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A RANDOMIZED OPEN LABELLED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF *AMLAKYADI GHRITA* AND *SHATAVARI GHRITA* NASYA IN THE MANAGEMENT OF *RAJONIVRITTIJANYA LAKSHANAS* W.S.R. POST MENOPAUSAL SYNDROME

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ABSTRACT

Background: Menopause is a physiological transition characterized by permanent cessation of menstruation due to ovarian follicular depletion and declining estrogen levels. The associated vasomotor, psychological, musculoskeletal, and urogenital symptoms substantially impair the quality of life. In Ayurveda, these manifestations are correlated with *Rajonivrittijanya Lakshanas*, primarily resulting from *Vata* predominance secondary to *Dhatukshaya*. Although hormone replacement therapy remains the standard treatment, its long-term use is associated with significant adverse effects, highlighting the need for safe and effective alternative therapies. *Nasya Karma*, one of the *Panchakarma* procedures, is considered beneficial in disorders involving the head and central nervous system and may exert neuroendocrine effects. *Amlakyadi Ghrita* and *Shatavari Ghrita* possess *Rasayana*, *Vata-Pitta Shamaka*, antioxidant, and phytoestrogenic properties that may alleviate menopausal symptoms. A randomized open-labelled controlled clinical study will be conducted on 42 postmenopausal women divided equally into two groups of 21 each. Group A will receive *Amlakyadi Ghrita Nasya* and Group B will receive *Shatavari Ghrita Nasya*. The primary outcome will be change in serum estradiol levels, while secondary outcomes include menopausal symptom scores. The study is expected to provide scientific evidence supporting *Amlakyadi Ghrita Nasya* as a safe, effective, and evidence-based Ayurvedic intervention for postmenopausal syndrome. **Methodology:** 42 patients of Rajonivritti will be selected on the basis of selection criteria. All patients will be divided into two groups. Each group having 21 patients. In group A patients *Amlakyadi ghrita nasya* will be given for 7 sittings in between 7 to 21 days and in group B patients *Shatavari ghrita nasya* will be given for7 sittings in between 7 to 21 days. Observations will be done on the basis of before and after subjective and objective parameters and clinical investigations.

KEYWORD: Post menopausal syndrome, *Rajonivritti*, *Nasya karma*, *Amlakyadi ghrita*, *Shatavari ghrita*, Serum estradiol, *Ayurveda.*

INTRODUCTION

Rajonivritti is a significant event in woman's life.It represents the end of the reproductive era.The ancient *acharyas* termed it as *Rajonivritti*.This word is derived from *Rajah* and *Nivritti* meaning cessation of *Artava pravritti.*

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(Su.sha.3/11)[1]

According to *Acharya Sushrut* & various other refererences 50 years is mentioned as the age of *rajonivritti* when the full body is fully in grip of senility.Menopause is the permanent cessation of menstruation for 12 consecutive months due to loss of ovarian activity.[2] Every women faces various physiological & psychological changes during this change of life as a part of hormonal derangement sometimes such disturbances attains the stage of disease or syndrome called as menopausal syndrome accompanied by Vasomotor, psychological, genital. Locomotor and GIT related symptoms.[3] In menopause menstrual cycle stops and sex hormones level decreases including that of estrogen.Menopause is linked with ageing which is *vata* dominant stage of life,therefore symptoms of menopause experienced by some women are similar to *vriddhi lakshanas* of *vata dosha*.There is connection between *nasa* and *shira*. *Nasa* is considered as a gate way for the *shira*. When we administered the drugs through nasal route, through the *sukshmastrotas* in nasal route it reaches the *shiragata marma* and spreads throughout the *mastishka* and takes out *doshas* from *urdhvajatrugata* region.*Nasya karma* is a natural route for delivering, rejuvenating substance to the brain.This may be helpful to women to enter is menopausal phase gracefully.Menopausal symptoms generally occur due to disturbed *Vata Dosha. Dhatukshay* is responsible for *Vata Vruddhi* and vitiated *Vata Dosha* affects various systems in women's body. From the above theory we can conclude that drugs like *amlaki,madhuyashti,shatavari* having properties of *Rasayana*, *Vatapitta Shaman* and *Kapha Vardhan* can be helpful for the management of menopausal syndrome.[4] Therefore, it has been believed that working in this area and making a contribution—that is, menopause from an *Ayurvedic perspective*—is imperative.

