is estimated that the disease affects 5 to 10 % of population.

Human & economic burden associated with this condition is severe.Symptoms interfere with sleep, work activities & psychological disturbances like anxiety,mood disorders e.t.c. Studies show that early & prolonged use of corticosteroids reduce lung function & may increase the frequency of attacks , may lead to other complications .High cost of the medicines make it s availability difficult to poor classes of people.

In the context of explaining treatment modalities in Tamaka swasa , Acharya after mentioning sodhana & samana therapies , finally emphasizes more

on the importance of samana & brimhana therapies in swasa .When sodhana (purgation & emesis) and samana therapies are taken , sodhana even if considered superior to samana can be done only when dosa vitiation is more, need hospitalization and can be done only in persons of good body strength . Samana can be done in all age groups and even in patients of moderate and less body strength ,can be done in O.P. basis also . Here arises the need of an effective Polyherbal combination which can alleviate kapha and vata dosas , having agni deepana , srotho sodhana , anulomana properties and which can actively interfere in the disease pathology , which can be accessible to all sections of people.

<sup>2/3,4</sup>Vyaghradi kashaya have vata –kapha samana property , Rajanyadi choorna have vata anulomana and agni deepana property . Evaluation of pharmacological properties of ingredients of the combination reveals that Rajani , Daru , Sarala , Prisniparni , Satahva have anti-inflammatory property . Kantakari and Sarala have antiseptic property . Satahva have anti-spasmodic property . Prisniparni and kantakari are expectorants . Haridra and Pippali have immuno-modulatory action. Because of all these properties the selected combination is supposed to be effective in disrupting the etio -pathogenesis of Tamaka Swasa.

Therefore we decided to make a humble attempt to evaluate the efficacy of the compound in Tamaka swasa,so that if found effective serve useful to the society.

## II. REVIEW OF LITERATURE:

1. Charaka samhita chikitsa sthana <sup>3/1,2</sup> both pratamaka and santamaka swasa are mentioned . Even if acharya mentions sodhana , brmhana (nourishing) or samana (alleviating) is considered more relevant in swasa.
2. Susruta samhitha uttaratantra <sup>4</sup> only pratamaka type has been mentioned. Sodhana for strong patients and samana therapies have been mentioned.
3. Astanga Hridaya Nidanasthana & Chikitsa sthana <sup>2/1,2</sup> Pratamaka & santhamaka swasa are mentioned with their treatment modalities.
4. Madhavanidana <sup>11</sup> mentions tamaka swasa as which persists throughout the patient's life even after suitable treatments.

5. Bhavaprakasha<sup>13</sup> mentioned only pratamaka type of tamaka swasa, abhyanga, sweda and samana treatments are mentioned.
6. Yogaratnakara<sup>12</sup> mentions tamakaswasa as caused by kapha dosa only, various samana and sodhana therapies had been mentioned.
7. Sharangdhara Samhita Madhyama Khanda<sup>9&10</sup> mentions about swasa, in madhyama khanda various preparations which can be used in swasa are mentioned, but specific mentioning tamaka swasa is not found.
8. Kumar & Clark's Text book of Medicine<sup>7</sup> explained Bronchial Asthma as a common inflammatory condition of the Lung airways represented with symptoms cough, wheeze, chest tightness and shortness of breath often at night.
9. Fishmann's Text book of Chest Diseases<sup>15</sup> explains Bronchial Asthma as intermittent airflow obstruction, airway inflammation and airway hyper-responsiveness.

### **The Review of previous works on Tamakaswasa**

1. A Clinical evaluation of Kanakasava & Swasanandam gulika in Tamaka Swasa w.s.r. to Bronchial Asthma, by Dr. Rashin Chandrasekharan-2012-13, Muniyal Institute of Ayurvedic Medical Science, Manipal, Uduppi, Karnataka.<sup>5</sup>
2. A study of tamaka swasa w.s.r. to kasamarda. Swapna.K.S. - 1999- Government Ayurvedic College Kerala University Thiruvananthapuram.<sup>4</sup>
3. A clinical study of management of tamaka swasa w.s.r. to virechana & samana. Sujatha.Tenginakai.- 2001- A.L.N. Rao Ayurvedic Medical College-Koppa.<sup>5</sup>
4. Randomized controlled trial to assess the efficacy of Aya-Patra Pralipita Pippali Rasayana in Bronchial Asthma, Dr. Seeba -2003, Government Ayurveda College Trivandrum, Kerala.<sup>4</sup>
5. Management of Tamaka swasa with Vyaghri Choorna w.s.r. to Bronchial Asthma, Mahanteshwarayya 2007, A.L.N. Rao Memorial Ayurvedic Medical College and PG Centre, Koppa, Karnataka.<sup>5</sup>
6. Clinical efficacy of the herbal Padmapathradi yoga in Bronchial asthma (Tamaka swasa) by Panda A.K.-2011 P.G. Department of Kaya Chikitsa, D.G.M Ayurveda Medical College, Gadag, Karnataka<sup>11</sup>

7.Clinical evaluation of Amritadi kwatha along with pranayama in the management of Tamaka swasa w.r.t.Bronchial Asthma .5 th World Ayurveda Congress 2012, Bhopal .M.P.<sup>5</sup>

8.Effect of Agasthya Rasayana and Kushmanda Rasayana in Tamaka swasa-A clinical comparative study w.s.r.to Bronchial Asthma 2012 , Clement Jose , Alva” Ayurveda Medical College , Moodbidri , Karnataka.<sup>5</sup>

9.A study on the concept of vatanulomana in the treatment of pranavaha srotho dushti vikara w.s.r. to Gudabhaya prayoga in Tamaka swasa,Dr.Sivajothy-2012,S.D.M.College of Ayurveda,Hassan,Karnataka.<sup>5</sup>

10.A comparative clinical study on the effect of Vyaghradi Kashayam and Pippalyadi Choornam on Tamaka swasa w.s.r.to Bronchial Asthma,Unnikrishnan 2013,A.L.N.Rao Memorial Ayurvedic Medical College and PG centre ,Koppa,Karnataka.<sup>5</sup>

Review of previous works reveals the efforts done to find a better remedy in the management of Tamaka swasa. it is found that so many works had been conducted in Tamaka swasa . In the search of a better remedy the polyherbal combination of Rajannyadi Choorna and Vyaghradi Kashaya has been selected based on the pharmacological properties of the ingredients to evaluate the combined effect.

### **III.AIM AND OBJECTIVE OF THE STUDY:**

To clinically evaluate the efficacy of Rajannyadi Choorna & Vyaghradi Kashaya in mild to moderate condition of Tamaka swasa.

### **2.MATERIALS AND METHODS**

## **1.SOURCE OF DATA:**

30 Patients will be selected from O.P.D. and I.P.D.of Amrita Ayurvedic Hospital having classical signs & symptoms of Tamaka Swasa from mild to moderate will be selected . Detailed history taking will be done using a pre-designed case proforma.

