

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



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

**TITLE**

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

**BY**

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**AYURVEDIC MEDICAL COLLEGE,**

**DANIGOND POST GRADUATION CENTRE,**

**PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE,**

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

**2022-2023**

**FROM,**

**DR. SREELEKHA SETHI**

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DEPARTMENT OF PRASUTI TANTRA EVUM STREE ROGA

SDM Trust's Ayurvedic Medical College

Danigond Post-graduation Centre,

Padma Ayurvedic Hospital & Research Centre, Terdal.

**TO,**

**THE REGISTRAR**

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,

BENGALURU, KARNATAKA.

**THROUGH,**

**THE PRINCIPAL AND**

**H.O.D OF DEPARTMENT OF PTSR.**

SDM Trust's Ayurvedic Medical College,

Danigond Post-Graduation Centre,

Padma Ayurvedic Hospital and Research Centre, Terdal.

**Subject: Submission of Completed Proforma for Registration of the Synopsis of Dissertation work in M.S (Ayu).**

Respected Sir,

I request you to kindly register the below mentioned subject in my name for the submission of the dissertation to the Rajiv Gandhi University of health sciences, Bengaluru for partial fulfilment M.S (Ayurveda) in *Prasuti Tantra Evum Stree Roga*.

**TITLE:**

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

Herewith I am enclosing the completed proforma for the registration of the subject for dissertation in M.S (Ayu) *Prasuti Tantra Evum Stree Roga*.

Thanking you,

Place: Terdal

Date:25/09/2023

Yours faithfully,  
(Dr. Sreelekha Sethi)

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

**ANNEXURE - II**

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

- 1.NAME OF THE CANDIDATE AND ADDRESS** : DR. SREELEKHA SETHI  
SDM TRUST'S AYURVEDIC  
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CENTRE, TERDAL 587315,  
KARNATAKA
- 3. COURSE OF THE STUDY AND SUBJECT** : M.S(AYURVEDA), PRASUTI TANTRA  
EVUM STREE ROGA
- 4. DATE OF THE ADDMISSION OF COURSE** : 1/04/ 2023
- 5. TITLE OF THE DISSERTATION** :

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

## **6. BRIEF REVIEW OF THE INTENDED WORK**

### **6.1. NEED FOR THE STUDY**

The pivotal component and source of nutrition in every being's life is *Stanya*. It is addressed as *Jeevana*<sup>1</sup> 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. *Swasharira pushti*, *Garbha pushti* and *Stanya pushti*<sup>2</sup>.

In Ayurveda different types of *Stanya Vikara* 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 WHO<sup>3</sup>. About 64% are exclusively breastfed in India of which Karnataka accounts for about 61% as per the data of NFHS-5<sup>4,5</sup>. *Stanya Kshaya* is the common problem noticed in about 40% patients in our clinical practice<sup>6</sup>. 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 Sampata* and *Stana Sampata* are elaborately explained in the classics. The causes of *Stanya Kshaya* are multi-factorial in nature explained by various *Acharya* such as *Ati Shrama*, *Langhana*, *Ruksha Annapana*, *Krodha*, *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 and formulations. *Musta Churna* is explained in *Chakradatta* whereas *Shatavari Churna* is explained in *Sushruta Samhita*. Both of them are *Stanya Janana* in nature. Hence, an attempt is made to see the probable mode of action and the effect of *Musta Churna* in the management of *Stanya Kshaya*.

