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Protocol

A study protocol for assessing the efficacy of Shatavaryadi Kashaya and Shatavari Ghrita ointment in the management of genitourinary syndrome of menopause: an open labelled randomized standard-controlled clinical trial

Anjana B. Thanki*, Shilpa Donga

Department of Prasutitantra Evum Streeroga, Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat, India

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***Correspondence:**
Dr. Anjana B. Thanki,
E-mail: thankianjana22@gmail.com

ABSTRACT

Background: Genitourinary syndrome of menopause (GSM) is a chronic, progressive condition in postmenopausal women characterized by genital, sexual and urinary symptoms due to estrogen deficiency. Ayurveda attributes such degenerative symptoms to Vata dominance and Dhatukshaya in Jara Avastha, with management focused on Rasayana and Snehana therapies. This study aims to provide efficacy of oral administration of Shatavaryadi Kashaya along with per vaginal application of Shatavari Ghrita ointment in the management of GSM and to compare it with standard treatment using Multivitamins and Estriol cream.
Methods: Open-labelled, randomized, standard-controlled clinical trial, participants, patients fulfilling inclusion criteria of genitourinary syndrome of menopause; interventions: group A will receive Shatavaryadi Kashaya (40 ml orally twice daily) and Shatavari Ghrita ointment (2 gm per vaginal application daily with applicator), while group B received Weltive 4G (oral multivitamin) and Evalon cream (0.5 gm per vaginal application twice weekly) for 60 days. Primary outcome measures include improvements in Vaginal Health Index (VHI), Female Sexual Health Index (FSHI) and urinary tract infection symptoms assessment by UTISA, secondary outcome includes changes in the Vaginal Maturation Index (VMI) measured by Pap smear.
Conclusions: This trial aims to assess the potential of Shatavaryadi Kashaya and Shatavari Ghrita ointment as Ayurveda treatment for Genitourinary syndrome of menopause, offering a promising non-hormonal alternative to conventional estrogen therapy.
Trial registration: The trial is registered with the Clinical Trials Registry of India (CTRI) CTRI/2025/07/091397.

Keywords: Evalon cream, Genitourinary syndrome of menopause, Rajonivruttijanya Lakshana, Shatavari ghrita ointment, Vaginal maturity index by pap smear

INTRODUCTION

Genitourinary syndrome of menopause (GSM) previously referred as vulvovaginal atrophy VVA, encompasses a range of symptoms affecting the genital and lower urinary tract in postmenopausal women. The term was presented and discussed at the annual meeting of NAMS (North American Menopause Society) and ISSWSH (International Society for the Study of Women's Sexual Health) formally endorsed the new terminology GSM in 2014.[1] GSM is a chronic, progressive, vulvovaginal, sexual and lower urinary tract condition characterized by decrease in estrogen involving changes mainly to vagina, urethra and bladder. The syndrome mainly includes three domains of symptoms genital symptoms dryness, burning and irritation of vagina sexual symptoms reduced lubrication, dyspareunia and loss of libido, urinary symptoms of urgency, dysuria and recurrent urinary tract

infections (UTIs). Women may present with some or all of the signs and symptoms, which is bothersome and it leads to impaired quality of life of menopausal women. The pathophysiology of GSM is primarily driven by the loss of estrogen, which plays a critical role in maintaining the integrity and elasticity of the urogenital tissues. As estrogen levels decrease, these tissues become more fragile, leading to symptoms such as vaginal dryness, irritation and painful intercourse.

The urinary tract also becomes more vulnerable to infections and contributing to a variety of urinary problems. There is no direct reference of genitourinary syndrome of menopause in Ayurvedic literature; However, the condition can be compared on basis of symptoms. All Acharyas opined that age of approaching Rajo Nivrutti is from 50 years onwards that is included in Madhyama Avastha and Jeerna Avastha of life span which is accompanied by process of Parihani. Acharya Susruta has opined that Jara is one among Swabhavika Vyadhi that occur by nature itself. It is dominated by Vata Dosha.[2] Dhatukshaya causes Vata, Pitta Dosha Vruddhi and Kapha Dosha Kashaya. Factors such as Vata Vruddhi due to Jara Avastha, generalized Raukshya, Shosha leads to aggravation of Laghu, Ruksha, Khara, Chala Guna of Vata, which will lead to various symptoms i.e., Yoniraukshya, Yonikandu, Maithunashahishnuta. Pittavruddhi and Kaphakshaya causes Yonidaha, Mutrakruccha, Aharsha which are typically observed in genitourinary syndrome of menopause.

