## RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,

**BENGALURU, KARNATAKA.**

COMPLETED PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION IN M.S (AYURVEDA)

**TITLE**

**“A CLINICAL COMPARATIVE STUDY TO EVALUATE THE EFFECT OF *VACHADI CHURNA* AND *SHATAVARI CHURNA* IN THE MANAGEMENT OF *STANYA KSHAYA* W.S.R TO LACTATION FAILURE”**

BY

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2022-2023

**GUIDE**

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**NAME OF THE INSTITUTE**

**SDM TRUST’S**

**AYURVEDIC MEDICAL COLLEGE,**

**DANIGOND POST-GRADUATE CENTRE AND**

**PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE**

**DR SIDDHANT NAGAR, TERDAL – 587315, KARNATAKA.**

**2022-2023**

**FROM,**

**Dr. SREELEKHA SETHI**

1st Year M.S PG Scholar

Dept. of PG Studies in Prasuti Tantra and Stree Roga

SDM Trust’s Ayurvedic Medical College,

Danigond Post Graduation Centre,

Padma Ayurvedic Hospital and Research Centre,

Dr. Siddhant Nagar, Terdal - 587315

**TO,**

**THE REGISTRAR,**

Rajiv Gandhi University of Health Sciences Bangalore, Karnataka.

**THROUGH,**

**THE PRINCIPAL AND HOD DEPT OF PTSR**

SDM Trust’s Ayurvedic Medical College

Danigond Post Graduation Centre,

Padma Ayurvedic Hospital and Research Centre,

Dr. Siddhant Nagar, Terdal-587315, Karnataka.

Respected Sir/Madam,

**SUBJECT:** Submission of completed proforma for registration of synopsis for

Dissertation

I Request you to kindly register the below mentioned subject in my name for submission of dissertation to Rajiv Gandhi University of Health Sciences, Bengaluru as the partial fulfillment for the award of the Degree M.S(Ayu) in *PRASUTI TANTRA AND STREE ROGA .*

**TITLE:**

**“A CLINICAL STUDY TO EVALUATE THE EFFECT OF *VACHADI CHURNA* IN THE MANAGEMENT OF *STANYA KSHAYA* W.S.R TO LACTATION FAILURE”**

Here with, I am enclosing the completed proforma for Registration of the Dissertation subject.

Thanking you,

Place: TERDAL Yours Sincerely,

Date: DR. SREELEKHA SETHI

**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, BENGALURU, KARNATAKA**

**ANNEXURE-II**

**PROFORMA FOR THE REGISTRATION OF SUBJECT FOR THE DISSERTATION OF M.S (AYURVEDA).**

**1** . NAME OF THE CANDIDATE :Dr. SREELEKHA SETHI

AND ADDRESSPreliminary MS (Ayu) scholar

PG Dept of Prasuti Tantra evum Stree Roga

SDM Trust’s AMC, Padma Ayurvedic

Hospital & Research Centre Siddhant Nagar

TERDAL- 587315.

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**2.** NAME OF THE INSTUTUTION:SDM Trust’s Ayurvedic Medical College,

Danigond Post Graduation Centre,

Padma Ayurvedic Hospital and Research Centre,

Siddhant Nagar, Terdal. -587315.

**3.** COURSE OF STUDY AND **:** M.S (PRASUTI TANTRA AND STREE ROGA)

SUBJECT

**4.** DATE OF ADMISSION **:** 27/04/2023

**5.** TITLE OF DISSERTATION **:**

**“A CLINICAL COMPARATIVE STUDY TO EVALUATE THE EFFECT OF *VACHADI CHURNA* AND *SHATAVARI CHURNA* IN THE MANAGEMENT OF *STANYA KSHAYA* W.S.RTOLACTATION FAILURE”**

**6. BRIEF RESUME OF THE INTENDED WORK**

**6.1NEED FOR THE STUDY**

The pivotal component and source of nutrition in every being’s life is *Stanya.* It is addressed as *Jeevana1* due to the qualities such as *Pushtikara, Vruddhikara, Bala Vardhana.* During pregnancy period the *Rasa-Dhatu* has three major functions in female body i.e. *Swasharirpushti* *, Garbhapushti and Stanyapushti2*.

In Ayurveda different types of *Stanya* *vikaras* are mentioned such as *Stanya Kshaya ,Stanya vruddhi* and *Stanya dushti*. The less formation of breast milk is known as “*Stanya Kshaya”* which can be co-related to “lactation failure” explained in modern science.