AIMS AND OBJECTIVES

Aim: To evaluate the efficacy of *Amlakyadi ghrita nasya* in *Rajonivrittijanya lakshanas* wsr post menopausal syndrome

Primary Objective: To assess the effect of *Amlakyadi ghrita nasya* on serum estradiol in *rajonivrittijanya lakshanas.*

Secondary Objective: Detailed Study of *Rajonivrittijanya lakshanas* in ancient literature and correlate it with Modern science.

Research Question: Does *Amlakyadi Ghrita Nasya* has significant role in the management of *Rajonivrittijanya lakshanas* w.s.r post menopausal syndrome?

Research hypothesis

Amlakyadi Ghrita Nasya is significantly effective than *Shatavari Ghrita Nasya* in the management of *Rajonivrittjanya lakshanas*.

Null hypothesis-

Amlakyadi Ghrita Nasya is not significantly effective as *Shatavari Ghrita Nasya* in the management of *Rajonivrittjanya lakshanas.*

Experimental Source- It will be a pure Human Clinical trial; no animal experiment will be done.

Materials and methods

To fulfil the Aim and Objectives, the study plan is divided into 2 sections

- Literary review
- Clinical study.

Study design

- Type of Trial – Interventional
- Design- Randomized clinical trial
- Purpose – To evaluate the efficacy of Amlakyadi ghrita nasya in comparision with Shatavari ghrita nasya in Rajonivrittijanya lakshanas wsr to post menopausal syndrome.
- Masking- No, Open Label
- Timing- Prospective
- End Point- Efficacy
- Duration of trial- 18 months
- Phase of trial- phase 2
- Subjects- 42(21 in each group)
- Statistical tool- Appropriate tool will be apply

Selection of patients: The patients fulfilling the criteria and attending OPD and IPD of Prasuti tantra evam stree roga department of the I.A.S.R Kurukshetra Haryana will be selected for research study.

Inclusion criteria

- Patients willing to sign the consent form.
- Patients of age between 45 and 60 years.
- Amenorrhoea for more than or equal to 12 consecutive months.
- Women having clinical features of Menopausal Syndrome.
- Willing and able to participate in the study.

Exclusion criteria

- Patients with evidence of malignancy.
- Surgical menopause.
- Patients with uncontrolled Diabetes Mellitus(Blood sugar fasting
- >250mg/dL), uncontrolled hypertension (BP>160/100 mm of Hg).
- Patients who have a past history of Atrial Fibrillation, Coronary Artery Disease (CAD),Acute Coronary Syndrome, Myocardial Infarction, Stroke or Severe Arrhythmia,Renal diseases, in the last 6 months.
- Symptomatic patients with clinical evidence of Heart failure.
- Any other condition which the Principal Investigator

thinks may jeopardize the study.
- Patients who are taking supplements like Vit.E, Vit D capsules

Investigations
For assessing the general condition of patient and exclusion of other pathogenesis the following investigation may be performed: Blood and Serological test -
1. Hb
2. RBS
3. Serum Estradiol
4. TSH

MATERIAL AND METHODS
Clinical study materials: patients indicated and fit for trial were selected from outpatient & in patient department of Prasuti Tantra Evam Stree Roga, I.A.S.R, Kurukshetra,Haryana.

Conceptual study materials: Literary references are be collected from Ayurvedic Samhitas and their Commentaries, Modern literature, Research journals, online portal like PubMed, Ayush research portal, Google scholar are analysed to frame the conceptual work.

Drug review
Intrventions for each group - Group A: - Trial group
Amlakyadi ghrita[5] (GMP certified) - 8 bindu (4ml in each nostril) 7 Sittings in between 7-21 days. Route of administration - Nasal route.

Group B: Controlled group
Shatavari ghrita[6] (GMP certified) -8 bindu (4ml in each nostril) 7 Sittings in between 7-21 days. Route of administration - Nasal route.

Method of preparation: *Amlakyadi Ghrita and Shatavari ghrita* will be prepared with *Kalka, Sneha* and *Drava dravya* mentioned in the resepective samhitas.