## **MATERIALS REQUIRED FOR THE STUDY**

### **i . METHOD OF COLLECTION OF DATA:**

#### **1)SAMPLE:**

Consisting of 30 patients diagnosed as Tamaka swasa from OPD & IPD of Amrita Ayurveda Hospital ,Vallikkavu.

#### **2 ) INCLUSION CRITERIA:**

1. Patients having classical signs and symptoms of Tamakaswasa & Bronchial Asthma of mild to moderate nature.
- 2.Age group between 18 to 60years.
- 3.Patients having 75% of the history of following signs & symptoms:-
  1. Swasa krichrata (Breathing difficulty )
  2. Ghurghuratvam (Wheezing )
  3. Kasa (Cough )
  4. Urah peeda (Chest tightness )
  5. Inspiration and prolonged expiration with added sounds a
  6. Use of broncho dilators

#### **3 ) EXCLUSION CRITERIA:**

- 1.Tamakaswasa associated with other systemic diseases.
- 2.Age group below 16 years & above 60 years.
- 3.Severe bronchial asthma cases , Pulmonary Tuberculosis
- 4.Lung carcinoma & Pneumonia.
- 5.Pregnant Women & lactating mothers.

6. Patients with Other Lung pathologies.

## ii .PROCEDURE AND DESIGN OF THE STUDY:

### MATERIALS AND METHODS:

#### Ingredients:

##### Rajannyadi Choorna

Rajani

Daru

Sarala

Sreyasi

Brihathi

Kantakari

Prisniparni

Satahva

##### Vyaghradi Kashaya

Vyaghri

Sunti

Amrita

**Prakshepa Curna**

Pippali

#### Preparation of Medicine

Drugs will be identified and collected as per classical reference in the Pharmacy of Amrita School of Ayurveda.

Rajannyadi Curna :

Ingredients of Rajannyadi Churna mentioned in the above table will be taken in equal quantity and grounded in to fine powder.

Vyaghradi Kashaya:

Ingredients of Kashaya curna as mentioned in the table will be taken in equal quantity will be mixed with 8 times of water <sup>2/5</sup> boiled and reduced to 1/4<sup>th</sup>. Pippali will be added as prakhepa curna.

#### 2.Design Of The Study:

It will be a single group clinical study with pre-test and post-test design.



30 patients will be selected based on inclusion & exclusion criteria from OPD & IPD of Amrita Ayurveda Hospital . Pre- test according to subjective & objective parameters are done.

Rajannyadi Choorna 4gm will be advised to take thrice daily<sup>10</sup> just before food (morning & lunch )along with kashaya. Kashaya 32 ml are advised to take three times daily<sup>9</sup> (6am, 11am & 6pm ) . Patients are advised to take consultation once in a week for 30 days and to take follow up thereafter.

### **3.Assessment Criteria:**

#### **a)Subjective Parameters:**

Grading as mild , moderate & severe was done considering cardinal symptoms of tamaka swasa like

- 1.Swasa krichrata (difficulty in breathing)
- 2.Ghurghura dwani (wheezing )
- 3.Kasa (cough)
- 4.Kapha nishteevana (expectoration of sputum)
- 5.Urah Peeda (Chest Tightness)

#### **b)Objective Parameters:**

- 1.Peak Expiratory Flow Rate(PEFR)
- 2.Breath Holding Time(BHT)
- 3.Absolute eosinophil count(AEC)

### **4.Investigations :**

- 1.Total Blood Count (TC)
- 2.Erythrocyte Sedimentation Rate (ESR)
- 3.Hb%

Peak Expiratory Flow Rate(PEFR) , Breath holding time(BTH) , Absolute Eosinophil Count will be measured at the beginning and at the end of the treatment.

A standard multi dimensional scoring will be adopted for assessment .

### **5 ) Statistical Methods:**

Patients selected will be assessed subjectively & objectively before & after treatment and follow up will be recorded and analysed by using appropriate statistical methods and final conclusion will be drawn.

### **Intervention:**

- 1.The patients will be assessed before & after the treatment as per assessment criteria.
- 2.The nature of the study will be explained to the patients in detail and pre treatment consent will be taken.
- 3.The confidentiality of the data will be maintained.

### **2. LIST OF REFERENCES:**

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  - 2)ChikitsaSthana Chapter 4 Sloka No:2-6
  - 3)ChikitsaSthana Chapter1 Sloka No:61
  - 4)Uttara Stana Chapter 2 Sloka No: 38-40
  - 5)Kalpa- Siddhi Stana Chapter 6 Sloka 13
- 3.Agnivesha Charaka Samhita,redacted by Charaka & Dridabala with Ayurveda Deepika Commentary by Sri.Chakrapanidatta,edited by Yadavji Trikamji Acharya.,Varanasi.,Choukhambha Surbharati prakashana.,Reprint2011
  - 1)Chikitsa Sthana Chapter 17 Sloka No:15
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**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 KAYACHIKITSA**

**“Title”**

**OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARITIVE  
EFFECTIVENESS OF VAJIGANDHADI TAILA PANA AND MATRAVASTI IN  
GRIDHRASI(SCIATICA)**

**BY**

**GOPIKRISHNA.A.S**

**1ST YEAR P.G SCHOLAR**

**DEPARTMENT OF P.G STUDIES IN KAYACHIKITSA**

**AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O. KOLLAM**

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**SESSION – 2013 – 14**

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I Year M.D. (Ay) Scholar

Department of Post Graduate Studies in Kayachikitsa

Amrita School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala.

**To**

The Registrar

Amrita Viswa Vidyapeetham, Ettimadai ,Coimbatore, Tamilnadu

**Through -** The Principal and Head of Department of P.G. studies in Kayachikitsa, Amrita  
School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala

**Subject:** 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 submission of the dissertation to the Amrita Viswa Vidyapeetham , Coimbatore, Tamilnadu, as partial fulfillment of M.D (Ay) in Kayachikitsa.

THE TITLE OF DISSERTATION

**“OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARITIVE  
EFFECTIVENESS OF VAJIGANDHADI TAILA PANA AND MATRAVASTI IN  
GRIDHRASI(SCIATICA)”**

I am enclosing completed proforma for registration of subject of dissertation.

Thanking You.

Yours faithfully,

**(Dr.GOPIKRISHNA.A.S.)**

**Date:**            **Place:** Vallikkavu

# **1.BRIEF RESUME OF THE INTENDED WORK.**

## **I.NEED FOR STUDY**

*Gridrasi* is one among the 80 types of *Nanathmaja Vata Vyadis*<sup>1</sup>. This is a clinical condition characterised by severe pain starting from the lowback region and radiating down towards the foot. This is a common entity encountered in a clinical practice. *Stambha*, *Ruk*, *Toda* and *Spandana* starting from *spik*(waist) and extend through *kati*(low back) *prishtha*(buttocks) *uru*(thigh) *janu*(knee) *jangha*(calf) *padam*(foot) in an order<sup>2</sup>.