## **6.2. REVIEW OF LITERATURE:**

### **1. DISEASE REVIEW:**

- *Nidana* of *Stanya Kshaya* is mentioned in *Sushruta Samhita Sharira sthana*<sup>7</sup>, *Ashtanga Hrudaya Uttartantra*<sup>8</sup>, *Ashtanga Sangraha Uttartantra*<sup>9</sup>, *Kashyapa Samhita Sutra Sthana*<sup>10</sup>, *Bhavaprakasha Purvakhanda*<sup>11</sup>.
- *Lakshana* of *Stanya Kshaya* is mentioned in *Sushruta Samhita Sutra Sthana*<sup>12</sup>, *Bhavaprakasha Purvakhanda*<sup>13</sup>.
- *Chikitsa* of *Stanya Kshaya* is mentioned in *Charaka Samhita Sharira Sthana*<sup>14</sup>, *Sushruta Samhita's Sutra Sthana*<sup>15</sup>, *Sharira Sthana*<sup>16</sup>, *Chikitsa Sthana*<sup>17</sup>, *Ashtanga Hrudaya Uttartantra*<sup>18</sup>, *Kashyapa Samhita in Sutra Sthana*<sup>19</sup> and *Siddhi Sthana*<sup>20</sup>, *Bhavaprakasha Purvakhanda*<sup>21</sup>, *Yogratnakara in Kshiradosha*<sup>22</sup>, *Harita Samhita Trutiya Sthana*<sup>23</sup>.

## DESCRIPTION OF LACTATION FAILURE<sup>24</sup> (INADEQUATE MILK SUPPLY):

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

## 2. DRUG REVIEW<sup>25</sup>:

- The trial formulation *Musta Churna*<sup>26</sup> explained in *Chakradatta* in *Stree Roga Chikitsa Prakarana*.

SL. NO	Drug	Latin Name Family	Rasa	Guna	Veerya	Vipaka	Part Used	Doshaghnata & Karma
01	<i>Musta</i>	<i>Cyperus rotundus</i> linn. (Family- <i>Cyperaceae</i> )	<i>Tikta, Katu, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Sheeta</i>	<i>Katu</i>	<i>Kanda (Rhizome)</i>	<i>Kaphapittashamaka, Stanyajanana Stanyashodhana</i>

- The control formulation *Shatavari Churna*<sup>27</sup> explained in *Sushruta Samhita* in *Garbhini Prakarana Sharira*.

SL. NO	Drug	Latin Name Family	Rasa	Guna	Veerya	Vipaka	Part Used	Doshaghnata & Karma
01	<i>Shatavari</i>	<i>Asparagus racemosus</i> (Family- <i>Liliaceae</i> )	<i>Madhura Tikta</i>	<i>Guru, Snigdha</i>	<i>Sheeta</i>	<i>Madhura</i>	<i>Kanda (Rhizome)</i>	<i>Vatapittashamaka Stanyajanana</i>

### 6.2.1 PREVIOUS RESEARCH WORK:

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

### **6.2.2 HYPOTHESIS:**

#### **NULL HYPOTHESIS:**

**H<sub>0</sub>**- *Musta Churna* is not effective in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

#### **ALTERNATIVE HYPOTHESIS:**

**H<sub>1</sub>**-*Musta Churna* is effective in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

**H<sub>2</sub>**-*Musta Churna* is more effective than *Shatavari Churna* in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

**H<sub>3</sub>**-*Musta Churna* is less effective than *Shatavari Churna* in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

**H<sub>4</sub>**-*Musta Churna* and *Shatavari Churna* are equally effective in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

### **6.3 AIMS AND OBJECTIVES:**

- To evaluate the effect of *Musta Churna* in the management of *Stanya Kshaya* w.s.r to Lactation Failure.
- To compare the effect of *Musta Churna* and *Shatavari Churna* in the management of *Stanya Kshaya* w.s.r to Lactation Failure.

## **7. MATERIALS AND METHODS:**

### **7.1. SOURCE OF DATA:**

#### **(A). LITERARY SOURCE:**

Literary aspect of the study will be collected from *Ayurvedic* classics, modern textbooks, updated with recent medical journals, e-journals, websites and library of SDMTAC, Terdal

#### **(B).SAMPLE SOURCE:**

Subject will be incidentally selected from the OPD/IPD and Medical camps conducted by SDM Trust's Padma Ayurvedic Hospital and Research Centre, Terdal 587315, Karnataka.

#### **(C). DRUG SOURCE:**

Raw drugs will be collected from herbal garden or local market and its proper Identification and Authentication will be done in *Dravyaguna* Department. *Musta Churna* and *Shatavari Churna* will be prepared by classical reference in department of *Rasashastra* and *Bhaishajya Kalpana* SDMT's AMC, Terdal.

## **7.2. METHODS OF COLLECTION OF DATA:**

40 Female patients irrespective of parity, caste, religion and socioeconomic status with classical signs and symptoms of *Stanya Kshaya* will be selected from OPD/IPD of SDMT's Ayurvedic Medical College and Padma Hospital, Terdal.

