

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

Department of PRASOOTITANTRA AND STREEROGA

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27.	Dr. Anjali M V	“Pharmaceutical Development Of Śirīsādi Cūrna, Safety Analysis And An Open Label Pre And Post Test Clinical Study To Assess Its Efficacy In Kikkisa (Striae Gravidarum)”	Dr. Hemavathi. S. K	
28.	Dr. Parvathy Unnikrishnan	Open Label Single Arm Clinical Study To Evaluate The Effect Of Rasnadi Sulahara Kshirapaka In Primary Dysmenorrhoe With Reference To Kastartava”	Dr. A. Nalinakshan	
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From

DR. ANJALY. M. V

Preliminary M. S. (Ay) Scholar,

Department of Post Graduate Studies in Prasūtitantra & Strīroga

Amrita School of Ayurveda, Vallikkavu, Kollam

To

The Registrar,

Amrita Viswa Vidyapeetham,

Coimbatore,

Tamilnadu

Through:

The Principal & Head of Department of P.G. studies in Prasūtitantra & Strīroga, Amrita School of Ayurveda, 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 for partial fulfillment of M.S. (Ay) in Prasūtitantra & Strīroga to the **Amrita Viswa Vidyapeetham University Coimbatore.**

THE TITLE OF DISSERTATION

“PHARMACEUTICAL DEVELOPMENT OF ŚIRIṢĀDI CŪRNA, SAFETY ANALYSIS AND AN OPEN LABEL PRE AND POST TEST CLINICAL STUDY TO ASSESS ITS EFFICACY IN KIKKISA (STRIAE GRAVIDARUM)”

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

Thanking You,

Date: 28/05/2014

Place: Vallikkavu

Yours faithfully,

DR. ANJALY.M.V

**AMRITA SCHOOL OF AYURVEDA
AMRITA VISWA VIDYAPEETHAM
DEEMED UNIVERSITY
ETTIMADAI-COIMBATORE
(University under sec.3 UGC Act 1956)**

**PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION FOR
AYURVEDA DHANWANTARI (M.S) IN PRASŪTITANTRA & STRĪROGA**

**“PHARMACEUTICAL DEVELOPMENT OF ŚIRĪṢĀDI CŪRNA, SAFETY
ANALYSIS AND AN OPEN LABEL PRE AND POST TEST CLINICAL STUDY
TO ASSESS ITS EFFICACY IN KIKKISA (STRIAE GRAVIDARUM)”**

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Session - 2013-2014

1. BRIEF RESUME OF THE INTENDED WORK

I. NEED FOR THE STUDY:

Kikkisa is a tridoshaja condition which appears in the 7th month of pregnancy. It is characterized by Vidāha (burning sensation), Kandu (itching) and Rekhāsvaroopa Twak Sankocha (linear striae) caused by the displacement of tridosha upwards by the growing fetus.^{1, 2, 3, 4, 5} The causative factors and symptomatology of Kikkisa has close resemblance with Striae Gravidarum.

- Striae Gravidarum are the depressed linear marks with varying length and breadth found in pregnancy, predominantly in the abdominal wall below the umbilicus sometimes over the thighs and breasts. Apart from the mechanical stretching of the skin, increase in the aldosterone production during pregnancy is the responsible factors. It creates health issues such as itching, burning and emotional distress^{6, 7}.
- Stretch marks are not an illness but many women are upset by the appearance of such marks during pregnancy especially due to its cosmetic nuisance. The current literature suggests that in the general population, there is a 50%-90% prevalence of striae associated with pregnancies.⁸
- There are several methods available today for managing stretch marks which involve even invasive procedures like laser surgeries, dermabrasions, tummy tuck, which could be expensive and painful. Even more important than the treatment, is the knowledge imparted to a worried mother that her child will be fine and that the management is without complication and priceless.
- In Ayurveda many preparations are mentioned for the Kikkisa like Pāna, Lēpa, Abhyanga, Parishēka which are very easy to prepare, safe to use, and without any side effects and also cost effective. Hence an attempt will be made in present study to evaluate the efficacy of śirīṣadi choorna in the management of Kikkisa which will be prepared in an easiest form (cream) for easy application.
- OP based procedure can be adopted along with antenatal check-up which is convenient for the patient so that she can resume with day to day activities.

All these factors aim at the need for a study on clinical management of kikkisa with śirīṣadi choorna.

II. REVIEW OF LITERATURE:-

- Review of kikkisa includes screening of classical literature, Sanskrit dictionaries, from other authentic text books in Ayurveda, journals and from previous research on this topic.
- Review of striae gravidarum includes screening of modern books of obstetrics and gynecology, medical dictionaries, journals, internet sources, digital libraries and from the previous research.
- Detailed description of śirīṣadi choorna will be collected from classical literature, Ayurvedic Pharmacopeia of India, books on dravyaguna sastra, modern books on pharmacology, magazines and from previous research on these drugs.

