

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

**Department of SHALYA TANTRA**

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35.	Dr. Anuja Nair N.J	<a href="#"><u>“Uncontrolled Single Armed Clinical Study In The Management Of Non-Toxic Goitre By Triphaladyoguggulu And Sarshapadipralepa”</u></a>	Dr. Rabinarayan Tripathy	Dr. Shaithya Raj.
36.	Dr. Neelima Sherly John	<a href="#"><u>“Open Label Clinical Study To Evaluate The Comparative Effectiveness Of Gunavathi Varthi And Nishadi Taila In Low Anal Fistula.”</u></a>	Dr. Rabinarayan Tripathy.	Dr. Shaithya Raj.
37.	Dr. Sreedevi V	<a href="#"><u>“Uncontrolled Single Armed Clinical Study In The Management Of Fissure-In-Ano By Durvaadi Kera Taila”</u></a>	Dr. Rabinarayan Tripathy.	Dr. Shaithya Raj.
38.	Dr. P. Suresh	<a href="#"><u>“Open Label Case Controlled Clinical Study To Evaluate The Effectiveness Of Nyagrodhadi Gana In Bhagna Sandhaana.”</u></a>	Dr. G.S.Raju	Dr. Rabinarayan Tripathy.

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

**PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR  
AYURVEDA VACHASPATI M.S (Ay) IN SHALYATANTRA**

**“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE  
MANAGEMENT OF NON-TOXIC GOITRE BY TRIPHALADYO-GUGGULU &  
SARSHAPADI PRALEPA”**

**BY  
ANUJA NAIR. N.J**

**GUIDE  
Prof.Dr. RABINARAYAN TRIPATHY. MS (Ay)**

**CO-GUIDE  
Dr. SHAITHYA RAJ. MS (Ay)  
LECTURER**

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

**SESSION - 2013-14**

**From**

**Dr. ANUJA NAIR N.J**

I Year M. S. (Ay) Scholar

Department of Post Graduate Studies in Shalyatantra

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 Shalyatantra, 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.S (Ay) in Shalyatantra.

THE TITLE OF DISSERTATION

**“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE  
MANAGEMENT OF NON-TOXIC GOITRE BY TRIPHALADYO-GUGGULU &  
SARSHAPADI PRALEPA”**

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

Thanking You.

Yours faithfully,

**(Dr.ANUJA NAIR N.J)**

**Date:**

**Place:** Vallikkavu

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

Goitre is defined as diffuse enlargement of the thyroid gland <sup>(1)</sup>. Goitre has ceased to be a major problem in many developed countries and it continues to be a serious health problem in many Third World Countries. The magnitude of the problem in India is far great, than what had been in the 1960s, when it was estimated that about 9 million people were affected by goitre. Now it is estimated that more than 71 million people are suffering from goitre and other iodine deficiency disorders in the country <sup>(2)</sup>. Galaganda is a similar condition explained in the classical texts of Ayurveda. It is told as a mamsa pradoshajavikara <sup>(3)</sup> presented with glandular swelling, produced by the vitiation of vata and kapha accumulated & localized at neck (Gala) along with medas <sup>(4,5)</sup>. Goitre is often treated by anti thyroid drugs, radioactive iodine therapy and surgery, but successfully by subtotal thyroidectomy, where most of the thyroid gland is removed. Management of Galaganda is documented in ancient compendium like Brihatrayee & Laghutrayee. Triphaladyo-guggulu is mentioned in Yogaratnakara <sup>(6)</sup> which is found effective in management of Gandamala and Galagranthi. Sarshapadipralepa is also highly praised in the management of Galaganda as a local application in Bhavaprakasa <sup>(7)</sup>, Bhaishajyaratnavali <sup>(8)</sup> and Chakradatta <sup>(9)</sup> which can dissolve serious types of Galaganda, Granthi and Gandamala.

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

- Goitre is most common now a day in every part of the world. Often it may be associated with complications like difficulty in breathing, swallowing, change in voice etc and inevitably with some cosmetic problems.
- Modern management measures have their own side effects and most of them are very costly. Surgical removal may lead to an underactive thyroid and medicinal management like use of Thyroid hormone pills needs long term therapy.
- Ayurveda can offer safe and effective management for Galaganda, without producing any side effects or complications.
- The etiopathogenesis of Galaganda and Gandamala is same. Since Triphaladyo-guggulu is mentioned in the treatment of Gandamala, hence the effect of Triphaladyo-guggulu on Galaganda has to be evaluated.
- According to Ayurvedic classical texts Sarshapadipralepa plays an important role in management of Galaganda, as it can dissolve even serious types of Goitre.
- Sarshapadipralepa is in the form lepa. So as an external application, it is very easy to use.

- Both the internal and external medication contains a few indigenous drugs which are easily available and cost effective so that it is within the reach of poor people.

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

- The review of literatures includes thorough screening of classical Ayurvedic literature, Modern textbooks, Journals, internet sources etc.

### **Previous work done:**

1. Badaruddin.- Clinical trial of Yashtimadhu in the cases of Thyrotoxicosis ,Faculty of Ayurveda, I M S, BHU 1979
2. Pandit R K- Use of Indigenous drugs in Galaganda Faculty of Ayurveda, I M S, BHU, 1987.
3. Rakesh Kumar- Studies on management of different types of Goitre by Ayurvedic compounds, Faculty of Ayurveda, I M S, BHU, 1988
4. Kamal S.V- Clinical trial of an Ayurvedic compound Shankapushpi, Madhuyashti & Kanchanara on Goitre, Faculty of Ayurveda, I M S, BHU, 1993.
5. Virendra Kumar- A Clinical study of Galaganda & its management with jalaukavacharana w.s r to Non-toxic goitre NKJAMC Bidar, RGUHS, 2008

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

- To evaluate the clinical efficacy of Triphaladyo-guggulu & Sarshapadipralepa in the management of Non Toxic Goitre.
- To evaluate the efficacy of Triphaladyoguggulu & Sarshapadipralepa on TSH value.

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

### **I. SOURCES OF DATA:**

Patients suffering from Non Toxic Goitre will be selected from the OPD & IPD of Amrita Ayurveda Hospital, Vallikkavu, Kollam and other nearby hospitals and clinics. For inclusion and exclusion of patients under the study the pathological laboratory attached to the hospital will be used.

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

Materials required for the present study includes one internal medicine Triphaladyo-guggulu & one external medicine Sarshapadipralepa. Ingredients for the preparation of the drug will be collected from the local market. Triphaladyo-guggulu will be prepared according to

textual reference of Yogaratnakara & Sarshapadipralepa according to the textual reference of Bhaishajyaratnavali under the supervision of Bhaishajya & Dravyaguna Departments.

## **DRUG REVIEW**

### **Triphaladyo-guggulu:**

Guggulu is purified in triphalaquatha in dolayantra and fried in ghee & powdered. The fine powder of Triphala, Trikatu , Kanchanaratvak and Guggulu is pounded well in a mortar and ground along with Honey and made into the form of gutika and dried.

Triphaladyo-guggulu contains the following ingredients.