## **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 case report form (CRF) with a complete history, examination and necessary assessment before treatment and at the time of every follow up.

### **7.2.1 RESEARCH/STUDY DESIGN:**

- A Randomized controlled clinical trial.
- 40 Female Patients who fulfil the inclusion criteria of *Stanya Kshaya* will be selected randomly by software generated chart and placed under 2 groups 'A' and 'B' respectively.

## **STUDY DURATION:**

- Total study duration: - 45 days
- Duration of drug intervention: 30 days.
- Number of visits: - 0<sup>th</sup> day, 15<sup>th</sup> day, 30<sup>th</sup> day, 45<sup>th</sup> day.
- Post Medication follow up: - 45<sup>th</sup> day.

0 <sup>th</sup> day (BT)	15 <sup>th</sup> day (DT)	30 <sup>th</sup> day (DT)	45 <sup>th</sup> day (AT)
1)Screening 2)Enrolment 3) Drug Administration	1)Assessment 2)Drug administration	1)Assessment	1)Follow up 2)Assessment

Note: BT- Before Treatment, DT- During Treatment, AT- After Treatment

### **7.2.2 INTERVENTIONS:**

GROUP 'A': Patient under this group will be given *Musta Churna*

#### *1) Musta Churna*

<i>Aushadha Pramana</i>	6g <sup>28</sup> (3g BD)
<i>Aushadha Sevana Kala</i>	<i>Pragbhakta</i> <sup>29</sup> (starting from 5 <sup>th</sup> day after the delivery)
<i>Anupana</i>	<i>Godugdha</i> (50ml )
<i>Aushadha Yojana Kala</i>	30 days
<i>Aushadha Yojana Vidhi</i>	Oral

GROUP 'B': Patient under this group will be given *Shatavari Churna*.

2) *Shatavari Churna*

<i>Aushadha Pramana</i>	6g <sup>28</sup> (3g BD)
<i>Aushadha Sevana Kala</i>	<i>Pragbhakta</i> <sup>29</sup> (starting from 5 <sup>th</sup> day after the delivery)
<i>Anupana</i>	<i>Godugdha</i> (50ml )
<i>Aushadha Yojana Kala</i>	30 days
<i>Aushadha Yojana Vidhi</i>	Oral

Note:- Individual sachets of each dose will be prepared and given to patient.

### **7.3 DIAGNOSTIC CRITERIA<sup>30</sup>:**

- The diagnosis is based on *Pratyatma Lakshana* of *Stanya Kshaya*.–  
**Mother-**

1. *Stana Mlanata*
  - *Stana Shuskatva*
  - *Stanya Alpata*
  - *Stanya Asambhava*
2. Breast feeding frequency

**Baby-**

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

### **SELECTION CRITERIA:**

#### **7.3.1 INCLUSION CRITERIA:**

- Lactating mothers with classical signs and symptoms of *Stanya Kshaya*
- Patients with feeding frequency less than 4-5 times/day.
- Patients from 5<sup>th</sup> day of delivery to 6 months.
- Age group of patient is between 21 - 40 years.

#### **7.3.2 EXCLUSION CRITERIA:**

- K/C/O Mastitis, CA Breast, and Cystic breast disease.
- Patients with Congenital Breast Anomaly.
- K/C/O Psychiatric illness.
- Patients with history of alcoholism, smoking.



- Diagnosed cases of uncontrolled diabetes.
- Mother having a baby with congenital anomaly like cleft lip, cleft palate.
- Patient denying consent.

### WITHDRAWAL CRITERIA:

During the course of treatment if any serious condition or serious adverse effect occurs and patient not following the instructions or patient herself wants to withdraw from the study such patients may be withdrawn from the study.