Previous research work

The research works (Clinical Study, Survey Study) carried out at various postgraduate research institutions on Jara/Rajonivrittijanya Vikara/Menopausal Syndrome/ Genitourinary syndrome of menopause and published articles in peer review journals were reviewed based on available sources like PubMed, Google scholar, CTRI, Dhara and Ayush research portal using keywords (Jara, Rajonivritti, Menopause, Menopausal Syndrome, Genitourinary syndrome of menopause) and (Ayurveda or Complementary and Alternative Medicine or Management). Total 40 research work available on menopausal syndrome but there is no research work has been found regarding genitourinary syndrome of menopause. There are only two previous works carried out at RGGPGAY at Paprola for assessment of vaginal symptoms of menopause.

Clinical trial to evaluate the efficacy of Balasatavari Kwatham and Bala Tailam ointment in vaginal symptoms in women who attained menopause; 2004. A clinical trial to assess the combined effect of Sukumara Kashayam and Shasthika Taila in Menopausal Vaginal symptoms; 2009.

Research lacunae

Previous researches have largely focused on general menopausal syndrome, with most studies examining systemic effects of Rasayana. However, there has been no specific research on Genitourinary Syndrome of Menopause (GSM) carried out despite its significant impact on postmenopausal women's quality of life. Additionally, Shatavari (Asparagus racemosus) is well-known Ayurvedic medicine for its hormone-balancing and anti-inflammatory properties, most studies have focused on its oral administration, with no specific research on the local application of Shatavari ointment for GSM symptoms has been carried out. This represents a research gap, as local treatments may offer targeted, non-invasive relief for symptoms like vaginal dryness and irritation. Investigating the efficacy, safety and potential mechanisms of Shatavari ointment could provide an important alternative to reduce symptoms of GSM and offer valuable insights in modern therapeutic contexts.

The prevalence of GSM rises with age and up to 50% of postmenopausal women experience at least some degree of the syndrome. However, many women do not report symptoms due to embarrassment or the misconception that these changes are merely a natural consequence of aging, rather than a treatable medical condition.[3] If GSM is not treated early, it can lead to chronic vaginal dryness, dyspareunia and recurrent infections. Urinary complications such as frequent UTIs, incontinence and overactive bladder may develop. These issues can significantly impair sexual health, pelvic integrity and overall quality of life. Moreover, many healthcare providers fail to recognize that these symptoms are treatable and often assume they are simply part of the aging process.[4] Effective management of GSM involves a range of therapeutic options, including local vaginal estrogen therapy, non-hormonal treatments and lifestyle modifications. The key to successful treatment lies in early recognition and open communication between patients and healthcare providers. By addressing GSM proactively, symptoms can be alleviated and women's quality of life can be significantly improved.[5] There is no direct reference of genitourinary syndrome of menopause in Ayurvedic literature; However, the condition can be compared on basis of symptoms.

Aim

To evaluate the efficacy of oral administration of Shatavaryadi Kashaya along with per vaginal application of Shatavari Ghrita ointment in the management of Genitourinary syndrome of mrnopause

Objective

To assess the effect of trial drug and compare their effectiveness with standard care - multivitamins along with estriol ointment in the management of genitourinary syndrome to assess the effect of trial drug measured by standardized symptom scoring tools VHI, Female Sexual Health Index (FSHI), Urinary tract infection symptoms

assessment (UTISA). To evaluate the Changes in the vaginal maturity Index by Pap smear.

METHODS

Patient and public involvement

Written consent will be taken in local language before enrolment of patients into the trial. Though public will not be involved directly in the conduct or data analysis of the study, the findings will be reported in a manner accessible to the public and summaries will be shared with participants and relevant community groups to promote transparency and engagement.

Trial design

This study is a randomized, controlled, parallel-group clinical trial with an allocation ratio of 1:1. It follows a superiority framework to compare the effectiveness of the intervention against the control. The method of randomization will be computer-generated randomization using a random number table to ensure unbiased allocation.