Sans. Name	Bot. Name	Family	Rasa	Guna	Veerya	Vipaka	Karma
Hareethaki	<i>Terminalia chebula</i>	Combretaceae	Puncharasa Except Lavana	Laghu, Ruksha	Ushna	Madhura	Kantha rogagna
Vibheetaki	<i>Terminalia bellerica</i>	Combretaceae	Kashaya Tiktha	Laghu, Ruksha	Ushna	Madhura	Kantha rogagna
Amalaki	<i>Emblica officinalis</i>	Euphorbiaceae	Amla Kashaya Madura	Laghu, Ruksha	Seetha	Madhura	Tridosahara
Nagara	<i>Zingiber officinale</i>	Zingiberaceae	Katu	Guru Ruksha	Ushna	Madhura	Kantha rogagna
Pippali	<i>Piper longum</i>	Piperaceae	Katu	Laghu Tikshna	Ushna	Katu	Kaphahara Medohara
Maricha	<i>Piper nigrum</i>	Piperaceae	Katu	Laghu Tikshna	Ushna	Katu	Kapha vatahara
Kanchanara	<i>Bauhinia variegata</i>	Caesalpiniaceae	Kashaya	Laghu Ruksha	Seetha	Katu	Gandamalagna
Guggulu	<i>Commiphora mukul</i>	Burseraceae	Thiktha Kashaya	Laghu Ruksha	Ushna	Katu	Sophagna
Kshaudra	–	–	Kashaya Madhura	Guru Ruksha	Ushna	Katu	Chedya

**Sarshapadi pralepa:** Seeds of Sarshapa ,Sigru, Sana, Athasi, Yava and Moolaka is made into powder and triturated along with sour butter-milk. This mixture is applied as lepa. Sarshapadipralepa contains the following ingredients:

Sanskrit Name	Botanical Name	Family	Rasa	Guna	Veerya	Vipaka	Karma
<i>Sarshapa</i>	<i>Brassica nigra</i>	Brassicaceae	Katu Tikta	Guru Ruksha	Ushna	Katu	Sophagna
<i>Sigru</i>	<i>Moringa</i>	Moringaceae	Katu	Laghu	Ushna	Katu	Sophagna

	<i>oleifera</i>		Tikta	Tikshna			
<i>Sana</i>	<i>Crotalaria retusa</i>	Fabaceae	Tikta Kashaya	Guru Tikshna	Ushna	Katu	Kantharogagna
<i>Athasi</i>	<i>Linum usitatissimum</i>	Linaceae	Tikta Madhura	Guru Pichila	Ushna	Katu	Sophagna
<i>Yava</i>	<i>Hordeum vulgare</i>	Poaceae	Kashaya Madhura	Guru Ruksha	Seetha	Katu	Kantharogagna
<i>Moolaka</i>	<i>Raphanus sativa</i>	Brassicaceae	Katu Tikta	Laghu Ruksha	Ushna	Katu	Sophagna
<i>Takra</i>	–		Amla Kashaya	Laghu	Ushna	Madura	Sophagna

### **i) METHODS OF COLLECTION OF DATA:-**

#### **1. SAMPLE**

Thirty patients suffering from Non Toxic Goitre will be selected on the basis of simple random sampling (SRS).

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

- i) Patients between the ages of 15-60 years, irrespective of sex.
- ii) Patients suffering from non –toxic goitre including colloid goitre, diffuse goitre, non-toxic multi nodular goitre, and non-toxic single nodular goitre

#### **3. EXCLUSION CRITERIA:-**

- i) Patients below 15 years & above 60 years.
- ii) Patients having Toxic-goitre, Neoplastic goitre, Thyroiditis, Physiological goitre.
- iii) Patients having difficulty in swallowing, breathing and change in voice.
- iv) Patients having other systemic pathology (TB, DM, HIV, HBsAg, etc)
- v) Patients under medications for thyroid abnormalities.

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

Thirty patients of Non Toxic Goitre will be selected in a systematic random sampling procedure according to the inclusion and exclusion criteria. Patients should be informed about the package of treatment for the clinical trial and the consent will be taken. After getting consent from the patients / guardian, they will be registered under Trial. The ingredients for the preparation of the trial drug will be collected from local market and will be prepared under the guidance of Bhaishajya & Dravyaguna departments. Patients will be given Triphaladyo-guggulu internally & Sarshapadipralepa externally.

**Internally** – Triphaladyoguggulu will be given to each patient in a dose of 4gm (2 tablets 2 gm each) three times a day (8hrly) depending upon the age of the patient with anupana of luke warm water

**Externally** – Sarshapadipralepa, will be applied in approximately 0.5cm (1/4angula) thickness, in the anterior part of neck, once daily in the morning for 3months. Pralepa will be wiped off before drying depending upon the climatic conditions.

All the patients will be advised to take same type of food and to maintain same life style as prescribed. The treatment duration will be 3 months in total. Assessment of clinical sign/ symptom and of investigations will be done on 0day, 30<sup>th</sup> day & 60<sup>th</sup> day, 90th day and will be recorded in specially prepared case sheets.

#### **4. ASSESMENT CRITERIA -**

- i) Swelling
- ii) TSH value
- iii) Size of lobe and isthmus

#### **Investigations required.**

1. Thyroid Function Test
2. Neck USG
3. FNAC(if required)
4. Routine Blood, Urine, Stool examinations in order to rule out systemic pathologies(if necessary)

#### **5. STATISTICAL METHODS**

Paired T Test, or Chi-square Test will be adopted for Statistical analysis.

#### **SINGLE GROUP DESIGN**

T <sub>G</sub> BT V <sub>S</sub> AT	The efficacy of trial drug will be evaluated
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**3.Does the study require any investigations or interventions to be conducted on patients, healthy volunteers, cadaver or animal ? 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.

**4. Has ethical clearance been obtained from your institution in case of (human/animal)study? YES**



## **5.LIST OF REFERENCES:-**

- 1.Dr.Rajagopal Shenoy K, Manipal Manual of Surgery, CBS Publishers,2<sup>nd</sup> Edition,2005,Chapter-19,Pg.No.248
2. K.Park, Park's Text Book of Preventive & Social medicine, M/s Banarsidas Bhanot Publishers, 21st Edition 2011, Pg No.594,595
3. Acharya Charaka, Charaka Samhita text with English translation edited by Dr.Ram Karan Sharma & Vaidya Bhagavan Dash,Chowkhamba Sanskrit Series Publications, Reprint Edition,2008,volume 1,Chptr.No 28/18-19.,Pg.No.79.
- 4.Acharya Susruta, Susruta samhita with English Translation of text & Dalhana's commentary edited by P.V Sharma, Chaukamba Visvabharati Orientalia Publications, Reprint Edition,2005,Volume 3,Chptr.No11/ 22,Pg. No.77
- 5.Acharya Vagbhata, Ashtanga Hridaya English translation edited by Prof.Srikanthamurthi, Chawkamba Publications, Reprint Edition,2007,Volume 3,Chapter 21/53,Pg.No.194
- 6.Anonymous, Yogaratnakara with Vidyotini Hindi Commentary edited by Vaidya Lakshmi pathi Sastri, Chaukamba Krishnadas Academy,2007,Volume 2,Uttarardha,Sh.No.1-2 ,Pg.No.150
- 7.Bhavamisra,Bhavaprakasa with Vidyotini Hindi Commentary edited by Sri Brahmasankara Misra and Sri Rupalalaji Vaidya, Chaukamba Sanskrit Bhavan Publications,9<sup>th</sup> Edition,2005,Volume 2,Chapter 44/27-28,Pg.No.448
- 8.Sri Govind Das,Bhaishajya Ratnavali with Hindi Commentary edited by Sri Kaviraja Ambikadatta,Chaukamba Sanskrit Prakasan Publications,20<sup>th</sup> Edition,2010,Chptr.No44/8-9,Pg.No.822
- 9.Chakrapani,Chakradatta Sanskrit Text with English Commentary edited by P.V Sharma,Chaukamba Orientalia Publications ,Reprint Edition 2013,Chapter 41/3-4,Pg.No.342.