Sciatica is a condition where there is distribution of pain along the course of sciatic nerve, i.e, which the pain radiates from the low back to buttock and leg<sup>3</sup>. This is commonly accepted as being caused by lumbar disc prolapses. Sciatica of contemporary Medical science is closely equivalent to *Gridrasi* by its similarity in the course of pain from low back radiating down through the posterior part of leg.

The chance of *gridrasi* is expected to increase in the upcoming years due to sedentary life style, the increased use of computerization and also due to increasing body weight, mental stress, hectic work schedules and transportation methods. All these adds on to the improper posture which is one of the highlighted cause for spine and nerve compression disorders in the present scenario.

Low back pain is the 2<sup>nd</sup> most common reason for all physician visits<sup>4</sup> and it is a condition that affects as many as 80-90% of people during their life time, among them true sciatica cases occurs in about 5% of cases. On considering sciatica as an independent disease it is a relatively common condition with lifetime incidences varying from 1.6%-43%<sup>5</sup>.Sciatica is more common among the age group between 30-50 years of age.

It is a fact that despite recent progress of modern neurology, it is unable to provide an effective cure for Sciatica, except for giving temporary relief through analgesics or surgical interventions. Continuous use of NSAIDs and steroids for relieving pain may in later course lead to secondary complications like Kidney failures, Liver disorders and Gastritis.

Keeping these facts in mind this study has been undertaken to bring out a treatment modality with no side effects and long lasting relief.

In this study the role of *Vajigandadi taila*<sup>6</sup> which is a simple and potent yoga described in *Yogaratanakara*, *Vatavyadhi adikaranam* with specified indication only on

Gridrasi will be researched by administering to two groups of patients as internal administration(snehapana) and Matra Basthi.<sup>7</sup>

## **II.REVIEW OF LITERATURE**

Gridrasi mentioned under vatavyadhi is again subdivided into Vatika and Vata-kaphaja gridrasi. In Vatika gridrasi Shoola(pain) Sthamba(stiffness) and Thodam(pricking pain) are prominent symptoms while in vata-kaphaja gridrasi there will be more of tandra(stupor) gauravam(heaviness) and arochakam(anorexia). Pain starts from spik(waist) and extend through kati(low back) prishta(buttocks) uru(thigh) janu(knee) jangha(calf) padam(foot) in an order<sup>2</sup>..

The yoga *Vajigandadi tailam* is told in *Yogarathnakaram vatavyadi chikitsa adhikaranam* which is specifically indication only to gridrasi and the method of administration told as snehapanam and vasthi<sup>6</sup>.

Eranda taila is the main ingredient in Vajigandadi taila. *Ēranda taila* is quoted as the best *snehavirechaka* and *vatanulomanam*. Apart from these eranda taila is also having qualities such as *vātakapha hara*, *deepana*, *srotoviśodhana*, *vayasthāpana*, *ārōgyakara*, *balakara* and *Adho dosa hara*<sup>8</sup>. It also has specific indication in *ruk* and *śopha* of *kati*, and *prusta*<sup>9</sup>. It is the best drug for *katiśūla*<sup>10</sup> as per *Gadanigraha*. These said qualities will be best suited for the selected condition. Eranda taila has a broad spectrum action depending upon its dose, duration, route of administration, combinations, mode of preparations etc..

Classical preparations like *sindhuvara erandam*, *gandarvahasthadi erandam*, *sukumaram erandam* etc had shown its efficacy in treating similar *Vata vyadis*. The trial drug here is also processed with potent drugs like *Aswagandha*, *bala moola*, *vilwa*, and *dasamoola* which is known for its *deepana*, *grahi*, *pachana*, *vata kapha hara* properties. So it is understood that the said combination will be a unique drug for subsiding both types of *gridrasi*.

## **III.PREVIOUS WORK DONE**

1. Comparative clinical trial of castor oil and diclofenac sodium in patients with Osteoarthritis<sup>11</sup>.

(Department of Pharmacology and Physical Medicine and Rehabilitation,  
Postgraduate Institute of Medical Education Research, Chandigarh and All India  
Institute of Medical Sciences, New Delhi, India)

2. Mahesh.K.P. Dpt of Panchakarma.Samana snehapana with Gandarvahasthadi eranda tailam in low back pain- A comparative clinical trial.-2011-13
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On a review of the previous work done it can be concluded that neither efficacy of *Vajigandhadi taila* as *pana* and *matra vasthi* has been evaluated nor a comparison of route of administration has been done. So the study has been undertaken.

#### **IV.AIMS AND OBJECTIVES OF THE STUDY**

1. To evaluate the efficacy of *Vajigandadi taila* *Snehapana* in the management of Gridrasi.
2. To evaluate the efficacy of *Vajigandadi taila* *Matra basthi* in the management of Gridrasi.
3. To compare the efficacy of *Vajigandadi taila* administration as *Snehapana* and *Matra basthi* in the management of Gridrasi.



4. To standardize the dose of *vajigandadi taila* in gridrasi.

## **2.MATERIALS AND METHOD**

### **I.SOURCE OF DATA**

OPD and IPD of Post graduate Dept. of Kayachikitsa Amrita School of Ayurveda and Hospital,

### **II.METHOD OF COLLECTION OF DATA**

#### **A)Sample**

40 patients fulfilling the criteria will be selected and divided randomly into 2 equal groups.

#### **B)INCLUSION CRITERIA**

1. Positive SLR test
2. Patient having Sciatica with mild to moderate osteoporotic changes and where surgical interventions are not absolutely necessary and medical management are suggested.
3. Patient between the age group of 20-60 years of either sex.
4. Patient with madhyama or kroora koshta.

#### **C)EXCLUSION CRITERIA**

1. Mrudu koshta
2. Fracture of vertebrae
3. Dislocation of vertebrae.
4. Deformities and congenital defects..
5. Known case of Tuberculosis of spine.
6. Known case of Neoplasm of spine.
7. Chronic osteoporotic degeneration.
8. Pregnancy

### **3.PROCEDURE AND DESIGN OF THE STUDY.**

#### **1.MATERIALS AND METHOD.**

##### Collection of drug

Ingredients of the yoga will be identified and collected from the local market and vicinity of Vallikavu

##### Composition of the trial drug.

##### **Vajigandadi tailam.**

<b>Sl.no:</b>	<b>DRAVYA</b>
1	ASHWAGANDAM
2	BALA
3	VILWA
4	AGNIMANTHA
5	SYONAKA
6	KASHMARI
7	PATALA
8	KANTAKARI
9	BRIHATI
10	SALAPARNI
11	PRISHNIPARNI
12	GOKSHURAM
13	ERANDA TAILA

##### **PREPARATION OF MEDICINE**

*Aswagandha, bala, vilwa* and *dasamoola*(whole 10 drugs together) will be taken in equal quantity and made into coarse powder. To this 16 times water is added and boiled and reduced to 1/4<sup>th</sup>.