Study setting

The study will be conducted in the Department of PTSR, Institute for Teaching and Research in Ayurveda (ITRA), Jamnagar. Eligible patients visiting the OPD/IPD of the Prasutitantra evum streeroga and diagnosed with Genitourinary syndrome of menopause will be screened and enrolled. The total sample size will be equally divided between the two groups over the recruitment period.

Inclusion criteria

The study includes women with a confirmed diagnosis of menopause (natural- absence of menstruation>12 months) or surgical- A history of bilateral oophorectomy, age between 40-65 years having presence of at least 3 common symptoms of GSM i.e., Yoniraukshya, Yonikandu, Mutrakruccha, Mutradaha, Yonivedana, Yonidaha (vaginal dryness, vaginal itching, dysuria, burning micturition, dyspareunia, burning sensation per vagina) and person willing to provide informed consent and comply with study protocol.

Exclusion criteria

The study excludes Women if they are below 40 or above 65 years of age, premenopausal, had irregular menstrual cycles or currently using systemic hormone replacement therapy or vaginal estrogen. Other exclusion criteria include active vaginal or severe urinary tract infections with systemic symptoms, history of genital or breast cancers, severe pelvic organ prolapse, gynecological disorders requiring surgery, use of medications affecting sexual or vaginal health (e.g., antidepressants, antihistamines) and uncontrolled hypertension or diabetes. (Blood Pressure >150/100 mm of Hg) and Diabetes (RBS >200 mg/dl).

Study interventions

Patients in Group A will receive ayurveda Intervention. Deepana and Pachana with Guduchi, Haritaki and Sunthi Choorna will be given orally 3 days prior to administration of Shatavaryadi Kashaya. 20 gm of coarsely powdered drugs should be boiled with 16 parts of water in steel vessel, over a mild flame till the liquid is reduced to 1/4th of the original quantity. 40 ml of Shatavaryadi Kashaya with 5 ml of Goghrita Prakshepa will be given before meal to patient. 2 grams Shatavari ointment per vaginal application/ day at bedtime will be given to the patient with applicator. This treatment will be continued for 60 days. On the other hand, Group B will receive standard treatment protocol. Weltive 4G - Multivitamins tablet once/day after breakfast will be given to the patient along with estriol ointment 0.5 mg/twice a week will be advised to patients for 60 days. Internal administration of hormone replacement therapy (HRT) is not the first choice for Genitourinary Syndrome of Menopause (GSM) because it involves systemic hormones that carry risks like blood clots and cancer. Studies have shown SERMs increases the risk of breast cancer, uterine cancer, coagulopathies, depression, impaired memory, as well as hot flushes.[6] Weltive 4G is combination of vitamins, minerals and antioxidants aimed at improving immunity and supporting vaginal and urinary tract health in post-menopausal women.[7]

Withdrawal criteria

Patients complaining of any adverse reaction, not willing to continue the treatment, having severe complications or any other symptoms of intolerance of oral medicine and local application of ointment like vaginal irritation, headache, vaginal spotting or allergic reaction will be withdrawn from the study.

Primary outcome

The primary outcome of the study is to observe changes in vaginal health index (VHI), female sexual health index (FSHI) and UTISA Score, which may indicate a beneficial physiological response to the interventions.

Assessment timepoints

At baseline (Day 0), Day 30 and at the end of the intervention (Day 60).

Secondary outcome

Vaginal maturity index assessment timepoints

Pap smear will be collected at baseline (Day 0) and post-intervention (Day 60) for vaginal maturation index.