**Name of the researcher/ Scholar** : ANUJA NAIR N.J

**Signatures** :

**Name & designation of the guide** : Dr.RABINARAYAN TRIPATHY.MS (Ay)  
PROFESSOR & HOD  
PG DEPARTMENT OF SHALYATANTRA.

**Remarks of the Guide** :

**Signatures with official seal** :

**Name and designation of**

**The Co-guide** : Dr. SHAITHYA RAJ. MS (Ay)  
LECTURER  
PG DEPARTMENT OF SHALYATANTRA

**Signatures with official seal** :

**Name and designation of**

**Head of Department** : Dr. RABINARAYAN TRIPATHY. MS (Ay)  
PROFESSOR & HOD  
P G. DEPARTMENT OF SHALYATANTRA

**Signatures with official seal** :

**Name & designation of**

**Head of Institution** : Dr.M.R.VASUDEVAN NAMPOOTHIRI. MD(Ay)  
PRINCIPAL, AMRITA SCHOOL OF AYURVEDA

**Signatures with official seal:**

**TOP**



**AMRITA SCHOOL OF AYURVEDA**

**AMRITA VISWAVIDYAPEETHAM**

**(University under sec.3 UGC Act 1956)**

**PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR**  
**AYURVEDA VACHASPATHI, M S (Ay) IN SHALYATANTRA**

**“OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE  
EFFECTIVENESS OF GUNAVATI VARTI AND NISHADI TAILA IN LOW ANAL  
FISTULA.”**

**BY**

**NEELIMA SHERLY JOHN**

**GUIDE**

**Prof. Dr. RABINARAYAN TRIPATHY. MS (Ay)**

**CO-GUIDE**

**Dr. SHAITHYA RAJ. MS (Ay); LECTURER**

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

**SESSION - 2013-2014**

**From,**

**Dr. NEELIMA SHERLY JOHN**

I Year M. S. (Ay) Scholar,

Department of Post Graduate Studies in Shalyatantra

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 Shalyatantra, 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 Viswa Vidyapeetham , Coimbatore as partial fulfillment of M.S. (Ay) in Shalyatantra.

**THE TITLE OF DISSERTATION**

**“OPEN LABEL CLINICAL STUDY TO EVALUATE THE COMPARATIVE EFFECTIVENESS OF GUNAVATI VARTI AND NISHADI TAILA IN LOW ANAL FISTULA.”**

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

Thanking You,

Yours faithfully

**(Dr.NEELIMA SHERLY JOHN)**

**Date:28-05-2014**

**Place :** Vallikkavu

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

*Bhagandara* is enumerated under *Ashta Mahagada*<sup>1</sup> & clinically co-related to Fistula-in-ano. It is a communicating tract lined by unhealthy granulation tissue; opens internally in the anal canal or rectum and superficially on the skin around the anus.<sup>10</sup>

ते तु भगगुदबस्तिप्रदेश दारणाच्च भगन्दर इत्युच्यते

अभिन्न पिडका भिन्नास्तु भगन्दर (सु. नि ४/३)<sup>2</sup>

*Bhagandara* often becomes embarrassing due to pain, itching, and soiling of cloth because of its location, nature and notoriety in healing. In Modern medical science this condition is treated by fistulotomy and fistulectomy that need prolonged hospitalization and chances of recurrence are also common. Economically poor patients cannot undergo these surgical procedures because of its high cost. That is why so many patients with *Bhagandara* are looking forward to be treated by an alternative system of medicine.

The hypothesis postulated in relation to *Gunavati Varti* and *Nishadi Taila* is encouraging in the management of fistula-in-ano. Hence the study is proposed.

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

- Fistulectomy, the procedure where the complete removal of fistulous tract creates a wide open wound takes months together to heal up. It is also an invasive technique which needs general anaesthesia and use of higher antibiotics.
- Fistulotomy, where the fistulous tract is laid open also needs anaesthesia and often the healing may be incomplete and chances of further fistula are common.
- Both procedures are having high recurrence rate.
- *Ksharasutra* ligation being a standard procedure is also accompanied with intolerable pain, discharge, frequent change of *Ksharasutra* and a long period for healing.

To overcome these disadvantages in the present study; the procedures like *Taila prayoga* and *Varti prayoga* are proposed for trial.

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

- The review of literatures includes thorough screening of classical Ayurvedic literatures, Modern textbooks, Journals, internet sources etc.
- *Bhagandara Nidana, Lakshana and Chikitsa* as per Ayurveda classics.
- In *Nadivrana Chikitsa* mentioned as *Poorana* of medicated *Taila* will help in the faster healing of track (Su.Chi17/41 Dalhana)<sup>4</sup>.
- The detailed description of *Nishadi Taila Yoga (Bhagandara chikitsa)* Bhaishajyaratnavali<sup>7</sup> (Chakradutta46/25)<sup>6</sup>

- The detailed description of *Gunavati Varti* as per *Bhaishajya Ratnavali*.<sup>8</sup>
- The detailed description of *Chiruvilwadi Kashaya* as per *Sahasrayoga*.<sup>11</sup>
- Fistula-in-ano as per modern science.

### **Previous work done**

1. Sameer chaudhary-The effect of *Padanakarma* with *Apamargadi lepa* in the management of *Bhagandara* NKJAMC,Bidar, RGUHS,2008
2. Momin Mohsin Bashir Ahmed : A clinical comparative study of *Somaraji Taila* & *Kasisadi Taila* instillation in the management of *Bhagandar*, RGUHS-2009
3. Shivaleela Mallappanavar - Clinical evaluation of *Nishadi Taila Poorana* with the standard *Ksharasutra* in the management of *Bhagandara* –RGUHS-2010
4. Renjith.R.Warier - A comparative clinical study on efficacy of *Kasisadi Taila Poorana* and *Aragwadadi varthi* in the management of *Bhagandara* (fistula-in-ano) RGUHS-2011

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

- 1 To evaluate the efficacy of *Nishadi Taila* in the management of *Bhagandara*.
- 2 To evaluate the efficacy of *Gunavati Varti* in the management of *Bhagandara*.
- 3 To compare the clinical efficacy of *Nishadi Taila* and *Gunavati Varti* in the management of *Bhagandara*.

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

#### **I. SOURCES OF DATA:-**

- Patient will be selected from the Shalyatantra OPD and IPD of Amrita Ayurveda hospital, other nearby hospitals and clinics, diagnosed as *Bhagandara* (Fistula-in-ano) and fulfilling the inclusion criteria.
- After being scrutinized, patients will be registered under the present study.
- Pathological laboratory attached to the hospital.

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

Material required for the present study is *Nishadi Taila* , *Gunavati Varti* and *Chiruvilwadi Kashaya*. It will be prepared in the pharmacy attached to college, according to the textual reference of *Bhaishajyaratnavali* & *Chiruvilwadi kashaya* according to *Sahasrayoga* under the direct supervision of *Dravyaguna* & *Rasasastra* department faculties in Amrita School of Ayurveda.

### **DRUG REVIEW:**

*Nishadi Taila*<sup>7</sup> - The *Nishadi Taila* will be prepared by *Tila Taila* taking as its base after making the *Taila Murchana*. The following ingredients will be mixed with *Murchita taila* as per the *Tailapaka Vidhi* .

San. Name	Bot. Name	Family	Rasa	Guna	Veerya	Vipaka	Therapeutic Use
Nisa	<i>Curcuma Longa</i>	Scitaminaceae	Tikta, Katu	Laghu	Ushna	Katu	Arsa, Bhagandara Nasana.
Arka	<i>Calotropis Procera</i>	Asclepedaceae	Katu, Tikta	Laghu Ruksha	Ushna	Katu	Vrana Sodhana
Sindhu	Rock Salt	Nacl + Kcl	Madura Lavana	Laghu Snigda	Anushna Seetha	Madura	Vrana Naasana
Agni	<i>Semicarpus Anacrdium</i>	Anacardaceae	Madura Kashaya	Laghu Snigda	Ushna	Madura	Kapha Vata Samana
Pura	<i>Commiphora Mukul</i>	Burseraceae	Tikta, Katu	Laghu Ruksha	Ushna	Katu	Vedanasthapana, Vrana Sodhana Ropana,
Vahni	<i>Plumbago Roseae</i>	Plumbaginaceae	Katu Tikta	Laghu Ushna	Ushna	Katu	Arsohara Sodha Hara
Vatsaka	<i>Holorrhena Antidysentrica</i>	Apocynaceae	Tikta, Kashaya	Laghu, Ruksha	Seetha	Katu	Arsohara
Sesame Oil	<i>Sesamum Indicum</i>	Pedaliaceae	Madura Kashaya Tikta	Guru Snigda	Ushna	Madura	Vatahara

**2.Gunavati Varti<sup>8</sup>** –The *Gunavati Varti* will be prepared by taking bees wax as the base with the following ingredients.