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

1. Sudhakaran - Clinical study on effect of chandanadi taila on kikkisa, Kerala (1999).
2. Rana S.S - A clinical study of Kikkisa and its management with Kikkisahara ghrta and kikkisahara lepa w.s.r to striae gravidarum, Gujarat ayurveda university Jamnagar (2005).
3. Joshi Jalpa - Savarnakara ghrta-savarnakara cream-Kikkisa-Striae Gravidarum”, IPGT & RA, GAU, Jamnagar (2007)
4. M A Reshma – Clinical Evaluation of External Application on Kikkisa W.S.R to Straie Gravidarum, A Comparative Study, Sri Kalabylaveshwara Swamy Ayurvedic Medical College, Hospital & Research Centre Bangalore (2011).
5. Kavitha – A Comparative Study Of Shirishadi Taila and Karanja Taila in the management of Kikkisa w.s.r to Striae Gravidarum, Alva’s Ayurvedic Medical College, Moodabidre (2011).
6. Koketso Ramoupi – the efficacy of “Thiosinaminum”1X cream on striae, Faculty of Health Sciences, University of Johannesburg.

III. AIMS AND OBJECTIVES OF THE STUDY:

AIM - To study the efficacy of śirīṣadi choorna in the management of kikkisa.

OBJECTIVE –

- To find the extent of occurrence of kikkisa in relationship with skin colour and other demographic variables.
- To find the mean gestational age in which striae gravidarum appears among the patients coming in the opd within the stipulated time period

2. MATERIALS AND METHODS:

I. SOURCES OF DATA:-

- The patients will be selected as per inclusion criteria from the OPD of Amrita Ayurveda Hospital, vallikkavu, kollam. After careful scrutiny the patients will be registered under the present study.
- Literary aspect of study will be collected from classical Ayurvedic and modern text updated with journals and e-data from ASA library and from the previous work done related to the same topic.
- The contents of shirishadi choorna such as śirīṣa (twak), dhātaki(pushpa), sarṣapa and madhu yaṣṭi choorna will be collected after proper identification².

II. MATERIALS REQUIRED FOR THE STUDY:-

i) METHODS OF COLLECTION OF DATA:-

1. SAMPLE

30 patients registering in the hospital satisfying the inclusion and exclusion criteria will be selected.

2. INCLUSION CRITERIA

- i. Patients with age 19 – 35 yrs.
- ii. Patients having classical signs and symptoms of kikkisa.
- iii. Primi gravidae and multi gravidae without previous occurrence of striae from 6th and 7th month of pregnancy

3. EXCLUSION CRITERIA

- i. Patients below 19yrs and above 35 yrs.
- ii. Multi gravidae with previous incidence of striae gravidarum.
- iii. Pre existing skin diseases which interferes with treatment.
- iv. Presence of previous surgical scars.
- v. Twin pregnancy and polyhydramnios.
- vi. Any systemic diseases affecting skin.
- vii. Pregnancy with complications.

ii) PROCEDURE AND DESIGN OF STUDY

1. MATERIALS AND METHODS

The drugs of shirishadi choorna are:

- Śirīṣa (twak) - Albizzia lebeck, Fabaceae
- Dhātaki (puṣpa) - Woodfordia fruticosa, Lythraceae
- Sarṣapa (seeds) – Brassica campestris, Brassicaceae
- Yastimadhu (root) - Glycyrrhiza glabra, Leguminosae

A cream will be prepared out of these drugs by AMRITA LIFE, the pharmacy attached to the hospital and under the guidance of Rasashastra and Bhaishajya Kalpana and Dravya guna experts.

The prepared product will be packed in suitable containers and then it is dispersed to the patients.⁹

The patients selected will be asked to apply sufficient quantity of sirishadi choorna which will be in the form of cream for thirty minutes twice daily for 45 days. During the treatment, patients will be regularly observed and progress is noted in the specially prepared case sheet. Review is advised on every 15 days.

2. DESIGN OF THE STUDY

With prior permission and consent from the college, hospital authorities and the patient, an open label uncontrolled clinical study with pre and post test design will be conducted on 30 selected pregnant women. A case proforma will be specially designed with details of history taking, physical signs and symptoms as mentioned in the texts. The parameters of signs and symptoms and investigations will be scored on the basis of standard method and will be analyzed statistically.

3. ASSESMENT CRITERIA:¹⁰

SUBJECTIVE PARAMETERS:-

- i) Kanḍu(itching):-
- ii) Vidāha (burning sensation):-

OBJECTIVE PARAMETERS:-

- i) No. of kikkisa marks present on lower abdomen
- ii) Length of kikkisa in centimeters
- iii) Colour of kikkisa
- iv) Surface area of concerned region measured before and after treatment.
- v) Photographs of the involved skin taken before and after the treatment as per need of the study.

4. STATISTICAL METHODS

Observation will be analyzed on the basis of assessment parameters (subjective & objective) clinically. Finally the results will be statistically evaluated by **paired‘t’ test**.¹¹

3. Does this study required any investigation or intervention to be conducted on patients, healthy volunteers, cadaver or animals? If so describe briefly.

Study requires investigations like:

- i) Complete blood count.
- ii) Urine routine and microscopic examination.