Only 44% infants are breastfed according to WHO3. About 64% are exclusively breastfed in India of which Karnataka accounts for about 61% as per the data of NFHS-54,5. *Stanya Kshaya* is the common problem noticed in about 40% patients in our clinical practice1. Lack of self-confidence, mental anxiety and physical stress in working women, incorrect breast-feeding practices, insufficient secretion due to lack of sleep are the main causes of lactation failure.

*Stanya Sampat* and *Stana Sampat* are elaborately explained in the classics. The causes of *Stanya Kshaya* are multifactorial in nature explained by various *Acharyas6,7,8,9,10* such as *Ati* *Shrama, Langhana, Ruksha Annapana, Krodh, Shoka,* and *Avatsalya*. Main factors involved in *Stanya kshaya* are *Vata-Pitta dosha* aggravation leading to *Stanya Kshaya.*

*Ayurveda* advocates a large number of drugs, diet and behavior regimens for *Stanya janana. Vachadi Churna11* is one of the *Stanya* *Vardhana* formulation explained in *Chakradatta* and *Shatavari churna* as *Stanya Janana*, in the management of *Stanya Kshaya*. Hence, an attempt is made to seethe probable mode of action and the effect of *Vachadi Churna* in the management of *Stanya Kshaya.*

**6.2 REVIEW OF LITERATURE:**

**1) DISEASE REVIEW:**

***STANYA KSHAYA***

* *Nidana* of *Stanya Kshaya* is mentioned in *Sushrut Samhita Sharir sthan6, Ashtang Hrudaya Uttartantra7, Ashtang Sangraha Uttartantra8, Kashyap Samhita Sutra Sthana9, Bhavaprakash Purvakhand10.*
* *Lakshana* of *Stanya Kshaya* is mentioned in *Sushrut Samhita Sutra sthan12, Bhavaprakash Purvakhand10.*
* The *Chikitsa* of *Stanya Kshaya* is mentioned in *Charak Samhita Sharir sthana13, Sushrut Samhita’s Sutra Sthana12, Sharir sthana6, Chikitsa sthana14, Ashtang Hrudaya Uttartantra7, Ashtang Sangraha Sutra sthan15, Kashyap Samhita in Sutra sthan9 and Siddhi sthan16, Bhavaprakash Purvakhand10, Yogratnakar in Kshiradosha17, Harit Samhita Trutiya Sthana18.*

**MODERN VIEW:**

LACTATION FAILURE19 (INADEQUATE MILK PRO- DUCTION):

This is caused due to infrequent suckling, endogenous suppression of prolactin. Pain, anxiety.

**2) DRUG REVIEW20**

The trial formulation *Vachadi* ***C****hurna11*explained in ***C****hakradatta* in *Stree Roga Chikitsa Prakaran.*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SL. NO** | **Ingredients** | ***Latin Name***  ***Family*** | ***Rasa*** | ***Guna*** | ***Veerya*** | ***Vipaka*** | ***Part***  ***Used*** | ***Doshaghnata & Karma*** |
| 01 | *Vacha* | *Acorus calamus linn.*  *(Family-Araceae)* | *Katu*  *Tikta* | *Laghu,*  *Ruksha* | *Ushna* | *Katu* | *Kanda*  (Rhizome) | *Kaphavatashamak,*  *Medhya* |
| 02 | *Musta* | *Cyperus rotundus linn.*  *(Family- Cyperaceae)* | *Tikta,*  *Katu,*  *Kashaya* | *Laghu,*  *Ruksha* | *Sheeta* | *Katu* | *Kanda*  (Rhizome) | *Pittashamak,*  *Stanyashodhan* |
| 03 | *Devadaru* | *Cedrus deodara roxb.*  *(Family-Pinaceae)* | *Tikta* | *Laghu,*  *Snigdha* | *Ushna* | *Katu* | *Tvak*  (Bark) | *Kaphavatashamak,*  *Stanyashodhan* |
| 04 | *Shunthi* | *Zingiber officinale rosc. (Family- Zingiberaceae* | *Katu* | *Laghu,*  *Snigdha* | *Ushna* | *Madhur* | *Kanda*  (Rhizome) | *Kaphavatashamak,*  *Vrushya* |
| 05 | *Ativisha* | *Aconitum heterophylslum wall.*  *(Family- Ranunculaceae)* | *Katu*  *Tikta* | *Laghu,*  *Ruksha* | *Ushna* | *Katu* | *Kanda*  (Rhizome) | *Tridosha-hara,*  *Stanyashodhan* |
| 06 | *Haritaki* | *Terminalia chebula*  *Family- (Combretaceae)* | *MadhuraAmla, Katu, Tikta, Kashaya* | *Laghu, Ruksha* | *Ushna* | *Madhur* | *Phala*  (fruit) | *Tridosha-hara*  *Vrushya* |
| 07 | *Shatavari* | *Asparagus racemosus*  *(Family- Liliaceae)* | *Madhura, Tikta,* | *Guru,*  *Snigdha* | *Sheeta* | *Madhur* | *Kanda*  (Rhizome) | *Vatapittashamak,*  *Stanyajanan* |