San. name	Bot. name	Family	Rasa	Guna	Veerya	Vipaka	Therapeutic use
Sarjarasa	<i>Shorea robusta</i>	Dipterocarpaceae	Kashaya, madura	snigdha	Ushna	Madura	Vranahara, sthambana
Lodhra	<i>Symplocos racemosa</i>	Symplocaceae	Kashaya	Laghu, ruksha	Seetha	Katu	Sravahara, sodhahara, vrana ropana
Sindhura (shoditha)	$Pb_3O_4$	Lead tetroxide	Katu,	Ushna	Ushna	Katu	Vranasodhana ropana
Ativisha	<i>Aconitum heterophyllum</i>	Ranunculaceae	Tikta katu	Ruksha	Ushna	Katu	Sodhahara raktasthambana
Nisa	<i>Curcuma longa</i>	Scitaminaceae	Tikta, katu	Laghu	Ushna	Katu	Arsa, bhagandara nasana.
Aksha	<i>Terminalia bellerica</i>	Combretaceae	Kashaya Tikta	Ruksha, laghu	Ushna	Madura	Krimi nasana, bhedana

Kampillaka	<i>Mallotus philippensis</i>	Euphorbiaceae	Katu	Laghu ruksha	Ushna	Katu	Rakta sodhaka, vrana kshata nasana
Sreevasam	<i>Pinus roxburghii</i>	Pinaceae	Madura, tikta	Snigda,	Ushna	Madura	Rakshogna, durgandahara vrana pranuth
Shoditha Guggulu	<i>Commiphora mukul</i>	Burseraceae	Tikta, katu	Laghu ruksha	Ushna	Katu	Vedanasthapana, Vrana sodhana ropana,
Ghritha			Madura	Guru	Seetha	Madura	Pittahara, vranahara
Taila	<i>Sesamum indicum</i>	Pedaliaceae	Madura, kashaya, tikta	Guru snigda	Ushna	Madura	Vatahara
Sikthaka	<i>Bees wax</i>		Madhura	Snigda	Seetha	Madura	Vranaropana, bhootaghna

#### i) **METHODS OF COLLECTION OF DATA:-**

**1. SAMPLE-**Forty patients will be selected from the recipients, who are suffering from fistula-in-ano and fulfilling the inclusion criteria, reporting to the Shalyatantra OP of Amrita Ayurveda hospital, according to simple random sampling.

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

- Patients with the clinical features of *Bhagandara* (Fistula-in-ano) like soiling of cloth, presence of external opening near the anal canal, pain and discharge on and off ,
- Age in between 20-60, irrespective of sex,
- Low anal fistula,
- Fistula tract measuring less than 3cm,
- Fistula with single external and single internal opening,

will be selected.

#### **3. EXCLUSION CRITERIA:-**

- Patients of age less than 20 and more than 60.
- High anal fistula,
- Multiple fistula,
- Trans sphincteric high anal fistula,
- Inter sphincteric high anal fistula,
- Extra sphincteric fistula,



- Fistula tract measuring more than 3 cm,
  - Patients with Fistulous tracts secondary to some pathology such as Tuberculosis, Crohn's disease, Actinomycosis,
  - Pregnancy ,
  - HIV and HBsAg positive , uncontrolled Diabetes and with other systemic disorders
- will be excluded.

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

### 1. MATERIALS AND METHODS;

- Forty *Bhagandara* patients will be randomly selected according to the inclusion criteria. After proper case taking, investigations and examinations, probing will be performed to find out the length of fistulous tract. Then medicines will be administered in both groups.
- Raw drugs for the preparation of *Gunavati Varti* , *Nishadi Taila*, *Chiruvilwadi kashaya* will be collected from local market under the supervision of faculties of Dravyaguna Department of Amrita school of Ayurveda.

### 2. STUDY DESIGN:

Present study is a comparative clinical study, in which forty patients will be selected on the basis of simple random sampling (SRS) procedure & will be divided in 2 equal groups,

- **G1-Trial 1:** - Patients will be treated with *Nishadi Taila* externally and *Chiruvilwadi Kashaya* internally.
- **G2-Trial 2:** - Patients will be treated with *Gunavati Varti* externally and *Chiruvilwadi Kashaya* internally.

After treatment, the patients will be regularly observed. The changes will be noted in the specially prepared case sheet.

### 3. GROUPING

Forty patients will be selected and randomly categorized into two Groups as Group A (trial 1) and Group B (trial 2)

#### Group A:

Sample size : 20 patients

Drug : *Nishadi taila* externally and *Chiruvilwadi Kashaya* internally.

Procedure : After preparing patient with proper cleaning and probing the tract, luke warm *Nishadi Taila* will be infiltrated into fistulous tract through the nozzle of syringe and it is dressed with a sterile guaze piece.

Dosage : 3 ml  
Duration : Once daily for 28 days.

**Group B:**

Sample size : 20 patients.  
Drug : *Gunavati Varti* externally and *Chiruvilwadi Kashaya* internally.  
Procedure : After preparing patient with proper cleaning and probing, *Gunavati Varti* is taken and made luke warm. It will melt because the base of *Varti* is bee's wax. Then it will be instilled into the fistulous tract through the nozzle of syringe and dressed with sterile gauze piece.  
Dosage : 3 ml  
Duration : Once daily for 28 days

**Follow-up:** The patients of both the group will be followed up for 3 months.

**4 ASSESEMENT CRITERIA:**

Assessment will be done on subjective and objective parameters before and after the treatment. Assessment is done on 0 day, 7th day, 14<sup>th</sup> day, 21<sup>st</sup> day, 28<sup>th</sup> day.

**Subjective parameters:**

- a) Pain. – pain will be assessed by VAS

**Objective parameters**

- a) Discharge –Discharge will be assessed by the soakage of gauze pad
- b) Length of the tract. –length of the tract will be assessed by probing and measuring in centimeters
- c) Healing index - Total length of tract healed divided by healing time in days, (will be measured in millimeters and will be filled in digits.)

**Investigations:**

1. Hb %.
2. BT,CT
3. ESR. .
4. RBS
5. HBsAg, HIV.
6. Chest X-ray (if necessary).
7. MRI-Fistulogram (if necessary)

## 5. STATISTICAL METHODS

Statistical calculations will be done by 'paired t test', f test and anova test

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

Yes, Study require investigations and interventions in *bhagandara* patients using medicated drugs. But no healthy volunteers, cadaver or animals will be used in the study.

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

(Human / animal)

## 5. LIST OF REFERENCES:-

- 1 Acharya Susruta, Dalhana and Gayadasa virachita Sanskrit Commentary, edited by Vaidya Jadavji Trikamji Acharya, Sushruta Samhita, Chaukamba Orientalia Publishers Varanasi. Reprint edition 2009 Sutra Sthana. 33/4 Pg.No - 144
- 2 Acharya Susruta, Dalhana and Gayadasa virachita Sanskrit Commentary, edited by Vaidya Jadavji Trikamji Acharya, Sushruta Samhita Chaukamba Orientalia Publishers Varanasi. Reprint edition 2009 . ,Nidana sthana 4/3 ,Pg.No280
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- 4 Acharya Susruta, , Dalhana and Gayadasa virachita Sanskrit Commentary, edited by Vaidya Jadavji Trikamji Acharya,Susrutha Samhitha Chaukamba Orientalia Publishers Varanasi. Reprint edition 2009 Chikitsa Sthana.17/41, Pg.No465
- 5 Acharya Vaghbata, Ashtanga Hridaya with Arunadatta and Hemadri Virachita Sanskrit commentary 2007<sup>th</sup> edition. Chaukambha Surabharati Publication-Varanasi .Uttara tantra 28/29 Pg.No879
- 6 P.V.Sharma, Chakradutta 3<sup>rd</sup> edition, Chaukambha Publishers. 46/25 Pg.No 379.
- 7 Shri Govinda Das edited by Bhishagratna Shri Brahmasankar Mishra,commented by Shri Ambikadutta Shastri English commentary 2007<sup>th</sup> edition, Bhaishajya Ratnavali. Chaukambha Sanskrit bhavan- Varanasi. 51/40. Vol.III Pg.No 11.
- 8 Shri Govinda Das edited by Bhishagratna Shri Brahmasankar Mishra,commented by Shri Ambikadutta Shastri English commentary 2007<sup>th</sup> edition, Bhaishajya Ratnavali. Chaukambha Sanskrit bhavan- Varanasi. (50/7,8). Vol.II Pg.No 780.