4. HAS ETHICAL CLEARNCE BEEN OBTAINED FORM YOUR INSTITUTION:

YES

5. LIST OF REFERENCES:

1. Sharma. R. K, Vaidya Bhagwan Dash, Caraka Samhitha – vol II, Chowkhamba Sanskrit Series Office, Varanasi, reprint – 2007,[P 485, 486]
2. Acharya JT, Charaka Samhita with Ayurveda Dipika commentary of Chakrapani Datta, Varanasi (India), Chaukambha Orientalia; reprint 2007, [P. 346].
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6. Cunningham F Professor. William's text book of Obstetrics. 22nd edition et al. Mc Graw-Hill.[P. 126.]
7. Dutta D C. Text book Of Obstetrics. 6th edition. Kolkata (India): New Central Book Agency (P) Ltd;[P. 50.]
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11. Dr. K. Syamalan, Dr. Shyamalan's statistics in medicine, published by global education bereau, Trivandrum, second edition 2012[248]

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

Signatures with official seal:

TOP

**AMRITA VISWA VIDYAPEETHAM
DEEMED UNIVERSITY
ETTIMADAI-COIMBATORE**

**PROFORMA FOR REGISTRATION OF SYNOPSIS FOR DISSERTATION
FOR AYURVEDA DHANWANTARI (M.S) IN PRASOOTITANTRA AND
STREE ROGA**

**“OPEN LABEL SINGLE ARM CLINICAL STUDY TO EVALUATE THE
EFFECT OF RĀSNĀDI ŚŪLAHARA KṢĪRAPĀKA IN PRIMARY
DYSMENORRHOEA WITH REFERENCE TO KAṢṬĀRTAVA”**

BY

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Session - 2013-2014

1. BRIEF RESUME OF THE INTENDED WORK:

I. NEED FOR STUDY:

Dysmenorrhoea is the cyclical pain associated with menstrual cycle so as to incapacitate day to day activities and the pain of primary dysmenorrhoea usually begins a few hours before or just after the onset of a menstruation period and may last 48-72 hrs¹.

Not less than 50% of women are said to experience some discomfort in relation to menstruation². Population surveys suggest that although prevalence rates vary considerably by geographical location, complaints of dysmenorrhoea are widespread in diverse population³. The severe pain which interferes with a woman's daily activity is responsible for highest incidence of absenteeism resulting in loss of work hours and economic loss⁴.

Conventional treatment consist of NSAID'S, oral contraceptive pills or analgesics. Prolonged use of these drugs causes many side effects. Treatment still has a failure rate of approximately 20-25% and many patients seek alternatives.⁵

The present study is with rāsnādi śūlahara kṣīrapāka (*Rāsna śvadamṣṭra vriṣakai sṛitam śūlaharam payaha*) reference taken from Aṣṭānga Hrudaya Uttarastāna, Guhyaroga pratiṣedha adhyāya which is useful in primary dysmenorrhoea due to its vāta anulomana and brimhana property⁶ and is also found to be cost effective and suitable. The present study is selected by considering the review of literature, viewing the extend of problem and understanding the efficacy of the preparation.

II. REVIEW OF LITERATURE:

The word dysmenorrhoea has a Greek origin (dys-men-or-rhea) means difficult, bad, painful, disordered flow monthly⁷. Kaṣṭārtava is a symptom mentioned in various yoni vyāpads⁸, apāna vāta vitiation being the main causative factor for this condition. As it is the painful menstruation, it is commonly compared with dysmenorrhoea of contemporary science.

Information regarding the disease are taken from ancient compendiums, relevant contemporary text books of Ayurveda, modern textbooks.

The list of previously done research work (dissertation) related to the disease are enlisted here.

1. Amruta B: 2011- Kerala University, Study on the effect of misreya arka on the signs and symptoms of spasmodic dysmenorrhoea.

2. Sukanya S Patil: 2009- RGUHS Karnataka, Clinical management of Kaṣṭārtava by Boladi Vati with Dashamula Katutrayadi Kashaya .
3. AnuradhaRay: 2006- Jamnagar, A comparative study on the effect of Dashamoola Taila UttaraBasti and Vijayadi Vati in the management of Kaṣṭārtava
4. Gupta Sangita: 2004- Gujarat Ayurved University, Jamnagar, A comparative study of Anuvasana Basti & UttaraBasti with Trivritadi taila in the management of kaṣṭārtava..
5. PandeApala : 2004- Banaras Hindu University, Varanasi , Role of Kāljāji (Nigella Sativa) in krichhrārtava.
6. Basabti Guru : 2002- Utkal University, Bhubaneshwar, A clinical study on Kaṣṭārtava & its management with some herbo mineral compound..
7. DhimanKamini - 2012, Chaturbeeja in primary dysmenorrhoea (kaṣṭārtava)

Detailed description of rāsnadi sūlahara kṣīrapāka will be collected from classical literature, Ayurvedic Pharmacopeia of India, books on dravyaguna śāstra, modern books on pharmacology, magazines and from previous research works on these drugs.