**6.3 PREVIOUS RESEARCH WORKS DONE:**

* Dr. Rajni Kanojiya- A comparative clinical study of effect of *Karpasabeeja* *Churna* and *Shatavari Churna* in the management of *Stanya Kshaya*. Rajiv Gandhi Ayurvedic Medical College, Ron. 2017
* Dr. Shashikala H P- A Clinico-comparative study to evaluate the efficacy of Y*ashtimadhu Choorna* and *Shatavari Choorna* in the management of *Stanya* *Kshaya*. Shri Jagadguru Gurusiddeshwar Co-operative Hospital and Research Institite (Shri J G C H Society), Ghataprabha. 2017
* Dr. Vidyavati Ranganata- An open label double arm compative clinical study to evaluate the efficacy of *Shatavari Churna* and *Musali Churna* in *Stanya* *Kshaya*. Shri Kalabyreshwaraswamy Ayurvedic Medical College Hospital & Research Centre, Bangalore. 2018
* Dr. Pallavi Suresh Bhangare- A clinical study to evaluate the efficacy of *Maricha* and *Pippalimool Sidhha Ksheerpaka* in *Stanya Kshaya.* Rajiv Gandhi Ayurvedic Medical College, Ron. 2019

**6.4 AIMS & OBJECTIVES OF STUDY:**

* To evaluate the effect of *Vachadi Churna*  in the management of *Stanya Kshaya* w.s.r to Lactation Failure.
* To study the detail aetiopathogenesis of *Stanya Kshaya* w.s.r to Lactation Failure.
* To compare the effect of *Vachadi Churna* and *Shatavari Churna* in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

**6.5 HYPOTHESIS:**

**NULL HYPOTHESIS:**

**H0** –*Vachadi churna* is not effective in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

# ALTERNATIVE HYPOTHESIS:

**H1** - *Vachadi churna* is effective in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

**H2** - *Vachadi churna* is more effective than *Shatavari churna* in the management of *Stanya kshaya* w.s.r to Lactation Failure.

**H3** - *Vachadi churna* is less effective than *Shatavari churna* in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

**H4** –Both *Vachadi churna* and *Shatavari churna* are equally effective in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

**7 MATERIAL AND METHODS:**

**7.1 SOURCE OF DATA:**

**1) Literary source:**

* All relevant Ayurvedic and Modern literature text books regarding the disease and treatment will be reviewed and documented for the planned study.
* Relevant research articles, journals, library of SDMTAC, Terdal.
* Internet.

**2) Drug Source –**

* Raw drugs will be procured from local market & Herbal Garden of SDMTAC.
* Authentication of raw drugs will be done in *Dravyaguna* department of SDMTAC, Terdal.
* *Churna*  will be prepared and will get Authentication by *RSBK* Department of SDMTAC, Terdal.

**3) Experiment source-**

Subjects fulfilling the inclusion criteria will be selected from the OPD/IPD of SDM

Trust’s Ayurvedic Medical College and Padma Ayurvedic Hospital, Terdal.

**RESEARCH/STUDY DESIGN:**

* A Randomised controlled comparative clinical trial.
* 40 Patients who fulfill the inclusion criteria of *StanyaKshaya* will be selected randomly by software generated chart and placed in to 2 groups ‘A’ and ‘B’ respectively.

**METHODOLOGY:**

Enrolment of the subject, for the trial is based on Inclusion Criteria. Consent will be taken, then screening of the subject is done and the data will be recorded in a specially prepared form (CRF) with a complete history, examination and treatment at the time of every follow up.

**7.2 METHOD OF COLLECTION OF DATA:**

* 40 Female patients irrespective of socio economic status, religion, place, who are suffering from *Stanya Kshaya,* will be selected from OPD/IPD of SDM Trust’s Ayurvedic medical College and Padma Ayurveda Hospital, Terdal.
* Patients who fulfill the inclusion criteria.

**Study design**- A Randomised control Clinical Trial

**Sample size –** 40 patients who fulfill the diagnostic and inclusive criteria will be selected and placed under two groups A and B with 20 patients in each group respectively.