**9** Bailey & love's Short practice of Surgery.

Edited by- Russell(M.S. FRCS), Norman S Williams(FRCS),Christopher J.K. Bulstrode (FRCS), Arnold Hodder Headline group ;London, 24<sup>th</sup> Edition 2004;  
Chapter no. 72- The Anus & Anal canal, Page no.- 1265 to 1268

**10** S.Das – A Concise Textbook of Surgery.Published by Dr,S Das(F.R.C.S.);  
Kolkata

7<sup>th</sup> edition, 2012, chapter 45 ,The Rectum & Anal canal. Page no.- 1071 to 1074.

**11** Sahasra yogam edited by T.B.Pandita Rao, Sarada Nair, MahendraPal Singh  
Aarya, 2011edition, Kendriya Ayurvedeeya Vijnan Anusandhan Parishath.  
Page No 27



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: Dr. M. R. VASUDEVAN NAMPOOTHIRI MD

Principal, Amrita School Of Ayurveda

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**TOP**



**AMRITA SCHOOL OF AYURVEDA**  
**AMRITA VISWA VIDYAPEETHAM**  
**(University Under Sec.3 UGC Act 1956)**

**PROFORMA FOR REGISTRATION OF SYNOPSIS FOR DISSERTATION FOR**  
**AYURVEDA DHANWANTARI (M.S Ay) IN SHALYATANTRA**

**“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE MANAGEMENT  
OF FISSURE-IN-ANO BY DURVAADI KERA TAILA”**

**BY**  
**SREEDEVI V**

**GUIDE**  
**Prof. Dr. RABINARAYAN TRIPATHY. MS (Ay),**

**CO-GUIDE**  
**Dr.SHAITHYA RAJ. MS (Ay),**  
**LECTURER**

**DEPARTMENT OF PG STUDIES IN SHALYATHANTRA**  
**AMRITA SCHOOL OF AYURVEDA**  
**CLAPPANA P.O, VALLIKKAVU, KOLLAM**  
**KERALA – 690525**

**Session - 2013-2014**

**From,**

**Dr. SREEDEVI V,**

I year M. S. (Ay) Scholar,

Department of Post Graduate Studies in Shalyatantra

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

**To,**

The Registrar,

Amrita Viswa Vidyapeetham, Ettimadai, Coimbatore, Tamilnadu

**Through** - The Principal & Head of Department of P.G. Studies in Shalyatantra,

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 Viswa Vidyapeetham, Ettimadai, Coimbatore as partial fulfillment of M.S. (Ay) in Shalyatantra.

**THE TITLE OF DISSERTATION**

**“UNCONTROLLED SINGLE ARMED CLINICAL STUDY IN THE  
MANAGEMENT OF FISSURE-IN-ANO BY DURVAADI KERA TAILA”**

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

Thanking You,

Yours faithfully,

**(Dr.SREEDEVI V)**

**Date: 28-05-2014**

**Place:** Vallikkavu

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

The major factors thought to influence the human susceptibility to diseases are diet and life style. The variations in these lead to altered bowel habit and diseases associated with it. Anal fissure is one such disease.

Anal fissure is an elongated ulcer in the long axis of the lower anal canal<sup>1</sup>. It is described as an acute superficial break in the continuity of anoderm usually in the posterior midline of anal margin<sup>2</sup>. The common cause is trauma due to passage of hard stool followed by chronic infection<sup>3</sup>. Spasm of external anal sphincter is common and associated with local pain<sup>4</sup>. It affects all age groups with an equal incidence irrespective of sex<sup>5</sup>. Symptoms include sharp pain, hyper-sensitivity, tearing feeling in anus especially during bowel movement, fresh blood in stool and on wiping, visible tear and / or external skin tag at the lower end of fissure<sup>6</sup>.

*Parikartika* is a similar condition explained in Ayurveda in which patient has excruciating cutting pain around anus<sup>7</sup>. Acharya Susruta documented it as *Virechana* and *Vasthi vyapat*<sup>8</sup>. Carakacharya described it as *Vasti-vyapat*, *Virechana-vyapat*, *Vasthinetra-vyapat*, complication of *Vatajaatisara* and due to excessive use of *Yapana vasthi*<sup>9</sup>. Acharya Vagbhata enumerated it under complication of *Vatajaatisara*<sup>10</sup> and with reference to Kasyapa Samhita the disease is prevalently seen in gravid women<sup>11</sup>.

Anal spasm results in severe pain, tearing of anoderm and decreased blood supply. The cycle of spasm, pain and ischemia contributes to the development of a chronic ulcer<sup>12</sup>. Keeping in view these factors, *Durvaadi taila*<sup>13</sup> which is highly praised in the management of *Vrana* is proposed, after substituting the *Tila Taila* with coconut oil (*Kera Taila*), to study the efficacy in the management of fissure in ano. The present treatment modalities for fissure include lateral sphincterectomy, chemical sphincterectomy, topical anaesthetics, botulinum injections etc which has many untoward effects. So a simple method which is having better patient compliance is suggested in this study.

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

- Lateral internal sphincterectomy bears risk of anesthesia, peri-anal infection, hemorrhage, fecal incontinence, urinary retention. Flatus and fecal incontinence are the significant concerns which have been observed in as many as 35.7% cases<sup>12</sup>.
- Chemical spincterectomy with nitrates generate headaches in 20-40% cases<sup>12</sup>.
- Botulinum toxin injection causes excessive weakness of anal sphincters and or injury to anal wall tissues. Transient incontinence to feces (5%) and flatus (18%), peri anal thrombosis and hematoma<sup>12</sup>.



- Search for cost effective and potent therapy to manage fissure in ano.
- *Durvaadi Taila* is an effective remedy for healing. The area of study is in Kollam district of Kerala where *Kera Taila* is easily available and widely used for therapeutic purpose, hence the *Tila Taila* was replaced with *Kera taila* to make it feasible to the patient.

All the above points suggest the necessity of opting a study for Clinical management of fissure using *Durvaadi Kera Taila*.

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

It includes an exhaustive screening through the Ancient Compendium , relevant contemporary text books of Ayurveda, Modern books of surgery, medicine, physiology, & pharmacology, Journals, magazines, seminars, conferences, digital library & web sites.

- *Nidana* of *Parikarthika* from *Su.Sa.Chi/36/36*, *Chi.36/16*, *Ca.Sa.Si.6/61*, *Ca.SaSi.7/56*, *Ca.Sa.Si.5/5*.
- *Lakshanas* has been mentioned in *Su.Chi.34/16*, *Ca.Si.6/62*, *Ca.Si.7/55*
- Description of *Durvaadi Taila* from *Sahasrayogam*, *Taila Kalpanas*, modified preparation by substituting *Tila Taila* with *Kera Taila*.
- Fissure in ano from modern textbooks.