### **7.3.3 ASSESSMENT CRITERIA<sup>30</sup>:**

#### OBJECTIVE PARAMETERS:

Sr No	Particulars	Grading
<b>(A) MOTHER</b>		
1.	Milk Ejection (Evaluated by manual pressure on nipple and observation recorded on 4 point scale).	<ul style="list-style-type: none"> <li>• Forceful– 0</li> <li>• Stream like – 1</li> <li>• Drop by drop – 2</li> <li>• No ejection – 3</li> </ul>
<b>(B) BABY</b>		
1.	Body Weight	<ul style="list-style-type: none"> <li>• &gt;175 g weight gain/week – 0</li> <li>• 100-175 g weight gain/week – 1</li> <li>• No weight gain – 2</li> </ul>

#### SUBJECTIVE PARAMETERS:

Sr. No.	Particulars	Grading
<b>(A) MOTHER</b>		
1.	<b><i>Stana Mlanata</i></b> A. <i>Stana Shuskatva</i> B. <i>Stanya Alpata</i> C. <i>Stanya Asambhava</i>	<ul style="list-style-type: none"> <li>• If no sign present – 0</li> <li>• If one sign present –1</li> <li>• If two signs present –2</li> <li>• If three signs present -3</li> </ul>
2.	<b>Breast Feeding Frequency</b>	<ul style="list-style-type: none"> <li>• 9-12 feeds/day– 0</li> <li>• 6-8 feeds/day - 1</li> <li>• 3-5 feeds/day- 2</li> <li>• 0-2 feeds/day – 3</li> </ul>

Sr. No.	Particulars	Grading
<b>(B)BABY</b>		
1.	<b>Sleep of Baby</b>	<ul style="list-style-type: none"> <li>• 3-4 hrs sleep – 0</li> <li>• 2-3 hrs sleep - 1</li> <li>• 1-2 hrs sleep – 2</li> </ul>
2.	<b>Cry For Demand Feed</b>	<ul style="list-style-type: none"> <li>• Demand feeds before every 3-4hrs-0</li> <li>• Demand feeds before every 2-3hrs-1</li> <li>• Demand feeds before every 2 hrs - 2</li> </ul>
3.	<b>Urine Frequency</b>	<ul style="list-style-type: none"> <li>• 6-7 times /day – 0</li> <li>• 4-5 times/day – 1</li> <li>• 2-3 times/day- 2</li> <li>• 1/&lt;1 time/day-3</li> </ul>

#### **7.3.4 STATISTICAL ANALYSIS:**

Data will be collected using case report form (CRF) designed by incorporating all aspects (Ayurveda and modern medicine) for the study. Such collected data will be tabulated and analyzed using SPSS (Statistical package for social science) version 20 by using appropriate statistical test. Demographic data and other relevant information will be analyzed with descriptive statistics, Continuous data will be expressed in mean+/- standard deviation, and nominal and ordinal data will be expressed in percentage. Nominal and ordinal data will be analyzed using non parametric tests like Friedman's test, Wilcoxon's signed rank test, Chi-square test. Continuous data will be analyzed using parametric test like repeated measure ANOVA, paired t / unpaired t test, as and when required. The changes (one tailed) with p value < 0.05 will be considered as statistically significant.

#### **7.4. Does the study needs any investigation or interventions to be conducted on patients or human being or animals? if so please describe briefly.**

Yes, the study requires intervention to be conducted on patients.

No interventions are conducted on animals.

#### **INVESTIGATIONS:**

- Serum Prolactin

#### **7.5 ETHICAL CLEARANCE:**

- **Ethical clearance been obtained from your institution case of 7.4?**

-Yes, Ethical clearance obtained from ethical committee, SDM Trust's Ayurvedic Medical College and Hospital, Terdal.

## **8. LIST OF REFERENCES:**

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- 4) National Family Health Survey (NFHS-5) 2019-21, Compendium of fact sheets, Key Indicators, India and 14 states/UTs (Phase-II), Ministry of Health and Family welfare, Government of India. [http://rchiips.org/nfhs/NFHS-5\\_FCTS/India.pdf](http://rchiips.org/nfhs/NFHS-5_FCTS/India.pdf)
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- 11) Professor Murthy K R Srikantha Bhavaprakasa of Bhavamisra Vol-1, Purva khanda 4/10, Reprint – 2016, Chowkhamba Krishnadas Academy Varanasi, pg. no. 67.
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**SIGNATURE OF THE  
CANDIDATE** :

**10. REMARKS OF THE  
GUIDE** :

**10.1 NAME AND  
DESIGNATION  
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