This kasaya is mixed with sufficient quantity of eranda taila and kalka as per the classical reference 1:4:16 for kalkam, sneham and kasayam respectively. For kalkam the above mentioned drugs will be taken in appropriate quantity mentioned in classics for sneha kalpana.<sup>13</sup>

The ratio of the individual drug is fixed as per the classical reference. The taila will be prepared in the pharmacy of Amritha School Of Ayurveda. The tailas prepared according to the direction available in the classical texts.<sup>14</sup>

First the kasaya is made with drugs and water taken in the ratio 1:16 respectively and is reduced to 1/4<sup>th</sup>.

For preparation of the medicine the kalka, eranda taila and kasaya are taken in the ratio 1:4:16.

The taila will be prepared in madhyama paka for the trial.

## **II.DESIGN OF STUDY**

40 patients who fulfill the inclusion criteria in the duration of study period will be randomly divided into 2 groups Group VJ.P and Group VJ.M each consisting 20 patients.

### **i.GROUPING & TREATMENT PROCEDURE**

Patients will be divided into two Groups, VJ.P and VJ.M by random sampling method with 20 patients in each group.

For both groups deepana-pachana is planned to be done with trikadu till deepana and pakwamala darshana is attained.

Patients in VJ.P. will be administered *Vajigandadi taila* orally as samana snehapana with initial Dose of 5ml and increased dose per day with 5ml for 15 days. If purgation occurs distressfully then the same dose of previous day would be fixed for the next day.

Patients in VJ.M. will be administered *Vajigandadi taila* through anus as matravasthi in a dose of 1 ½ Pala (=70ml) for 15 days.

The findings are then statistically analysed.

Groups	Vj.P	Vj.M
Poorvakarmam	Deepana-pachanam with trikadu choorna till agni deepanam and pakva mala is observed.	Deepana-pachanam with trikadu choornam till agni deepanam and pakva mala is observed.
Pradhana karma	Snehapaana starting with 5ml and adding on 5ml for each consecutive days for 15 days.	Matra basthi with 1 $\frac{1}{2}$ pala(72 ml) is done for 15 days.
Time of administration	7.30am	After lunch
Method of administration	Fixed dose is measured and given in empty stomach.	70ml is administered via anal route with disposable glycerine syringe.
Anupanam	Mudga yoosham	-
Pathyam	Ushna yavagu, ushnopacharam	Hithaaharam, ushnopacharam
Apathyam	Sheetopacharam,viruddha/guru aaharam,divaswapnam	Sheetopacharam,viruddha/guru aaharam,divaswapnam

#### **4.ASSESSMENT CRITERIA**

##### **OBJECTIVE**

1. Visual analogue scale for pain.
2. SLR test.
3. Lasegue's sign.
4. Schober's test.
5. Gaenslen's test.
6. Sitz test
7. Flip test
8. Barbers test

### **SUBJECTIVE**

1. Ruk - pain
2. Sthambhana-stiffness
3. Toda - pricking sensation
4. Spandana –fasciculation
5. Arochaka – anorexia
6. Gourava – heaviness
7. Tandra -stupor

### **FOLLOW UP**

Two follow ups with 15 days interval

### **STATISTICAL METHODS**

Subjective and Objective parameters before and after treatment and follow up will be recorded meticulously and analysed by using appropriate statistical methods and final conclusion will be drawn.

### **LABORATORY INVESTIGATIONS**

1. Routine blood test
2. Lipid profile
3. X-ray of lumbo sacral spine AP and Lateral view
4. LFT

### **DOES THE STUDY REQUIRED ANY INVESTIGATION OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS?**

The study requires;

1. X-ray lumbo sacral region AP and lateral view.
2. Blood routine
3. Lipid profile

#### 4. LFT

No animal experiments will be carried out.

#### **HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF HUMAN TRIALS ?**

Yes.

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Vidhya Bhavan 2009 Madhyamakhandha, Chapter 9/1

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AMRITA SCHOOL OF AYURVEDA.

Signature with official seal :

**TOP**



**AMRITA SCHOOL OF AYURVEDA**  
AMRITA VISWAVIDYAPEETHAM  
(University under sec.3 UGC Act 1956)

**COMPLETED PROFORMA FOR REGISTRATION OF SUBJECT FOR  
DISSERTATION FOR AYURVEDA VACHASPATI [M.D] IN KAYACHIKITSA**

**‘OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE  
EFFECTIVENESS OF KARPASASTHYADI NASYA AND UTTARABHAUKTIKA  
SNEHAPĀNA IN APABĀHUKAM’**

**Submitted by,**

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**1ST YEAR P.G SCHOLAR**

**DEPARTMENT OF P.G STUDIES IN KAYACHIKITSA**

**AMRITA SCHOOL OF AYURVEDA, VALLIKAVU, CLAPPANA P.O. KOLLAM**

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**2013-2014  
AMRITA SCHOOL OF AYURVEDA,  
VALLIKAVU, KOLLAM**

**From,**  
**Dr. KRISHNA PRABHA. A**

I Year M.D (Ayu) scholar

Department of PostGraduate studies in Kayachikitsa

Amrita School of Ayurveda , vallikavu , clappana (p.o), kollam,Kerala,

**To**

The Registrar,

Amrita vishwa vidyapeetam,

Ettimadai, Coimbatore,Tamilnadu

**Through -** The Principal and Head of Department of P.G. studies in Kayachikitsa,  
Amrita School of Ayurveda,Vallikkavu,Clappana P.O, Kollam, Kerala

**Subject:** 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 the AMRITA SCHOOL OF AYURVEDA, AMRITA VISWAVIDYAPEETHAM, Coimbatore, Tamilnadu for partial fulfillment of M.D. (Ayurveda) .

**THE TITLE OF DISSERTATION:**

**‘OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE  
EFFECTIVENESS OF KARPASASTHYADI NASYA AND UTTARABHAUKTIKA  
SNEHAPĀNA IN APABĀHUKAM’**

Herewith I am enclosing completed Proforma for Registration of Subject of dissertation.

Thanking You

Yours faithfully,

**(KRISHNA PRABHA. A)**

**Date:**

**Place:** vallikavu

## **1.BRIEF RESUME OF THE INTENDED WORK:**

### **I.NEED FOR THE STUDY:**

In the fast developing technological era, most of the diseases may not be life threatening but hamper day to day life and human productivity. *Apabahuka* is one among those diseases which is painful and affects the normal routine life style of an individual. It is one among the *Vatavyadhi* which affects the normal functioning of the upper limbs.

Self-reported prevalence of shoulder pain is between 16% and 26%. of general population. It is the third most common cause of musculoskeletal consultation in Primary Care. 5% of consecutive new patients attend a shoulder clinic for the complaint of Gleno-humeral disorders. Shoulder pain is the third most common cause of musculoskeletal consultation in primary care. 1% of adults with new shoulder pain consult their General Practitioner each year<sup>1</sup>. Most common in 5<sup>th</sup> and 6<sup>th</sup> decades of life, with the peak age in mid 50s. Onset before the age of 30 is rare. Women are more often affected than men. The non-dominant shoulder is slightly more likely to be affected. In 6-17% patients the other shoulder becomes afflicted within 5 years.