**SELECTION CRITERIA:**

1. **INCLUSION CRITERIA:** 
   * Lactating mothers with classical signs and symptoms of *Stanya Kshaya*
   * Patients with feeding frequency less than 4-5 times/ day.
   * Age group of patient is between 20 - 40 years.
   * Patients from 5th day of delivery to 6 months.
   * The selection is irrespective of parity, caste, religion and socio economic status
   * Patient willing to sign and give consent.

**B) EXCLUSION CRITERIA:**

* + - K/C/O Mastitis, CA Breast, and Cystic breast disease.
    - Patients with Congenital Breast Anomaly and Breast surgery.
    - K/C/O Psychiatric illness.
    - Patients with history of alcoholism, smoking.
    - Diagnosed cases of diabetes, hypertension.
    - Mother having a baby with congenital anomaly like cleft lip, cleft palate.
    - Patient denying consent.

**C) WITHDRAWAL CRITERIA:**

During the course of treatment if any major ailment or adverse effect occurs or patient herself wants to withdraw from the study such patients may withdraw from the study.

**DIAGNOSTIC CRITERIA** :

The diagnosis is purely based on the clinical signs and symptoms of *Stanya Kshaya.*

**Mother-**

1. *Stana mlanata21*

* *Stana Shuskatva*
* *Stanya alpata*
* *Stanya asambhava*

1. Breast feeding frequency

**Baby-**

1. Sleep of baby
2. Cry for demand
3. Urine frequency

**Drop-Outs**

An attempt shall be made to record the reason for drop outs, if any during the clinical trial.

**D) INVESTIGATIONS:**

* Sr. Prolactin (if needed)

**E) ASSESSMENT CRITERIA:**

**SUBJECTIVE CRITERIA:**

**Mother-**

1. *Stana Mlanata*

* *Stana Shuskatva*
* *Stanya Alpata*
* *Stanya Asambhava*

1. Breast feeding frequency

**Baby-**

1. Sleep of baby
2. Cry for demand
3. Urine frequency

**OBJECTIVE CRITERIA:**

**Mother-**

1. Milk ejection was evaluated by manual pressure on nipple and observation recorded on 4 point scale.

**Baby-**

1. Baby weight

**F) ASSESSMENT PARAMETERS:**

**SUBJECTIVE PARAMETERS:**

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Particulars** | **Grading** |
| **(A)** | **MOTHER** |  |
| 1. | ***Stana Mlanata***   1. *Stana Shuskatva* 2. *Stanya Alpata* 3. *Stanya Asambhava* | * If no sign present – 0 * If one sign present –1 * If two signs present –2 * If three signs present -3 |
| 2. | ***Breast Feeding*** | * 9-12 feeds/day– 0 * 6-8 feeds/day - 1 * 3-5 feeds/day- 2 * 0-2 feeds/day – 3 |
| **Sr. No.** | **Particulars** | **Grading** |
| **(B)BABY** | | |
| **1.** | **Sleep of Baby** | * 1-2 hrs sleep – 2 * 2-3 hrs sleep - 1 * 3-4 hrs sleep – 0 |
| **2.** | **Cry For Demand Feed** | * Demand feeds before every 2 hrs-2 * Demand feeds before every 2-3 hrs- 1 * Demand feeds before every 3-4 hrs -0 |
| **3.** | **Urine Frequency** | * 1/<1 time /day – 3 * 2-3 times/day – 2 * 4-5 times/day- 1 * 6-7 times/day-0 |

**OBJECTIVE PARAMETERS:**

|  |  |  |
| --- | --- | --- |
| **Sr No** | **Particulars** | **Grading** |
| **(A)** | **MOTHER** |  |
| 1. | ***Milk Ejection*** | * Forceful– 0 * Stream like – 1 * Drop by drop – 2 * No ejection – 3 |
| **(B)BABY** | | |
| **1.** | **Body Weight** | * No weight gain – 2 * 100-175 g weight gain/week - 1 * >175 g weight gain/week – 0 |

**G) PROCEDURE OF ADMINISTRATION OF DRUG**

**INTERVENTIONS-**

**GROUP ‘A’** : Patients under this group will be given *Vachadi Churna.*

|  |  |
| --- | --- |
| Sample size | 20 patients |
| *Aushadha* | *Vachadi Churna11* |
| *Aushadha Pramana* | *Eka Karsha22* (6g BD) |
| *Aushadha Sevana Kala* | *Pragbhakta23*  (starting from 5th day after the delivery) |
| *Anupana* | *Godugdha11* (50ml ) |
| Duration of medication | 30 days |
| Total duration of study trial | 45 days |
| Follow up   * 0th day * 15th day * 30th day * 45th day | There will be 3 follow ups.   * 2 follow ups with treatment on 15th day and 30th  day. * 1 follow up post treatment on 45th day. |
| Route of administration | Oral |