**The list of previously done research work (dissertation)** related to the present work are enlisted :

1. Mukkera Gautham Kumar- Effect of *Ropana Lepamam* and *Vyswanara Choorna* in the Management of *Parikartika* (Fissure in ano); Dr.B.R.K.R. Ayurvedic College; Hyderabad; 2003.
2. Kumar Sachin- Clinical Study on *Parikarthika* with *Karpooaraadi Ghrita*, SDM College of Ayurveda; RGUHS, Hassan; 2005.
3. Rachana- Clinical Study on the Management of Fissure in ano (*Parikartika*) using *Karpura Ghrita*, NKJAMC, Bidar, RGUHS, 2006.
4. Suchith M.S- Management of Fissure-in-ano with *Shata Dhautha Ghrita*, Alvas Ayurveda Medical College, Moodabidri, RGUHS , Bengaluru; 2008.
5. Abhinetri Hegde- Management of Fissure-in-ano (*Parikarthika*) with *Doorva Taila* and *Yasti Madhu Taila*- A Comparative Study. Govt Ayurvedic Medical College, Bengaluru, RGUHS; 2010.

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

1. To study the effect of *Durvaadi Kera Taila* in anal fissure.
2. To study the clinical effect of *Durvaadi Kera Taila* in different signs and symptoms of anal fissure
3. To derive a standard, easily accessible and cost effective therapy for the management of fissure -in -ano.

## 2. MATERIALS AND METHODS:

### I. SOURCES OF DATA:-

The study is strictly confined to the cases of anal fissure, hence patients will be collected as per inclusion criteria from the Out Patient Department of Amrita Ayurveda Hospital, Vallikkavu, Kollam and other nearby hospitals and clinics. After careful scrutiny the patients will be registered under the present study.

### II. MATERIALS REQUIRED FOR THE STUDY:-

The required materials are *Durva* and *Kera Taila*. The *Durvaadi Kerataila* will be prepared by *Kera taila* taken as its base. The *swarasa* and *kalka* of *durva* will be mixed to *Kera taila* as per classical method of *taila paka vidhi*.

**DRUG REVIEW:** The formulation contains the following ingredients:

Name	Botanical Name /Family	Rasa	Guna	Veerya	Vipaka	Therapeutic Use
<i>Durva</i>	<i>Cynodon dactylon</i> Poaceae	<i>Kashaya,</i> <i>madhura</i>	<i>Laghu</i>	<i>Sita</i>	<i>Madhura</i>	<i>Vranyam,</i> <i>Dahaharam,</i> <i>kapha pitta hara</i> <i>Twak doshagna</i>
<i>Kera</i> <i>Tila</i>	<i>Cocos nucifera</i> Arecaceae	<i>Madhura</i>	<i>Guru</i> <i>Snigdha</i>	<i>Sita</i>	<i>Madhura</i>	<i>Kshate</i> <i>hitam, Vajeekara,</i> <i>Dhatuposana</i> <i>Vata pitta hara</i>

### i) METHODS OF COLLECTION OF DATA:-

#### 1. SAMPLE

Number of patients is 30 and is selected as per simple random sampling.

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

- iii) Patients in between 15 - 60 years of age, irrespective of sex.
- iv) Patients suffering from anal fissure with or without sentinel pile.
- v) Fissure at 6'O clock and 12'O clock positions.
- vi) Fissure with a history of more than 7 days of symptoms.
- vii) Patients with pain during defecation and with linear ulcer on inspection at the muco-cutaneous junction.
- viii) Patients complaining of severe burning sensation in anus after defecation.
- ix) Patients with complaints of streaks of blood over stools.

## **3. EXCLUSION CRITERIA:-**

- i) Patient less than 15 years of age and above 60 years.
- ii) Patients suffering from anal fissure with other ano-rectal diseases like piles, fistula, abscess etc.
- iii) Patients having anal carcinoma, papilloma, ulcerative colitis, Crohn's disease, syphilitic fissure, tubercular ulcer & fistula.
- iv) Patients having other systemic pathology (TB, DM, HIV/AIDS, HBsAg, +ve & VDRL).
- v) Fissure at positions other than 6'O clock and 12'O clock.

## **ii. PROCEDURE AND DESIGN OF STUDY**

The study will be a randomized control study in which 30 patients will be selected on the basis of simple random sampling (SRS) procedure. After proper Case taking, examination and investigations, data will be recorded in specially designed case sheets.

Raw drugs for the preparation of *Durvaadi Kera Taila* will be collected from the local available sources under the guidance of *Dravyaguna* Department of Amrita School of Ayurveda.

## **1. MATERIALS AND METHODS**

Consent will be obtained from the patient / guardian for the study. For the selection of patients, to evaluate the morbidities and to assess the progress during and after treatment, investigations will be carried out in the Pathological laboratory attached to the hospital.

*Taila* will be prepared in the pharmacy attached to the hospital under the guidance of faculties in *Bhaishajya Kalpana* and *Dravya guna* Department of Amrita School of Ayurveda

## **2. DESIGN OF THE STUDY**

The present study is an uncontrolled single arm clinical trial to manage the fissure in ano using *Durvaadi Kera taila*. Thirty patients diagnosed with fissure will be selected randomly and registered in the study.

## **3. GROUPING AND TREATMENT/PROCEDURE**

All the 30 patients will be included under the present clinical trial procedure.

The patient will be in lithotomy position; manual anal dilatation up to two fingers will be done for two minutes after applying topical anaesthesia.

### **• TRIAL GROUP**

Sample size : 30 patients

Drug : *Durvaadi Kera Tailam*

Procedure : After cleaning of site, prepared trial drug will be administered through the anal canal using a 2ml disposable syringe

Dose : 2ml

Duration : Once daily for 7 days

Patient will be asked to lie on the table for 15 minutes and during this time a pillow will be kept under the pelvic region. After the speculated observation time, a gauze pad will be given to avoid the spillage of oil.

A specially prepared chart for *Ahara* and *Vihara* will be given to all patients and hot Sitz bath will be advised 2 times, daily for 15 minutes. The treatment will be done for 7 days.

**FOLLOW UP** will be done on 14<sup>th</sup> day and 28<sup>th</sup> day.

**4. ASSESMENT CRITERIA:** - Assessment will be done on subjective and objective parameters before and after treatment on 0 day & 7<sup>th</sup> day for the noting the efficacy of trial treatment, on 14<sup>th</sup> day and 28<sup>th</sup> day for recurrence study. The changes will be noted in the specially prepared case sheet.

### **SUBJECTIVE PARAMETERS:-**

- |                                      |  |
|--------------------------------------|--|
| i) Pain (MRC Grading / VAS of pain). | iv) Discharge                              |
| ii) Burning sensation                | v) Pruritus ani                            |
| iii) Constipation.                   | vi) Bleeding (Nature, character & amount). |
| iv) Sphincteric Spasm                |  |

### **OBJECTIVE PARAMETERS:-**

- i) Healing of ulcer.
- ii) Wound / Healing index = size of wound / time of healing in days.

**INVESTIGATION REQUIRED:** The necessary investigation if required will be done

8. Hb%
9. BT,CT
10. ESR
11. RBS
12. HBsAg, HIV
13. VDRL
14. Chest X RAY and MANTOUX TEST if Tuberculosis is suspected.

### **STATISTICAL METHODS**

Statistical calculations will be done 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 the study requires investigations and interventions on fissure-in-ano patients using medicated drugs. But no Healthy Volunteers, Cadaver or animals will be used in this study.