III. AIMS AND OBJECTIVES OF THE STUDY:

AIM: To study the effect of rāsnadi sūlahara kṣīrapāka in primary dysmenorrhoea.

OBJECTIVES: To assess the severity of pain and other symptoms and their association with selected socio demographic variables⁹.

2. MATERIALS AND METHODS

I. SOURCE OF DATA:

Sample data: A minimum of 40 patients will be selected from the OPD and IPD of Amrita Ayurveda Hospital, Vallikkavu.

Literary aspects of the study will be collected from classical ayurvedic and modern texts, updated with journals and e-data from ASA library, different media sources and previous research works done related to the same topic.

1.MATERIALS REQUIRED FOR THE STUDY:

i. METHODS OF COLLECTION OF DATA:

1) SAMPLE:

A minimum of 40 patients satisfying the inclusion and exclusion criteria will be selected through systematic random sampling technique¹⁰.The primary data would be collected using VAS¹¹,Faces pain rating scale¹¹ and the other subjective criteria grading.

2) INCLUSION CRITERIA:

- a) Patients who are suffering from primary dysmenorrhoea
- b) Patients who are giving consent to the study
- c) Patients within age group 14-40 years
- d) Patients suffering for more than 3 consecutive cycles
- e) Patients with regular menstrual cycle

3) EXCLUSION CRITERIA:-

- a) Patients having secondary dysmenorrhoea
- b) Patients with irregular menstrual bleeding
- c) Patients with concomitant genitourinary infection
- d) Dysmenorrhoea secondary to any drug intake,long standing smoking,other chronic general disorders
- e) Those under hormonal therapy

ii. PROCEDURE AND DESIGN OF STUDY:

1. MATERIALS AND METHODS:

Collection and Preparation of drug:

- a) Rāsna- Alpinia galanga, Zingiberaceae
- b) Śwadamṣṭra- Tribulus terrestris, Zygophyllaceae

c) Vāsa- *Adathoda vasica*, Acanthaceae¹²

The useful parts will be collected from the authentic source. Under the guidance of Dept of Rasashastra & Bhaishajya Kalpana and Dept of Dravyaguna, the authenticity will be checked, the drugs will be cleaned, properly dried & powdered in the pharmacy attached to Amrita Ayurveda hospital, Vallikkavu, Kollam. The moderately coarse powder of the drugs will be prepared and will be stored in an airtight container. The required quantity of the prepared powder for each day will be dispensed in separate airtight packets for the preparation of kṣīrapāka.

Drug schedule: The powdered drug (20g) will be packed separately in airtight packets and such 15 packets will be given to the patients for one month. They will be taught regarding the preparation of kṣīrapāka^{13, 14} using Milk-100ml, Water-400ml daily. They will be asked to start the kṣīrapāka almost 10 days prior to the menstruation till first five days of menstrual phase. The study will be continued for 3 consecutive cycles. The patient will be advised to visit the hospital after each menstrual phase. Dose of kṣīrapāka will be 50 ml twice daily before food.

2. DESIGN OF STUDY:

The present study will be conducted as an open label single arm clinical study.

With prior permission and consent from college and hospital authorities and the patient, a before and after study will be designed. The purpose and process of the study will be explained to the subject properly.

3. ASSESSMENT CRITERIA:

The effect of treatment will be assessed regarding the clinical signs and symptoms on the basis of VAS grading and scoring system¹¹, Faces pain rating scale¹¹, a self-modified subjective criteria.

a) Based on the pain criteria- grade0, grade1, grade2, grade3

b) Menstrual flow: Duration and amount of menstrual flow will be assessed.

c) Associated complaints: grade0, grade1, grade 2, grade 3 ²

- Nausea
- Vomiting
- Breast tenderness
- Head ache
- Giddiness
- Diarrhea
- Anorexia
- Nervousness
- Irritability
- Constipation
- Weakness
- Bloating

STATISTICAL METHODS:

The obtained data will be subjected to statistical analysis in terms of paired 't' test¹⁵

3. INVESTIGATIONS NEEDED:

Routine investigations of blood and urine will be carried out to rule out any associated systemic pathology.

USG will be done if needed to rule out any uterine or adnexal pathology.

4. HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION:

5. LIST OF REFERENCES

1. Jonathan S Berek, Berek and Novak's Gynaecology, 14th edition, Lippincott Williams and Wilkins, Wolters Kluwer Health , New Delhi2007, section 4, page-506.

2. T.N.A. Jeffcoate, Principles of Gynaecology, 3rd edition, reprinted 1972, Butterworth and Co. Publishers Ltd, Printed by William Cloves and Sons Ltd, page:685-697.
3. Dhiman Kamini et al: Chaturbeeja in primary dysmenorrhoea (kashtartava): Journal of Pharmaceutical and Scientific innovation, JPSI 1 (3) May-June 2012, 27-31.
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10. Dr K.Syamalan, Dr Syamalan's statistics in medicine, Published by Global education bureau, Trivandrum, 2nd edition, 2012, page-56.