Man has become more prone to many health problems due to altered food habits & life styles. If these problems are not dealt immediately they may lead to permanent disabilities. *Ayurveda* has given more importance to *vata vyadhis* since the era of Vedas and later on in *samhitha kala* the study of *vata vyadhis* have been done more elaborately.

*Apabahuka* is a *vata vyadhi* localizing around the *amsa pradesa* and there by causing *soshana* of *amsa bandha* as well as *akuncana* of *sira*<sup>2</sup> at this site leading to symptoms like *bahupraspandita hara*.<sup>3</sup> *Amsa shosha* can be considered as the preliminary stage of the disease where loss or dryness of the *Shleshaka Kapha* from the shoulder joint occurs. In the next stage, due to the loss of *Shleshaka Kapha* symptoms like *shoola* (pain) during movement, *amsa stabdada* (restricted movement) etc are manifested<sup>4</sup>.

There are some clinical conditions of modern science, which may be compared with that of *Apabahuka*. These may be categorized as Gleno humeral disorders which include Frozen shoulder or adhesive capsulitis, Sub-coracoid bursitis, Bicipital tendinitis<sup>5</sup> Sub-acromial or sub-deltoid bursitis, Osteoarthritis of shoulder joint, Gleno-humeral arthritis<sup>6</sup>

In *Astanga Hridaya Vatavyadhi Chikitsa*, *Nasya* and *uttarabhaktika snehapana* are the main treatment principles indicated for *Apabahuka*<sup>7</sup>. The present study is on the comparative effect of both the *nasya* and *uttara bhaktika snehapana* with *karpasasastyadi taila* in *apabahukam*

*Nasya* is one of the important procedure of classical *Panchakarma* therapy and *nasa* is told as *dwara* for *Shiras*<sup>8</sup> which is an *uttamanga*. Also the drug administered through nose nourishes the *Shiras*, *Skandha*, *Greeva* and *Vaksha*<sup>9</sup>

In Ayurveda, *oushada kala* (time for administration of medicine) is stating that the drugs which are taking after *sayam kala bhojana* will have great impact on diseases due to *udana vata*<sup>10</sup> affecting *vak*, *pravritti*, *prayatna*, *oorja*<sup>11</sup> etc. and it is indicated in *Apabahuka*. *Uttarabhaktika sneha* is considered as *Brihmana snehana*. Here in this study for one group the *sneha* is administered in this modality. Also in *Yoga Ratnakara vatavyadhi chikitsa* *Acharya* mentions “*masha taila rasonabhyam bahvoscha parivartanath*” in the management of *Apabahuka*.<sup>12</sup> From this the need of *vyaayama* in the management of *Apabahuka* is clearly highlighted.

As *karpasasthyadi taila* contains *karpasaasthi*, *devadaru*, *masha*, *bala*, *pippali moola*, *kushta*, *aja ksheera* etc it is a *Vata-kaphahara* and *Brihmana yoga* mentioned in *sahasrayoga*<sup>13</sup>. In the present study, it will be administered in the form of *Nasya* and *Uttarabhaktika snehapana* as indicated in its *phala sruthi*. Hence an effort has been made to evaluate the efficacy of *Nasya* and *Snehapana* along with *vyaayama* in the management of *Apabahuka*.

Due to increased prevalence & incidence -rates need arises to treat the same with less cost & least side effects. Generally the sufferers go for usage of analgesics, corticosteroids, anti-inflammatory drugs. This approach may give only a timely cure but not permanent relief of the pain<sup>14</sup> and the long term usage NSAIDs and steroids for relieving pain may in later course lead to secondary complications like Kidney failures, Liver disorders and Gastritis.

Considering all the above points, looking into the plight of patients with *Apabahuka* and also the beneficial effect of Ayurvedic therapies like *Nasya* and *snehapana* with *Karpasasthyadi Thaila* and to bring out a treatment modality with no side effects and long lasting relief.

## **II. REVIEW OF LITERATURE:**

*Apabahuka* and its treatment has been explained in detail in both *Brihatrayees* and *Laghutrayees*. In *Astanga Hridaya*, *Vata vyadhi nidana*, it is mentioned that *Apabahuka* is a disease which affects movements of shoulder. The main *lakshana* is *bahupraspandita haram*. *Ayurvedic* classics explain the *chikitsa* of *Apabahuka* as follows.

1. In *Ashtanga Hridaya*, *Nasya* and *uttarabhaktika Snehapana* are mentioned in the management of *Apabahuka*.

2. *Astanga Sangraha* mentions *Navana Nasya* and *sneha pana* for *Apabahuka*.

3. *Sushrutacharya* advises *Vatavyadhi chikitsa* for *Apabahuka*, except *siravyadha*.

4. *Chikitsa sara sangraha* advises *Nasya*, *Uttara bhaktika Snehapana*, and *Sweda* for the treatment of *Apabahuka*.

5. *Brimhana nasya* is indicated in *Apabahuka* (*Urdhwajatrugata rogas*) in *Astanga Hridaya* *sutrastana Nasya vidhi*.

6. In *Yoga ratnakara vatavyadhi chikitsa*, *bahu parivartanam*(*vyaayama*) is mentioned

7. In *Caraka samhitha chikitsa stana*, *Vatavyadhi chikitsa Uttarabhaktika snehapana* is also having equal effect with *Nasya* in the management of *Apabahuka*.

## **PREVIOUS RESEARCH WORKS**<sup>15,16</sup>

- |   |      |   |
|---|------|---|
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- 3 1990 Jayan T S- Assessment of the effect of conventional treatment & rehabilitation therapy in Abhighatajanya Apabahuka comparing with the conventional treatment alone Trivandrum Kerala University.
- 4 1997 Shukla Niranjana -'Effect of Nasya and abhyanga on Apabahuka w.s.r to masha taila Gopabandhu Ayurveda Mahavidyalaya utkal university Bhuvaneshwar.
- 5 2004 Naveen.C.J.-A study on Apabahuka & its management through Nasya & Vatagajankush Rasa Ayurveda Mahavidyalaya Hubli.RGUHS
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- 7 2010 Dr.Febin.p.Jose-To evaluate the efficacy of Nagara Taila Nasya in the management of Apabahuka
- 8 2011 Dr.Rohini.M.Hosagoudar "A comparative clinical study of nasya karma and uttarabhaktika snehapana in apabahuka w.s.r to frozen shoulder"
- 9 2012 Dr.Kiran B Nair-To evaluate the effect of karpasasthyadi thail nasya in the management of apabahuka w.s.r to frozen shoulder"
- 10 2010 Dr.Gayathri.M.S A clinical study to evaluate the efficacy of nasyakarma with parinata keriksheeraditailam in the management of apabahuka"

The review of previous works indicate that some studies has been done on effect of nasya and about the efficacy of samana snehapana in Apabahuka.only one study has been carried out on comparison of effect of nasya and uttarabhakthika snehapana with mashataila in the management of Apabahuka.But according to my knowledge no trial study was conducted on comparative study between routes of administration of karpasasthyadi taila as nasya and

uttarabhakthika snehapana in Apabahuka. Hence this study is to carry out the comparative effectiveness of karpasasthyadi taila through nasal and oral routes of administration.