**4. Has ethical clearance been obtained from your institution? YES**  
**(Human / animal)**

### **5. LIST OF REFERENCES:-**

1. Bailey and Love's Short Practice of Surgery, Edited by RCG Russel, Norman S Williams, Christopher , J K Bulstrode, Arnold Hodder Headline group; London, 24<sup>th</sup> International Students Edition , Chapter 72 .The Anus and Anal Canal/Page 1252-1254.
2. Richard .S. Snell, Clinical Anatomy by Regions, Editors- Wolters Kluwer, Lippincott Williams and Wilkins, Edition. 8<sup>th</sup>, Chapter 8<sup>th</sup> Perineum, Page 396.
3. HarshMohan, Textbook of Pathology, Jaypee Publications, 12<sup>th</sup> Edition, Chapter 18<sup>th</sup> The Gastro-intestinal Tract /Page 597.
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5. The ASCRS Textbook of Colon and Rectal Surgery; Edited by Dykes S L Madoff RD, Wolff B G , Fleshman, J W Beck, DE Pemberton, Wexner S D ,Springer science and Bussiness Media New York, Chapter 1-Beningn Ano Rectal Fissure/Page 178-191.
6. John Hopkin's Family Health Book, Harper Collins Publishers , Part-4 Body Systems and Disorders/Page 1024.
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- 9.Acharya Agnivesha, revised by Dridhabala, with Cakrapanidutta Commentary-Ayurveda Dipika, CARAKA SAMHITHA, (Eds) Vaidya Yadavji Trikamji Acharya, Chaukhambha Prakashan, Varanasi, Reprint editn-2007,Chapter Si.6<sup>th</sup> /62,Si.7<sup>th</sup> 5/45, Si.12<sup>th</sup> /30,Chi.19<sup>th</sup> /5, pages 707,709,735,548.
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11. Acharya Vridha Jeevaka, KASHYAPA SAMHITHA, revised by Vatsya, Chaukhambha Sanskrit Santhan, Varanasi, Reprint edn. 2010, Chapter 10 Antharvarthni Chikitsitaadhyaya/102, page 299.
12. <http://www.wignet.com> ,Practice parameters for the management of Anal Fissure,Perry Wb,(Edited by Dykes SL,Buie WD,Raffery J F),3<sup>rd</sup> revision 2010 edition,53<sup>rd</sup> dis/1110-1120
13. *Sahasra yogam*, Edited by T.B.Pandita Rao,Sarada Nair,MahendraPal Singh Aarya,2011 edition,Kendriya Ayurvedeeya Vijnan Anusandhan Parishath,page 260
14. Illustrated Dravya Guna Vijnana, (Study of Essential Medicinal Plants in Ayurveda,) J.L.NShastry, ChaukhambhaOrientalia Publications, Varanasi.

\*\*\*\*\*

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**Signature with Official Seal** :

**Name & designation of**

**Head of Department** : Dr.RABINARAYAN TRIPATHY. M S. (Ay)

Prof.& H.O.D, P.G.Dept.of.Shalyatantra.

**Signatures with official seal** :

**Name & designation of**

**Head of Institution** : Dr.M.R.VASUDEVAN NAMPOOTHIRI M.D (AY)

Principal, Amrita School of Ayurveda.

**Signatures with official seal** :

**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.S(Ay) IN SHALYATANTRA**

**“OPEN LABEL CASE CONTROLLED CLINICAL STUDY TO EVALUATE THE  
EFFECTIVENESS OF NYAGRODHADI GANA IN BHAGNA SANDHAANA.”**

**BY  
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**SESSION - 2013-2014**



**From**

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**To**

The Registrar, Amrita Viswavidyapeetham, Coimbatore, Tamilnadu.

Through, - The Principal & Head of Department of P.G. studies in Shalya-Tantra, Amrita  
School Of Ayurveda, Vallikkavu, Clappana. 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 Viswa vidyapeetham, Coimbatore , Tamilnadu, as partial fulfillment of M.S. (Ay) in Shalya-Tantra.

THE TITLE OF DISSERTATION:

**“OPEN LABEL CASE CONTROLLED CLINICAL STUDY TO EVALUATE THE  
EFFECTIVENESS OF NYAGRODHADI GANA IN BHAGNA SANDHAANA.”**

I am enclosing completed proforma for Registration of Subject of dissertation.

Thanking you.

Yours faithfully

**(Dr. P.Suresh)**

**Place:** Vallikkavu

**Date:** 25-04-2014

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

Trauma is a major problem worldwide, due to widespread industrialization and use of vehicles, where incidence of accidents resulting in fracture and soft tissue injury is higher.

A fracture is a complete or incomplete break in the continuity of a bone or a crack. Ayurvedic texts have illustrated fracture as being the loss in the continuity of the bone due to pressure. Fractures commonly results following injuries<sup>1</sup>. However, the incidence of the long bone fracture is higher and thus, demands special attention. The management of long bone fracture runs through the basic principle of fracture management viz -1.Reduction, 2. Retention and 3. Rehabilitation. Even after following basic principles, sometimes the fractures may not heal properly and leads to complications like non-union, mal-union, avascular necrosis, shortening of limbs etc<sup>3</sup>.

According to the modern principles of management, fracture is reduced, immobilized and then, the role of medicine is negligible. Only some NSAID, Calcium supplements etc. are given to meet the symptomatic demand. But in ancient treatise so many indigenous compounds are mentioned which can promote the healing of fracture. With reference to Ashtanga Hrudaya, an indigenous compound named as Nyagrodhadi gana is also praised for bhagna sandhaana, ie fracture healing. Hence the present study was proposed to find out the effect of Nyagrodhadi gana on healing of fracture.

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

- The incidence of hospital occupancy due to fractures is very high and almost always incapacitating the individuals, bringing about a sudden stoppage of their daily activities, hindering their routine work , more severely affecting the elderly and have tremendous impact on both the health system and society in general<sup>4</sup>.
- In delayed healing, no proper medicine is prescribed in modern medicine. To reduce long term hospitalization and to make cost effective treatment with easily available drug, the present study is designed.
- While considering various factors and complications in fracture healing, it is essential to assess the different mode of actions of number of Ayurvedic drugs insisted by various Sages in the acceleration of fracture healing.
- Nyagrodhadi Gana described in Ashtanga Hrudaya Sutrasthana can be used as internal medication for 'bhagna sandhaana'<sup>5</sup>. Keeping in view the above factors, to

evaluate the efficacy of Nyagrodhadi gana on simple fractures, the present study is proposed.

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

- In Susrutha Samhitha Nidana sthana 15<sup>th</sup> chapter, Acharya describes about different nidanas which leads to injury as well as different types of fractures and dislocation<sup>6</sup>. Specific symptoms are clearly detailed in this chapter. In Chikitsa Sthana 3<sup>rd</sup> chapter the treatments are well explained.<sup>7</sup>

### **Previous research done:**

- Prabhakar Ramnarayan : Comparative study of Asthi Samharadhi compound and Peeta Varatika bhasma in Fracture healing, IPGT&RA, Jamnagar Gujarat Ayurveda University – 2000.
- Veerendra.K.Meenkire : The Management of Simple Fracture with Rasonadi yoga Internally and Kusumbhadya taila External application, NKJAMC Bidar, RGUHS - 2004
- Sanjeev Tiwary: Clinical Management of Urvasthi Griva Bhagna with Gandha taila, NKJAMC Bidar, RGUHS -2007
- Warang Sukesh: Clinical Study on the Management of Simple Long Bone Fracture with Asthismharadi Churnam Internally and Kusumbhadi taila External application, NKJAMC Bidar, RGUHS -2008.

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

- To study effect of Nyagrodhadi gana in bhagna sandhaana.
- To evaluate the efficacy of Nyagrodhadi gana on callus formation.
- To evaluate the efficacy of Nyagrodhadi gana on serum calcium.

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

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

- i) Patients with simple long bone fractures will be selected from the Amrita School of Ayurveda Hospital, Clappana, Kollam.
- ii) Samhita, modern books of Surgery, Medicine, Physiology, & Pharmacology.
- iii) Journals, Magazines, Seminars, Conferences, Digital library & Web sites.
- iv) Pathological laboratory attached to the hospital.

## II. MATERIALS REQUIRED FOR THE STUDY:

Nyagrodhadi gana will be prepared as per the classical reference as mentioned in Sharangadhar Shamhita under the supervision of Bhaishajya kalpana and Dravya guna Department s of Amrita School of Ayurveda.