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14. Sarangadhara Samhita, Madhyama khanda, Prof. Srikanta Murthy, Choukhamba Orientalia Varanasi, Reprint Edition 2012, chapter no 2,page-75.
15. Dr K.Syamalan, Dr Syamalan's statistics in medicine, Published by Global education bureau, Trivandrum, 2nd edition, 2012, page no 248.

TOP

**AMRITA VISHWA VIDYAPEETHAM
DEEMED UNIVERSITY
(University Under Sec.3 UGC Act 1956)
ETTIMADA-COIMBATORE**

**PROFORMA FOR REGISTRATION OF SYNOPSIS FOR DISSERTATION FOR
AYURVEDA DHANWANTARI (M.S) IN PRASŪTITANTRA AND STRĪROGA**

**“AN OPEN LABEL PRE AND POST TEST CLINICAL EVALUATION OF
EFFICACY OF ŚATAPUŚPĀ TAILA NASYA IN PCOS”**

BY

PRIYADARSHANA NARAYAN

1st year P.G. Scholar

GUIDE

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Session - 2013-2014

1. BRIEF RESUME OF THE INTENDED WORK

1.1 NEED FOR THE STUDY:

The word “strī” itself indicates the reproductive capacity of women. Today this capacity of women is being greatly challenged by a numerous disease conditions in them. PCOS is one of such conditions that have shown its emergence and prevalence into a large section of women rapidly. Absence of direct mentioning about this disease in Ayurvedic treatises may again indicate that this condition was comparatively less prevalent in that ancient era. Whereas, Puśpaghni Rewatī mentioned by Āchārya Kāśyapa bears some resemblance with symptoms of PCOS^{1a}.

The association of amenorrhea with bilateral polycystic ovaries and obesity was first described in 1935 by Stein and Leventhal and was known for decades as the Stein-Leventhal syndrome. It is now recognized as PCOS characterized by oligo/amenorrhea, anovulation, polycystic ovaries clinical / biochemical hyperandrogenism². PCOS produces symptoms in approximately 5% to 10% of women of reproductive age (approximately 18 to 45 years old) and the incidence appear to be on increase due to change in lifestyle and stress³. It is thought to be one of the leading causes of female subfertility and the most frequent endocrine problem in women of reproductive age.

In modern medicine, its treatment is mainly hormonal, symptomatic and anti-diabetic also surgical procedure is done even then a complete success has not been achieved yet. Therefore, there is wide scope of research to find out safe and potent remedy from Ayurveda for the treatment of PCOS.

GnRH is the main regulator of H-P-O axis that controls most of the ovarian hormones and the cells of GnRH originate in the olfactory area and migrate into the brain⁴. Keeping this in mind, Nasya karma, done through the *nāsā* which is said to be the *śiro dwārā*^{5a}, has been adopted to stimulate the hypothalamus and pituitary gland through its nearest route. Pratimarśa nasya will be done as the procedure is simple, with no complications^{5b} and that it will be more accessible to the common man.

Śatapušpā drug which is told in Kaś yapa Samhitā *Śatapušpā* - *Śatāvarī kalpa* has been chosen owing to its properties like *ṛtupravartinī*, *yonīvishōdhinī* etc^{1b}.

1.2 REVIEW OF LITERATURE:-

- A. Ancient compendiums and Relevant contemporary text books of Ayurveda
- B. Modern books of gynaecology, physiology, & pharmacology.
- C. Journals, magazines, seminars, conferences, digital library & web sites
- D. The list of previously done research work (dissertation) related to the present work are enlisted here.
 - a) Krupa D. Patel, Laxmipriya Dei, Shilpa B. Donga and Nalini Anand - Effect of Śatapušpā Taila Mātra Basti and Pāthadi Kwātha on PCOS, Ayu 2012 (Pubmed)
 - b) A. Ghose and P. K. Panda - Clinical efficacy of Śatapušpā (Anethum sowa Kurz.) powder in the management of Ārtava kshaya Ayu 2010 (Pubmed)
 - c) Dr Chaitali. S. Rao - Evaluation Of The Efficacy Of Varunā di Kwātha In PCOS - A Comparative Clinical Trial 2010, RGUHS
 - d) Dr Jeena Aravind.U – A Clinical Trial To Find Out The Efficacy Of Treatment Modality Including Śatapušpā Taila Nasya In Female Infertility With Special Reference To Ovarian Factors, Kerala University 2008
 - e) Dr Rajput Artiben- Comparative study of Śatapušpā and Mísreya on Beejotsarga- I.P.G.T & R.A, Gujarat Ayurveda University, Jamnagar, 2001.

1.3 AIMS AND OBJECTIVES OF THE STUDY:-

AIM

- To study the efficacy of pratimarśa nasyā with Śatapušpā taila in PCOS.

OBJECTIVES:

1. Effect of Śatapušpā taila pratimarśa nasyā on maturation of follicles
2. To evaluate the efficacy of Śatapušpā taila on regularization of menstrual cycle.