### **III. AIMS AND OBJECTIVES OF THE STUDY:**

- 1) To analyse the effect of *Karpasasthyadi taila* nasya in Apabahukam
- 2) To analyse the effect of utara bhakthika snehapana with karpasasthyadi taila in Apabahukam
- 3) To compare the efficacy of mode of administration as nasal and oral route in Apabahuka.

### **2. MATERIALS AND METHODS**

#### **I. SOURCE OF DATA**

The patients attending the OPD and IPD of PG Department of kayachikitsa, Amrita Ayurveda Hospital with classical signs and symptoms of Apabahuka are selected. Detailed history taking will be done using a predesigned case proforma

#### **II. MATERIALS REQUIRED FOR THE STUDY**

##### **i) METHOD OF COLLECTION OF DATA:**

##### **1. SAMPLE:**

Minimum number of 30 patients are randomly selected from the OPD and IPD,

PG Department of kayachikitsa, Amrita ayurveda Hospital, vallikavu.

##### **2. INCLUSION CRITERIA:**

- Either gender and age group of 20-60 years
- Patients having classical signs and symptoms of Apabahuka.
  - Bahupraspanditahara (Restricted movements)
  - Amsa Sthabdatha (stiffness),
  - Amsasandhi Shoola (pain),

- Bahushosha(wasting)
- Patients Fit for Brihmana Nasya Karma and snehapana.

### **3.EXCLUSION CRITERIA**

- Age group:less than 20yrs & exceeding 60yrs are to be excluded.
- Patients with history of Fracture of Shoulder,
- Any other Physical injuries to the shoulder joint(trauma)
- Infective Conditions
- Patients undergoing steroid therapy
- Pregnancy & Lactating mothers
- Pain related to secondary systemic diseases.

### **ii)PROCEDURE AND DESIGN OF THE STUDY:**

#### **1.MATERIALS AND METHODS:**

##### **i) Composition of trial ingredients: i) Karpasasthyadi Thaila**

The following drugs will be identified and procured from the local markets of vallikavu.

- Karpasa asthi
- Bala
- Masha                      Dravadravya
- Kulatha
- Devadaru
- Bala
- Rasna
- Kushta
- Sarsapa
- Nagara                      Kalka
- Satahwa
- Pippalimoola
- Chavya
- Sigru
- Punarnava
- Tila taila      -      Sneha
- Ajaksheeram



## **ii) Preparation of medicine:**

The drugs for preparing drava dravya will be taken in equal quantity and made into coarse powder. To this 16 times water is added and boiled and reduced to 1/4<sup>th</sup>. This kashaya is mixed with sufficient quantity of ajaksheera and Kalka. As per the classical reference 1:4:16 is the ratio for kalkam, sneham and kashayam respectively. For kalkam the above mentioned drugs will be used.<sup>17</sup>

The thaila will be prepared in the Pharmacy, Amrita Ayurveda Hospital, according to classical method and mridu paaka is taken for Nasya and madhyama paaka is taken for paana.

## **2)Design Of The Study**

30 Patients who fulfill the inclusion criteria in the duration of study period will be randomly divided into 2 Groups –Group A and Group B each consisting of 15 patients.

## **3)Grouping and treatment / Procedure etc.**

Patients are divided into 2 groups by random sampling method.

- Group A – In this group 15 patient will be given Nasya with karpasastyadi taila for 7days along with vyayama
  - Group B- In this group 15 patients will be given karpasasthyadi taila as Uttarabhaktika Snehapana (in samana matra) along with vyayama.
- a. Both the groups will be undergoing vyaayama for 30min in these 15 consecutive days

	Group A (Nasya karma)	GroupB (UttarabhaktikaSnehapana)
Poorvakarma	Deepanapachana with Trikatu choornam 3 – 5 gms bd with hot water till niramalakshanas for 3days  Mukhabhyanga done with moorchita tila taila and swedana done	Deepanapachana with Trikatu choornam 3 – 5 gms bd with hot water till niramalakshanas for 3days
Pradhanakarma	Nasya: karpasasastyadi Taila  Dose - 8 bindus <sup>18</sup> in each nostril in continuous flow (Avichinnadhara) for 2 consecutive 7 days with 2 days gap after sayankalabhajana	Uttarabhaktika Snehapana with karpasasatyadi taila 30ml <sup>19</sup> after Sayankalabhajana for 15 days.
Pashchatkarma	Gandusha with ushnajala	Ushnajala pana.

#### **4)ASSESSMENT CRITERIA**

Assessment will be done on the subjective and objective parameters before and after treatment. A special scoring pattern will be prepared for the assessment of subjective parameters.

##### **SUBJECTIVE PARAMETERS:**

- Pain(amsa sandhi soola) by Visual Analogue scale(0-10scale)
- Stiffness of the shoulder joint (amsa stabdada)
- Bahusosha(wasting)

## **OBJECTIVE PARAMETERS:**

- a. Bahupraspandita haram(Range of shoulder movements ,Goniometer examination & scales)
  - \* Flexion
  - \* Extension
  - \* Abduction
  - \* Adduction
  - \* External Rotation
  - \* Internal Rotation
  - \* Elevation
- **FOLLOW UP:**
  - 2months (weekly once)

## **5.STATISTICAL METHODS**

Subjective and Objective parameters before and after treatment and follow up will be recorded meticulously and analysed by using appropriate statistical methods and final conclusion will be drawn.

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, Study requires investigations in Goitre patients using medicated drugs. No healthy volunteers, cadaver or animal experiments will be conducted.

### **a)Investigations:**

To exclude other disorders following investigations will be done if necessary.

- Hb% , TC, DC ,ESR ,RBS, Routine urine, X-ray shoulder(AP & Lateral)

### **b) Intervention:**

- 1) The patients will be assessed before and after the treatment and after follow up as per assessment criteria.
  - 2) The nature of the study will be explained to the patients in detail and pre- treatment consent will be taken.
  - 3) The confidentiality of the data will be maintained.
2. Has ethical clearance been obtained from your institution in case of (3)? (Human / animal)

- Yes

## **STUDY PLAN**

### Step1

Minimum number of 30 patients are randomly selected from the OPD and IPD, PG Department of kayachikitsa, Amrita ayurveda Hospital ,vallikavu on the basis of inclusion and exclusion criteria.

### Step2

Lab investigations ie.Haematological, X-ray etc will be done for proper diagnosis of the disease.

### Step3

Grouping of the patients

#### Group A(Nasya)

Patients will be given karpasasthyadi Nasya  
8drops in both nostrils in 2 consecutive 7 days  
With 2 days interval with poorva,pradhana and  
Paschat karma

#### Group B(snehapana)

30ml karpasasthyadi taila given  
after sayamkala bhojana for 15days

### Step4

Effect of therapy will be observed on the basis Of clinical pictures,Range of movements,  
VAS and investigations after completion of therapy (16days)

### Step 5

To compare the effectiveness between Nasya and utara bhakthika snehapana with karpasasthyadi taila in Apabahuka.