San. Name	Bot. Name	Family	Rasa	Guna	Veerya	Vipaka	Karma
Nyagrodha	Ficus Benghalensis	Moraceae	Kashaya, Madhura	Guru	Seetha	Madhura	Kapha-Pitta Naasana
Pippala	Ficus Religiosa	Moraceae	Kashaya	Rooksha	Seetha	Madhura	Kapha Pithaghna
Sadaaphala	Ficus Racemosa	Moraceae	Madhura	Guru Rooksha	Seetha	Madhura	Kaphapitta Hara
Lodram	Symplocos Conchinchinensis	Symplocaceae	Kashaya	Rooksha	Seetha	Madhura	Kaphahara
Swetha Lodhram	Symplocos Laurina	Symplocaceae	Kashaya	Rooksha	Seetha	Madhura	Kaphahara
Jambu	Syzgium Jambolum	Myrtaceae	Tikta, Kashaya, Madhura	Guru Rooksha	Seetha	Katu	Kaphapitta Hara
Jambu	Syzgium Cumini	Myrtaceae	Tikta, kashaya, madhura	Guru Rooksha	Seetha	Katu	Kaphapitta Hara
Arjuna	Terminalia Arjuna	Combretaceae	Kashaya	Snigdha	Seetha	Madhura	Kaphahara, Vrana Nasana
Kapeethana	Ficus Arnottiana	Moraceae	Madhura	Snigdha	Seetha	Madhura	Krimi suklakaphaprad
Soma Valkam	Acacia Polyantha	Mimosaceae	Madhura Kashaya	Guru Snigdha	Seetha	Madhura	Pithahara
Plaksham	Ficus Microcarpa	Moraceae	Kashaya	Guru	Seetha	Katu	Raktapittahara
Aamram	Mangifera Indica	Anacardiaceae	Kashaya, Amla	Guru	Seetha	Amla	Kaphapitta Hara
Vanjula	Homonoia Riparia	Euphorbiaceae	Madhura	Snigdha	Seetha	Madhura	Mutrala
Priyala	Buchraria Latifolia	Anacardiaceae	Madhura	Guru Sara Snigdha	Seetha	Madhura	Vrushya, Vata Pitta Hara
Palasam	Butea Monosperma	Fabaceae	Katu Thikta Kashaya	Laghu Snigdha	Ushna	Katu	VataKapha Hara

Nandi	Tuna Ciliate	Meliaceae	Kashaya Thiktha Madhura	Laghu	Seetha	Katu	Vata Kaphahara
Koli	Zizuphus Mauritiana	Rhamnaceae	Madhura, Amla	Guru Snigdha	Seetha	Madhura, Amla	Vatapitta Hara
Kadambam	Anthocephalus Indicus	Rubiaceae	Thikta Kashaya	Guru Rooksha	Seetha	Katu	Vedana sthaapana
Viraalam	Diospyros Tomethamnosa	Madhura	Kashaya	Laghu Rooksha	Seeetha	Katu	Grahi
Madhookam	Madhuca Langiifolia	Sapotaceae	Madhura, Kashaya	Guru Snigdha	Seeetha	Madhura	Vata Pitta Hara
Madhukam	Glycyrrhiza Glabra	Fabaceae	Madhura	Guru	Seetha	Madhura	Vrushya Vranasodhana Ropana

POP bandage rolls, Cotton, Gauze as required, will be purchased from hospital pharmacy.

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

**1. Sample:** It is a clinical study in which 40 patients will be selected on the basis of simple random sampling (SRS) procedure.

#### **2. Inclusion Criteria:**

1. Patients between 25-60 year, irrespective of sex.
2. Patients with simple fractures.
3. Fracture with history of trauma.
4. Fracture diagnosed by radiograph.

#### **3. Exclusion Criteria:**

1. Patients aged below 25 years and above 60 years.
2. Patients having other systemic pathology (TB, Osteoporosis, etc..)
3. Multiple, Compound or Comminuted fracture.
4. Fracture associated with visceral injury.

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

The study is an open clinical study in which 40 patients will be selected on the basis of simple random sampling (SRS) procedure & will be divided in 2 equal groups. Consent will be obtained from the patients who are registered for the trial.

## 1. MATERIALS AND METHODS:

1. POP bandage rolls, Cotton,Guaze – as required.
2. The raw drugs of Nyagrodhadi gana .

### Design of The Study:

Patients will be clinically examined thoroughly and radiograph will be used for diagnosis. After confirmation, patients will be registered in the OPD of the College hospital and will be divided in 2 equal groups.

### Grouping and treatment / Procedure:

- **G1- Trial group:** - Patients will be given Nyagrodhadi gana in Kwatha form 50 ML twice daily.
- **G2 - Control group:** - Patients will be treated by the basic principle of fracture management.

Initially all the patients will be treated with reduction and immobilization . During treatment, the patients will be regularly observed. The changes will be noted in the specially prepared case sheet. The observations will be analyzed on the basis of assessment parameters (both subjective & objective) critically & scientifically; before, during & after treatment on 0<sup>th</sup>, 15<sup>th</sup>, 30<sup>th</sup> & 45<sup>th</sup> day.. Finally the result will be statistically evaluated for its significance.

### Assessment Criteria:

The clinical assessment will be done with the initial finding through clinical, Pathological and radiological statements & compared with the result of changes on 15<sup>th</sup>, 30<sup>th</sup>, & 45<sup>th</sup> day.

1. Pain: assessed by medical research council grading of pain & by VAS (visual analog scale).
2. Swelling: By measuring the circumference in cm and comparing with the normal limb.
3. Tenderness: Elicited by the back of the thumb on first day, On 15<sup>th</sup>, 30<sup>th</sup> & 45<sup>th</sup> day by springing Test.
4. Loss of function.
5. Shortening: By comparing with the normal limb.
6. Test of Union: Mobility between fragments & Pain with angulations' stress.
7. Radiograph: Visible callus on X-ray.

**Investigations:**

DC, TLC, Hb%	HIV, HbsAg
Serum Calcium.	ESR
Blood Sugar	X – Ray

**Statistical Methods:** Statistical calculations will be done to find out the significance by 'Paired T test' & Annova 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:**

Study will be conducted on the patients with simple fracture only. No animal experiments will be conducted.

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

**LIST OF REFERENCES:**

1. R M Shenoy, Essentials of Orthopedics, Jaypee Brothers Medical Publisher's (p) Ltd. New Delhi, First edition 2010, Chapter 1, page 6.
2. S. Das – A Practical Guide to Operative Surgery. Published by Dr. S Das (F.R.C.S.); Kolkata; 5<sup>th</sup> edition, 2007, chapter 9, Page no. - 99-105
3. Bailey & Love's Short practice of Surgery. Edited by- Russell (M.S. FRCS), Norman S Williams (FRCS), Christopher J.K. Bulstrode (FRCS), Arnold Hodder Headline group; London, 24<sup>th</sup> Edition 2004; Chapter no. 27 page no. 341-350
4. Dr. J. Maheswary, Essential Orthopedics, Jaypee Brothers Medical Publisher's (p) Ltd. New Delhi, Fourth edition 2011, Chapter 1, page no. 13.
5. Acharya Vagbhata, Ashtanga Hrudaya, Aruna Datta's Sarvangasundara and Hemadri's Ayurveda rasayana Sanskrit commentary edited by Pt. Hari Sadasiva Sastri Paraadakara, Chaukamba Sanskrit Sansthan, Varanasi, Reprint edition 2012, Suthra Sthana Chapter 15, sl.no. 41-42, page no. 239.
6. Acharya Sarngadhara, Sarngadhara samhita, edited by Sreekantha Murthy, Chaukamba Sanskrit Bhavan, Sixth Edition 2006 Madhyama kanda, Ch. 2/162, page no. 75
7. Acharya Susruta, Susruta Samhita, Dalhana's Nibandha sangraha Sanskrit commentary edited by Yadavji Thrikamji Acharya, Chaukamba Krishnadas Academy Publications, Reprint edition 2008. Nidana sthana chapter no. 15/sl.no. 3/page no. 328.
8. Acharya Susruta, Dalhana and Gayadasa virachita Sanskrit Commentary, edited by Vaidya jadavji trikamji acharya, Susruta Samhitha Chaukamba Orientalia Publishers Varanasi. Reprint edition 2009 Chikitsa Sthana. 3/3-70, Pg. 415-420.



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