2. MATERIALS AND METHODS:

2.1. SOURCES OF DATA:-

The study is strictly confined to the cases of PCOS; hence patients satisfying the inclusion and exclusion criteria will be selected from the OPD and IPD of Amrita

Ayurveda Hospital, Vallikkavu, Kollam .After careful scrutiny and obtaining the consent the patients will be registered under the present study.

Literary aspect of study will be collected from Classical Ayurvedic and Modern texts, updated with Journals and e-data from ASA library, different media sources and previous work done related to the same topic in different research centres.

2.2a METHODS OF COLLECTION OF DATA:-

A. SAMPLE

30 patients satisfying the inclusion and exclusion criteria will be selected.

B. INCLUSION CRITERIA:-

- i. Female patients between 18-35 years
- ii. Patients with irregular menstrual cycles, irregular bleeding pattern.
- iii. Patients with multiple ovarian follicles less than 12mm in diameter in the ovary on USG

C. EXCLUSION CRITERIA:-

- i. Patients having any malignancies of the reproductive system
- ii. Patients with congenital abnormalities or gross structural abnormality of uterus and appendages
- iii. Patients with any systemic HTN, DM, Thyroid abnormalities.

2.2b PROCEDURE AND DESIGN OF STUDY

A. MATERIALS AND METHODS

Śatapuspā (Bot.name- Anethum sowa – *Kalka*

Family – Umbelliferae)

Milk – Quantity required

Taila – Quantity required

The Śatapuspā taila will be prepared as per classical requirements of taila preparation in the pharmacy attached to the hospital under the guidance of Rasaśāstrā and Bhaishajya Kalpana and Dravyaguna experts.

The patients selected will be subjected for śodhana according to their condition. Taila is to be instilled 2 drops in each nostril. The pratimarśa nasyā shall be done for 10

days in a month for consecutive 3 months. After treatment, the patients will be regularly observed. The progress is noted in the specially prepared case sheet. Review is advised every 15 days. The patient will be assessed finally after 3 months of medicine.

First 5 days of menstrual cycle will be avoided for *nasya karma*.

B. DESIGN OF STUDY

With prior permission and consent from the college, hospital authorities and the patient, an open label, uncontrolled, pre and post test evaluation will be designed.

Patients Data will be recorded in specially designed case sheets and subjective – objective parameters will be statistically analyzed.

C. ASSESSMENT CRITERIA:-

SUBJECTIVE PARAMETERS:-

- 1) Regularity of menses
- 2) Quantity of bleeding
- 3) Duration of bleeding
- 4) Physical signs of ovulation

OBJECTIVE PARAMETERS:-

- 1) Follicle size
- 2) Fern test

D. STATISTICAL METHODS

Observation will be analyzed on the basis of assessment parameters (subjective & objective) clinically. The results will be statistically evaluated by **paired 't' test**⁶.

3. DOES THE STUDY REQUIRE ANY INVESTIGATION / INTERVENTION TO BE CONDUCTED ON PATIENTS, HEALTHY VOLUNTEERS, CADAVER OR ANIMALS?

YES, a clinical study will be conducted on patients.

INVESTIGATIONS REQUIRED:

- i) Blood routine.
- ii) Urine routine.
- iii) USG
- iv) Hormonal assay

4. HAS ETHICAL CLEARANCE BEEN OBTAINED FORM YOUR INSTITUTION?

YES

5. LIST OF REFERENCES:-

1. P.V Tewari, Kaśyapa Samhitā or Vruddhajīvakīya Tantra, English translation and Commentary, Chaukhambha Viswa Bharati, Varanasi, 9th Edition 2004, Pg.no. 192.
 - a. 1a – Kalpasthana 6/33.2-34.1
 - b. 1b - Kalpasthana 5/ 5-6
2. Jonathan S. Berek, Berek and Novak's Gynaecology, Published by Lippincott Williams & Wilkins, Philadelphia 14th edition
3. Howkin's and Bourne, Shaw's Textbook of Gynecology, Edited by V.G. Padubidri, Shirish. N.Daftary, Reed Elsevier India Pvt. Ltd, 14th Edition, Pg.no. 331.
4. D.C.Dutta. Text Book of Gynaecology including Contraception, 5th edition, Revised reprint: 2009, edited by Hiralal Konar, New Central Book Agency (P) Ltd. Pg 64
5. Aṣṭāṅga Hṛdayam, Arunadatta Commentary, Chaukambha Sanskrit Samsthan , Reprint 2012
 - 5a Sutrasthana 20/1, pg no 287
 - 5b Sutrasthana 20/ 32-33, pg no 293
6. Dr K. Syamalan, Dr Syamalan's Statistics In Medicine, Published By Global Education Bureau, Trivandrum, 2nd Edition 2012 Pg 248

Name of the researcher/ Scholar : PRIYADARSHANA NARAYAN

Signature :

Name & designation of the guide : Dr.A.NALINAKSHAN, MD (Ay)
PROFESSOR & HOD
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AND STRĪROGA

Remarks of the Guide :

Signatures with official seal :

**Name and designation of
Head of Department :** Dr.A.NALINAKSHAN MD (Ay)
PROFESSOR & HOD
DEPT. OF PG STUDIES IN PRASŪTITANTRA
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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

From,

Rakhee E P

Preliminary M. S. (Ay) Scholar,

Department of Post Graduate Studies in Prasūti tantra and Strīroga

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

To,

The Registrar,

Amrita Viswa Vidyapeetham University,

Coimbatore, Tamilnadu.