**LIST OF REFERENCES: Write references in Vancouver style**

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(University under sec.3 UGC Act 1956)

**PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR**  
**AYURVEDA VACHASPATI [M.D] IN KAYACHIKITSA**

**“OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE  
EFFICACY OF VAGBHATOKTHA BRAHMI GHRITA IN VISHADA W.S.R. TO  
DEPRESSIVE ILLNESS”**

**BY**

**DR. SETHULEKSHMI.S**

**GUIDE: DR C.NAGARAJAN**

**CO-GUIDE: DR.MAHESH.C.KUNDAGOL**

**DEPARTMENT OF POST GRADUATE STUDIES IN KAYACHIKITSA  
AMRITA SCHOOL OF AYURVEDA, VALLIKKAVU  
CLAPPANA P.O, KOLLAM, KERALA**

**SESSION - 2013-14**

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**To**

The Registrar

Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore, Tamilnadu

**Through -** The Principal and Head of Department of P.G. studies in Kayachikitsa, Amrita

School of Ayurveda, Vallikkavu, Clappana P.O, Kollam, Kerala

**Subject:** 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 submission of the dissertation to the Amrita Viswa Vidyapeetham, Coimbatore, Tamilnadu, as partial fulfillment of M.D (Ay) in Kayachikitsa.

THE TITLE OF DISSERTATION

**“OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF VAGBHATOKTHA BRAHMI GHRITA IN VISHADA W.S.R. TO DEPRESSIVE ILLNESS”**

I am enclosing completed proforma for registration of subject of dissertation.

Thanking You.

Yours faithfully,

**DR. SETHULEKSHMI. S**

**Date:**

**Place:** Vallikkavu

# **1. BRIEF RESUME OF THE INTENDED WORK**

## **I NEED FOR THE STUDY**

Vishada is one of the Vatananatmaja Vikaras<sup>1</sup> and it is further said that Vishada is the main factor that increases the range of all the diseases“Vishado Rogavardhanaanaam Shreshthah”<sup>2</sup>.Dalhana commented “Asiddhi Bhayat Vividheshu Karyasu Sado Apravrutihi”<sup>3</sup> i.e a condition originated from apprehension of failure, resulting in incapability of mind and body to function properly with significant reduction in activity. Symptomatic representation of the state of Vishada is explained in Shrimad Bhagvad Geeta.<sup>4</sup>

Depression is a state of low mood and aversion to activity that can affect a person’s thoughts, behaviour, feelings and physical well-being. It may include feeling of sadness, anxiety, emptiness, hopelessness, worthlessness, guilty, irritability or restlessness.<sup>5</sup> The symptoms of Vishada which are found in various references in Indian science when compared to depression almost appear similar, so we can co-relate Vishada with depression.

According to contemporary science Depression is a serious mental health concern that will touch most people’s life directly or indirectly.<sup>6</sup> Depression affects 121 million people worldwide. It can affect a person's ability to work, form of relationships, and destroy their quality of life. At its most, severe depression can lead to suicide and is responsible for 850,000 deaths every year<sup>7</sup>.15% of the population of most developed countries suffers with severe depression. 80% of depressed people are not currently having any treatment.<sup>8</sup>

Vagbhata explains Brahmi Ghrita in Unmada Chikitsa.<sup>9</sup> and is indicated as ‘Vakswara Smritimedhakrut. Acharya doesn’t explain its indication in any specific doshic unmada or Vishada. Samanya Unmada Chikitsa can be used in all kind of Manasika Rogas based on the understanding of the Doshas predominant in that particular condition. In Manorogas Chikitsa Ghrita Pana is directly indicated <sup>10</sup>, and we find most of the formulations in Ghrita forms. Therefore it may be an appropriate medicament to manage this condition.

Hence this study is planned to explore the efficacy of Vagbhatokta Brahmi Ghrita Pana in the management of Vishada (Depression).

## **II) REVIEW OF LITERATURE**

In ancient Indian science too, the term “Vishada” has been used as a catastrophe, which may be correlated with depression. “Rigveda” – the first ever-authentic human literature

denotes the use of a special invocation to God for getting rid of Vishada<sup>11</sup> i.e. this denotes to the fact that awareness about Vishada prevention was prevalent. According to the first chapter of “Shrimad Bhagvad Geeta” –Arjuna Vishada Yoga, the condition of Arjuna in the

battle field is mentioned as Sidanti Gatrani (loosening of muscles), Mukhashosha (dry mouth), Vepathu (tremors), Aruchi (anorexia), Prasveda (sweating), and Twak Paridaha (burning sensation in the skin) etc<sup>12</sup>, which commensurate with the symptoms of depression. Charaka Samhita mentions “Vishada” as one of the Nanatmaja Vata Vikara and it is further said that, Vishada is the main factor that increases the range of all the diseases.<sup>13</sup> Sushruta has mentioned it under the Mano Vikaras.<sup>14</sup> Further he mentioned that Vishada is common among Tamasika Manasa Prakruti.<sup>15</sup> Whereas Vagbhata has stated that person with predominant Tamasa Guna are more prone to suffer from Vishada.<sup>16</sup> Commenting on Anumanagamy Bhavas in Charaka Samhita says “Bhayam Vishadena<sup>17</sup>” i.e. understanding the feeling of fear in a person by seeing his depressed state or behaviour.

**Depression-** is a state of low mood and aversion to activity that can affect a person's thoughts, behaviour, feelings and physical well-being. It may include feeling of sadness, anxiety, emptiness, hopelessness, worthlessness, guilty, irritability or restlessness.<sup>18</sup>

Charaka has mentioned the benefits of Ghrita as Medhya, Smriti Vardhaka and Indriya Parsadaka.<sup>19</sup> Brahmi Ghrita is explained in the context of Unmada Chikitsa Adhyaya of Ashtanga Hridaya.<sup>20</sup>

### **Drug review**

Drugs used in Brahmi Ghrita are:

Brahmi, Vyosha, Syama, Trivrut, Danti, Sankhupushpi, Saptaparni, Aragwada, Vidanga

### **III) Previous works done**

1. Nath sushil kumar(1988)-A clinical study on depressive illness and its Ayurvedic management-IMS,BHU
2. Tripathy A.K.(1994)-Studies on some plant drugs as anti depressive w.s.r. to kapikacchu(mucuna pruriens)
3. Tripathy A.K. & Singh R.H.-Clinical study on an indigenous drug(Acorus calamus) in the treatment of depressive illness IMS,BHU.
4. Singh R.H. ,Nath S.K. & Behere P.M.- Depressive illness-A therapeutic evaluation with herbal drugs-IMS,BHU.

5.Himanshu Pareek(1998)-A clinical study on effect of Lashuna in the management of Avasada (depression).GAU,Jamnagar.