Sr No.	Group	Medications	Dose[7]	No. of Patients	Duration[8]
1.	Group A (Trial group)	*Amlakyadi ghrita nasya*	8 bindu (4ml in each nostril.)	21	7 Sittings in between 7-21 days
2.	Group B (Controlled group)	*Shatavari ghrita nasya*	8 bindu (4ml in each nostril.)	21	7 Sittings in between 7-21 days

(As per AFI 1 bindu = 10 drops = 0.5ml)

Procedure
1. Poorva karma
- Food, drink and bath should be avoided for at least two hours before and after the administration of *Nasya*. The patient is directed to clear the natural urges.He is asked to sit on a stool and Snehana is given by applying *Tila tail* to the scalp, face, neck and shoulders for five minutes.
- Then, *Swedana* is done with towel soaked in boiling water and after squeezing the water, towel was waved, touched and pressed on this area for 5 minutes.
- Position: *uttana shayan* (supine position), *Pralambita shirah* kinchita bend head.[13]

2. Pradhan karma
- Pour the lukewarm *ghrita* slowly into each nostril one by one with the help of dropper keeping the other nostril closed with hand.
- Patient is advised to keep in supine position for 100 Matra Kala or unless the administered ghrita comes in mouth.

3. Pashchat Karma
- A gentle massage is given to palms, planter aspects of the foot, face and shoulders.
- If there is discharge from the nose to the mouth patient should spit into the spittings or in the kidney tray without raising much.
- Vacha Churna is avachurnita on hot pan. Patient is asked to inhale 3 times with open mouth for 3 strokes covering his head along with pan with towel.
- After that Gandusha with lukewarm water mixed with saindhav lavana for 3 times.[14]

4. Follow Up
Patients will be followed up to assess variation in symptomatology and to know any complication.
- 1ST Follow up- on next day after last sitting
- 2nd follow up- 7 days after 1st follow up.
- 3rd follow up- 7 days after 2nd follow up.

Route of administration- Nasal Route. **Assessment criteria (Menopausal Rating Scale) Subjective criteria-**
- Hot flushes
- Excessive sweating
- Fatigue
- Palpitations
- Sensation of pins and needle prick
- Pain in joints
- Mood swings
- Depression
- Sleep disturbances
- Dryness of vagina
- Loss of urinary control

Objective criteria

Level of Serum estradiol pre and post nasya karma will be measured.

Outcomes

Primary outcome -The Proportion of patients showing improvement in the level of Serum Estradiol post *nasya* karma.

Secondary outcome

1. Reduction in symptoms of *rajonivritti* in the patients.
2. Assessment of *rajonivritti* by clinical features and post menopausal syndrome by subjective assessment criteria.
3. To improve the mental & physical well being of patient.
4. To improve the quality of life of patient.

Sample Size

Sample size is calculated on the basis of expected cured % among cases having Postmenopausal Symptoms with trial drugs using the sample size calculation formula.

$$n=\frac{\left(z_\alpha+z_\beta\right)^2}{\left[\ln(1-e)\right]^2}\left[\frac{1-p_1}{p_1}+\frac{1-p_2}{p_2}\right]$$

*P*1 = 1.00 (100%) the proportion of cases having Postmenopausal Symptoms before applying the trial drugs.

Where *p*2 = 0.47 (47%) the proportion of cases having Postmenopausal Symptoms after applying the trial drugs. (Ref: Shukla R, Ganjiwale J, Patel R. Prevalence of Postmenopausal Symptoms, Its Effect on Quality of Life and Coping in Rural Couple. J Midlife Health. 2018 Jan-Mar; 9(1): 14-20.)

e = (*p*1 – *p*2), the proportion difference considered to be clinically significant Type I error, α=5%

Type II error β=10% for detecting results for detecting results with power of study 90 % The sample size is **n = 21** each group**.**

Due to short time duration of the study ,financial limitations and limited patients of post menopausal syndrome in the OPD total no. of patients taken for the study will be 42.

Statistical Analysis

The observations and results will be analysed and presented on the basis of respective and applicable statistical tests.

Ethical Clearance & CTRI Registration

Study was started after obtaining ethical clearance from the Institutional Ethics Committee, I.A.S.R. Kurukshetra. **SKAU/Acad./2024/11569**

Study was registered in CTRI: - **CTRI/2024/12/078802**

OBSERVATION AND RESULT

The observations and results will be analysed statistically with relevant tests and level of significance will be reported.

DISCUSSION

The obtained results will be discussed on the basis of ayurvedic concept and modern parameters.

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