Through:

The Principal and HOD of P.G. studies in Prasūti tantra and Strīroga,

Amrita School of Ayurveda, Vallikkavu, Clappana P O, 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 for partial fulfillment of M.S. (Ay) in Prasūti tantra and Strīroga to the **Amrita Viswa Vidyapeetham University Coimbatore**.

TITLE OF DISSERTATION

**AN OPEN LABEL PRE AND POST TEST CLINICAL EVALUATION OF
EFFICACY OF TILA TAILA ABYANGA AND MASSAGE OF YONI IN
CYSTOCELE WITH SPECIAL REFERENCE TO CHYUTA AVASTHA OF
VASTI.**

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

Thanking You,

Place: Vallikkavu

Yours faithfully,

Date: 28/05/2014

Rakhee E P

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

**PROFORMA FOR REGISTRATION OF SYNOPSIS FOR DISSERTATION FOR
AYURVEDA DHANWANTARI (M.S) IN PRASŪTITANTRA AND STRĪROGA**

**AN OPEN LABEL PRE AND POST TEST CLINICAL EVALUATION OF
EFFICACY OF TILA TAILA ABHYANGA AND MASSAGE OF YONI IN
CYSTOCELE WITH SPECIAL REFERENCE TO CHYUTA AVASTHA OF
VASTI.**

BY

RAKHEE E P

1ST YEAR P.G. SCHOLAR

**DEPARTMENT OF P.G. STUDIES IN PRASŪTITANTRA AND STRĪROGA,
AMRITA SCHOOL OF AYURVEDA, VALLIKKAVU, CLAPPANA P O, KERALA**

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DR HEMAVATHI S K

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Session - 2013-2014

1.BRIEF RESUME OF THE INTENDED WORK

INTRODUCTION

Cystocele¹ is a medical condition characterized by hernial protrusion of the urinary bladder through the anterior vaginal wall. The origin of the term cystocele dates back to 1811 and is derived from Greek kystis – bladder/ pouch and kele – tumor. Studies show that, among women cystocele is the most common and the complex reproductive health problem. Global prevalence of genital prolapse is estimated to be 2-20% in females under the age of 45. In a 1997 study², in South India, 440 women under the age of 45 were evaluated and found 3.4% occurrence of prolapse. In an another study in the year 2000, in North India, among 2990 married women,7.6% cases were found to be prolapse prone.

I.NEED FOR THE STUDY

Women who develop prolapse are of menopausal age and it is due to the laxity of supporting structures. Increased intra-abdominal pressure that may be due to cough, constipation or occupational stress will also contribute for the prolapse. Pelvic organ prolapse is of three types: anterior, middle and posterior compartment defects. Anterior compartment defects comprises of cystocele and urethrocele. Cystocele is of two types³: anterior and posterior cystocele. In majority of the conditions, both will coexist.

Women who are having cystocele, suffers from incontinence while coughing, mass per vagina, urinary tract infection etc. While discussing the treatment the contemporary science doesn't have a major conservative remedy for this except the operative procedures and pessary treatment, which has got its own side effects with a chance of recurrence. Hence, a measure is needed which is non-invasive and is beneficial for women without hampering their family life and for many who don't want to undergo surgery.

Sushrutha ācharya explained tila taila for its sookshma, vyavāyi, brimhana, mārḍava, mamsasthairya, balakara properties. He also explained it can be used in chyutha avastha⁴. Ācharya Charaka explained for all vata related yoni rogas abhyanga can be performed⁵. Above all taila can be considered as best for women⁶. Hence, in this study an attempt has been made to find the therapeutic efficacy of tila taila yoni abhyanga in the treatment of cystocele.

II. REVIEW OF LITERATURE

- Ancient compendiums and relevant contemporary text books of ayurveda.
- Modern books of gynaecology and, anatomy.
- Journals, magazines, seminars, conference proceedings, digital library & web sites.
- No previous research works done in this topic.

III. AIM AND OBJECTIVE OF THE STUDY

- To evaluate the therapeutic effect of tila taila yoni abhyanga in the treatment of cystocele.

1. MATERIALS AND METHODS:

SOURCES OF DATA:-

- **Sample data:** The study is strictly confined to first degree cystocele, patients will be selected as per inclusion criteria and exclusion criteria from the OPD & IPD of Amrita Ayurveda Hospital, Vallikkavu, Kollam after careful examination.
- Literary aspect of study will be collected from classical ayurvedic and modern texts updated with journals and e-data from ASA library and from the previous works done related to the same topic.