6.Chandra.R(2004)-Therapeutic evaluation of nasya karma medicated ghrita and Ayurvedic drugs in cases of depressive illness.IMS,BHU.

7.Shaik Anwar.K.S.(2004)-A study on Kaphaja unmade in relation to depressive disorder.kottakkal.

8.C.B.singh(2005)-A clinical study on etiopathogenesis of Vishada (depression) and role of jyotishmati taila and Satvavajaya chikitsa(counselling) in its management.R.G.U.H.S.

Conclusion-Jyotishmati Taila and Satvavajaya Chikitsa proved significant relief in sign and symptoms of the patients of Vishada(Depression),but the quantum of relief provided by Jyotishmati oil was better in comparison to Satvavajaya Chikitsa.

9.Savitha H.P.(2006)-A comparative study on the role of jyotishmati taila administered as nasya and orally in the management of Vishada(depression). R.G.U.H.S.

Conclusion-On comparing the effect obtained in both groups, it was observed that oral administration of Jyotishmati Taila provided significant improvements in the signs and symptoms of Vishada, in comparison with the improvement obtained in Jyotishmati Taila Nasya group.

10.Aditya Subrahmanyam(2013)- A clinical study on the effect of hapushadi yapana basti in the +management of vishada w.s.r. to depressive disorder. R.G.U.H.S.(ongoing)

Conclusion-Hapushyadi yapana basti was found to have significant improvement in the symptoms of depression and was statistically significant too.

#### **IV) OBJECTIVES OF STUDY**

1. To evaluate the efficacy of Vagbhatokta Brahmi Ghrita Pana in the management of Vishada w.s.r. to Depressive Illness

#### **2. MATERIALS AND METHODS:**

##### **I) SOURCE OF DATA:**

30 Patients attending the OPD and IPD of Amrita School of Ayurveda, Kollam, who will be diagnosed with depression and eligible and willing patients will be enrolled in the study

## **II) METHODS OF COLLECTIONS OF DATA:**

Patients will be selected on the following criteria

### **1.CRITERIA FOR DIAGNOSIS:**

1. The diagnosis will be made on the basis of diagnostic criteria for mild and moderate depression in ICD 10<sup>21</sup>

**A.**

Depressed Mood

- 1) Loss of interest and pleasure in activities that are normally pleasurable.
- 2) Decreased energy or increased fatigability.

**B.**

- 3) Loss of confidence or self-esteem.
- 4) Unreasonable feelings of self-reproach or excessive and inappropriate guilt.
- 5) Recurrent thought of death or suicidal behaviour.
- 6) Diminished ability to think or concentrate.
- 7) Change in psychomotor activity, with agitation or retardation.
- 8) Sleep disturbance of any type.
- 9) Significant changes in appetite-increase or decrease.

Mild depressive episode: at least 2 of A and at least 2 of B.

Moderate depressive episode: at least 2 of A and at least 4 of B.

Severe depressive episode: all 2 of A and at least 5 of B.

2. The diagnosis will be made on the basis of sign and symptoms of Vishada as per Ayurved like; <sup>22</sup>

A) Psychic Symptoms:

Dukhita (Distressed, unhappy, grieved in mind)

Avasada (hopelessness, lassitude)

Manah khledah ( feeling of depression)

Vishanna (dejection, sorrow)

Chitta glani( fatigue of mind)

Asiddhi bhaya (fear and anxiety or apprehension of failure)

Dainya (miserable state / depression)

Chittodvega(Anxiety) ,Feeling of inadequacy ,Thought of death/suicide.

B) Somatic Symptoms:

Sidanti gatrani(loosening of muscles)  
Mukha Shosha (Dryness of mouth)  
Prasveda(Excessive sweating)  
Bramati Manas (Wandering mind)  
Tvak paridaha (Burning sensation of skin)  
Vepathu (Tremor)  
Roma Harsha(horripilation)  
Sransanam (Inability to hold)

## **2. INCLUSION CRITERIA:**

1. Patients diagnosed as per the criteria for mild and moderate depression as per ICD 10.
2. Age between 18 to 50 years.
3. Patients of either gender, irrespective of socioeconomic status.
4. Patients willing to sign the informed consent form.

## **3. EXCLUSION CRITERIA:**

1. Patients with other psychiatric disorders.
2. Pregnant women and children.
3. Patients with chronic illness like Cancer, Hypertension, Diabetes mellitus, Hyper and Hypo thyroidism.
4. Patients with suicidal tendency/ thoughts.

#### 4. PLAN OF STUDY:

##### 1. BRAHMI GHRITHA:

S.NO.	SANSKRIT NAME	BOTANICAL NAME	PART USED	PROPORTION
1.	Brahmi	<i>Bacopa monnieri</i>	whole plant	2prastha=1536gm
2.	Shunthi	<i>Zingiber officinalis</i>	Root	12gm
3.	Maricha	<i>Piper nigrum Linn.</i>	Phala	12gm
4.	Pippali	<i>Piper longum linn.</i>	Phala	12gm
5.	Syama trivrut	<i>Ipomoea petaloides chois</i>	Moolam	12gm
6.	Danti	<i>Baliospermum montanum</i>	Moolam	12gm
7.	Sankhu pushpin	<i>Convolvulus pluricaulis</i>	Whole plant	12gm
8.	Sapta parni	<i>Alstonia scholaris</i>	Twak	12gm
9	Aragwada	<i>Cassia fistula</i>	Twak	12gm
10	Vidanga	<i>Embelia ribes Burm</i>	Seed	12gm



2.

POORVA KARMA	PRADHANA KARMA
10gm Trikatu choorna is given twice daily for 3 days	Brahmi ghrita will be given to the patient in Arohana matra till attains 4pala and dose is maintained till 7days.

### **3.DOSE**

Day-1	Day-2	Day-3	Day-4	Day-5	Day-6	Day-7
1pala (48ml)	2pala (96ml)	3pala (144ml)	4pala (192ml)	4pala (192ml)	4pala (192ml)	4pala (192ml)

4. The patient should follow the Pathya-Apathya indicated in Virechna.

### **METHOD OF PREPARATION**

Ghrita will be prepared till Madhyama Paka as mentioned in classics<sup>23</sup> Pharmacy Amrita School of Ayurveda, Kollam.

### **5. ASSESSMENT CRITERIA:**

1. Hamilton's depression rating scale<sup>24</sup> will be used to measure the difference between before and after the treatment.

2. Manasika Bhava Pareeksha scale <sup>(25, 26)</sup> will be used to measure the difference between before and after the treatment

## **6. FOLLOW UP**

Before treatment	After completion of 7 days of snehapana	15 <sup>th</sup> day	30 <sup>th</sup> day	45 <sup>th</sup> day

## **7. STATISTICAL TEST TO BE USED:**

Statistical evaluation of results will be done by using student 't' test method.

### **3) DOES THIS STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTION TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS?**

The study will be a clinical study.

### **4) HAS THE ETHICAL CLEARANCE IS OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.2?**

Yes

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