**GROUP ‘B’:** Patients under this group will be given *Shatavari Churna.*

|  |  |
| --- | --- |
| Sample size | 20 patients |
| *Aushadha* | *Shatavari Churna11* |
| *Aushadha Pramana* | *Eka Karsha22* (6g BD) |
| *Aushadha Sevana Kala* | *Pragbhakta23*  (starting from 5th day after the delivery) |
| *Anupana* | *Godugdha11* (50ml ) |
| Duration of medication | 30 days |
| Total duration of study trial | 45 days |
| Follow up   * 0th day * 15th day * 30th day * 45th day | There will be 3 follow ups.   * 2 follow ups with treatment on 15th day and 30th  day. * 1 follow up post treatment on 45th day. |
| Route of administration | Oral |

**STATISTICAL ANALYSIS AND INTERPRETATION:**

Data will be collected using case report from (CRF) designed by incorporating all aspect (*Ayurveda* and Modern medicine) for the study. Such collected data will be tabulated and analyzed using SPSS (Statistical package for social sciences) version 20 by using appropriate statistical test. Demographic data and other relevant information will be analysed with descriptive statistics. Continuous data will be expressed in+/- standard deviation and nominal & ordinal data will be expressed in percentage. Nominal and ordinal data will be analysed using non parametric test like Friedman’s test, Wilcoxon’s signed rank test, chi square test. Continuous data will be analysed using parametric test like repeated measure ANOVA, paired t / upaired t test, as and when required. The changes (one tailed) with p value <0.005 will be considered as statistically significant.

**7.3. Does the study require any investigations or interventions conducted on animals, patients or humans? (If so describe briefly)**

This study will be conducted clinically. No animal experiment will be carried out.

**7.4. Has ethical clearance been obtained from your institution in case of 7.3?**

Yet to obtain.

**8. REFFERENCES:**

1) Bhujbal VV, Shelar SM. A case study of ayurvedic management in Stanyakshaya (lactation Insufficiency) . International journal of research in Ayurveda and Medical sciences [Internet]. 2020 Sep 23 [cited 2020 Sep 23];Vol.3(Issue 3):227. Available from: www. ijrams.com

2)https://www.thepharmajournal.com/archives/?year=2019&vol=8&issue=5&ArticleId=4069

3) https://www.who.int/news-room/fact-sheets/detail/infant-and-young-child-feeding

4) India Fact Sheet - District Level Household Survey http://rchiips.org/nfhs/NFHS-5\_FCTS/India.pdf

5) State Fact Sheet Karnataka- IM4Change https://www.im4change.org/docs/Karnataka%20NFHS-5%20Factsheet.pdf.

6)

|  |  |  |  |
| --- | --- | --- | --- |
| **9. SIGNATURE OF THE**  **CANDIDATE** | **:** |  |  |
| **10. REMARKS OF THE**  **GUIDE** | **:** |  |  |
| **10.1 NAME AND**  **DESIGNATION**  **OF THE GUIDE** | **:** |  | **Dr. SUKANYA PATIL M.S. (AYU)**  PROFESSOR ,  PRASUTI TANTRA AND STREE ROGA DEPARTMENT,  S.D.M. TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **10.2 SIGNATURE** | **:** |  |  |
| **10.3 NAME AND**  **DESIGNATION OF THE**  **CO-GUIDE** | **:** |  | **DR. PALLAVI R. KODAGE** M.S (AYU)  ASSISTANT PROFESSOR,  PRASUTI TANTRA AND STREE ROGA DEPARTMENT,  S.D.M. TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **10.4 SIGNATURE** | **:** |  |  |
| **11.1 HEAD OF THE**  **DEPARTMENT** | **:** |  | **Dr. PARSHURAM K. RAWALM.S.(AYU)**  PROFESSOR & HOD,  PRASUTI TANTRA EVAM STREE ROGA DEPARTMENT,  S.D.M. TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **11.2 SIGNATURE** | **:** |  |  |
| **12.1 REMARKS OF THE**  **PRINCIPAL** | **:** |  |  |
| **12.2 PRINCIPAL** | **:** |  | **Dr. P.B. APARAJM.D.(AYU) Ph.D(SCHOLAR)**  S.D.M. TRUST’S AYURVEDIC MEDICAL COLLEGE, DANIGOND POST-GRADUATION CENTRE, PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,  TERDAL-587315 |
| **12.3 SIGNATURE** | **:** |  |  |