II. MATERIALS REQUIRED FOR THE STUDY

i. METHODS OF COLLECTION OF DATA

1. SAMPLE

30 patients who are suffering from first degree cystocele satisfying the inclusion and exclusion criteria will be selected.

2. INCLUSION CRITERIA

- With age group 45-65 years.
- Stress incontinence.
- First degree cystocele.
- Incomplete bladder evacuation.
- Feeling of mass coming down on straining.
- Recurrent UTI.

3. EXCLUSION CRITERIA

- 2nd and 3rd degree prolapses.
- Vaginal infections.
- Uterine pathologies such as fibroids, bulky uterus.
- History of any surgical procedures in pelvic area.
- Polyuria associated with uncontrolled diabetics.
- Carcinoma of bladder and genital organs.

ii. PROCEDURE AND DESIGN OF STUDY

1. MATERIALS AND METHODS

- TILA TAILA⁴ –Quantity sufficient.
- Good quality Krishna Tila is collected with the help of a Dravyaguna expert and taila will be extracted out of it.
- TILA-Sesamum indicum, Pedaliaceae.
- Antiseptic precautions.

Patient is made to lie down in lithotomy position. External genitalia is shaved and cleaned. A 5cc syringe is taken, which is filled with luke warm tila taila and it is inserted into vagina with the help of a sterile rubber catheter. After oleating the gloved fingers it is mildly inserted into the vagina and abhyanga is done on anterior vaginal wall. This process is repeated for a period of 20 minutes with a maximum of 20 ml tila taila. Patient is advised to stay on the table for 15 minutes. After the speculated observation time a gauze pad is given to avoid the spillage of oil. The treatment will be continued for 10 days in a month and followup is done for next three months. The progress is noted in a specially prepared case sheet.

2. DESIGN OF THE STUDY

With prior permission and consent from the college, hospital authorities and the patient, an open label single arm clinical study with pre-test and post-test design will be conducted. A special proforma will be prepared with detailed history and other signs and symptoms. The parameters of subjective-objective, investigations will be recorded on the basis of standard methods and will be analysed statistically.

2. ASSESSMENT CRITERIA

Subjective criteria

- Frequency of urination
 - Increased/Decreased
 - Number of times during day/night time.
- Burning micturition
 - 0 – Nil
 - 1 – Mild
 - 2 – Severe
- Painful micturition
 - 0 – Nil
 - 1 – Mild
 - 2 – Moderate
 - 3 – Severe
- Foul smell
 - Present/Absent

Objective criteria

- Baden's system of classification⁷
 - 1st degree prolapse – above the level of hymen.
 - 2nd degree prolapse – at the level of hymen.
 - 3rd degree – below the level of hymen.
- For better assessment a measurement scale is made with the help of anatomic landmarks. Length of Anterior vaginal wall is 7.5cm and length of urethra is 4cm. so bladder can be felt 4cm above the hymen on Anterior vaginal wall. So from that

level three points are noted which are 1cm apart and the level of prolapse is assessed. Improvement is noted with this measuring scale⁸.

5 STATISTICAL METHOD

- Paired t- test⁹

3. DOES THE STUDY REQUIRE ANY INVESTIGATION OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS, HEALTHY VOLUNTEERS, CADAVER OR ANIMALS?

- Yes, Clinical study will be conducted on patients.

INVESTIGATION REQUIRED

- Urine routine examination.
- Blood sugar level.

3. HAS ETHICAL CLEARANCE BEEN OBTAINED FROM INSTITUTION?

YES

4. LIST OF REFERENCES

1. Dorland's Pocket Medical Dictionary, 27th Edition, Elsevier Publishers, New Delhi, 2005.
2. Ananta Raj Bajracharya, "Uterine Prolapse –A Hidden Trajedy for Woman", Article review, web version, 2013.
3. Neeraj Bhatla, "Jeffcoat's Principles of Gynaecology", 5th Edition, revised and updated international edition (Arnold), 2001,Page-265.
4. Sushrutha, Sushruta Samhita, Soothrasthana, Dalhana Commentary Yadaji trikamji acharya, bhumika by P V Sharma ,8th edition,chaukhambha orientalia, Varanasi Dravadravya vijnaneeeya, 45th Chapter, 112th Sloka. Page-205.
5. Agnivesa, Charaka Samhita, Chikitsa sthana, Chakrapani Tika Yadaji trikamji acharya, reprint-2004, chaukhambha orientalia, Varanasi Yonivyapat chikitsa, 30th Chapter, 61st Sloka, page-637.
6. Vagbhata, Astanga Hrdaya, commentaries of Sarvangasundara of Arunadatta and Ayurvedarasayana of Hemadri, collated by Dr Anna Moreswara Kunte, Krishna Ramachandra Sastri Navare, 9th edition,2005, Sareerasthanam 1st Chapter, 20th Sloka, page-366.

7. V L Bhargava, Text Book of Gynecology, published by Ane books, New Delhi, reprint 2012, page-288.
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9. Dr., K. Shyamalan, Dr. Shyamalan's Statistics In Medicine, 2012 edition, Global education bureau, Thiruvananthapuram, page-248.

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