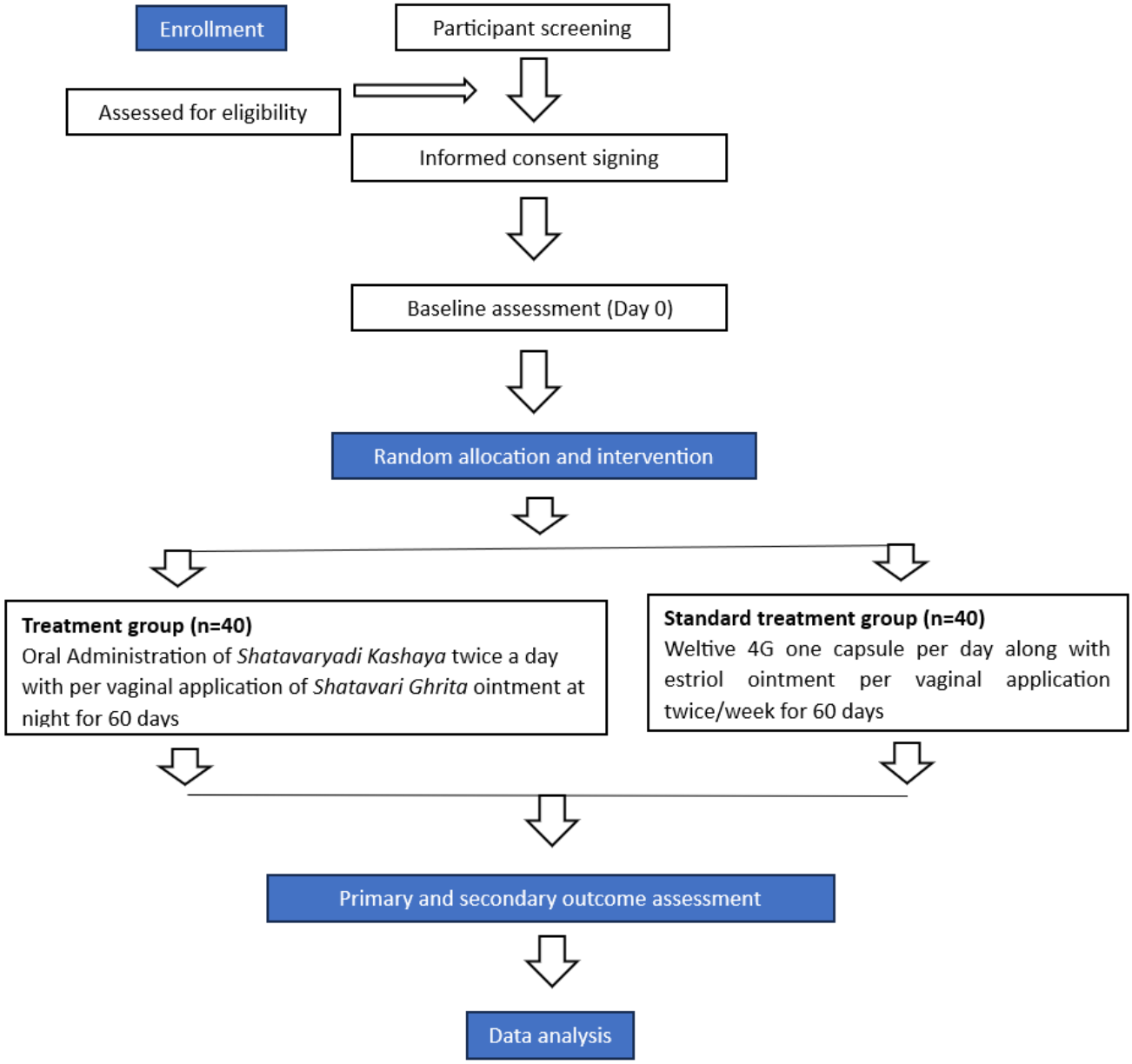

Figure 1: Participant timeline.

Randomization and allocation

The study utilizes a computer-generated randomization chart to ensure unbiased allocation of participants. Randomization is conducted in a 1:1 ratio, assigning individuals equally between the intervention and control groups. The randomization schedule is strictly maintained by the designated biostatistician or data analyst to uphold methodological integrity and prevent selection bias.

Sample size

Sample size calculation

For estimating the sample size, on the basis of previous research work regarding GSM, mean score of vaginal health index was observed 17.1+-5.1 (SD) in control group.[8] It is assumed that trial drug will improve further 20% of vaginal health. Considering above assumption, sample size was calculated by Software https://clinical.com/stats/samplesize.aspx. Allocation is 1:1. Power of test is 80%, Level of significance 95%, Error 5 %. In 2 side test, number of patients calculated as 35 per group but Considering 10% droupout,40 patients in each group will be selected.

Recruitment strategy

Screening criteria

Participants will be screened for Genitourinary Syndrome of Menopause in accordance with the predefined inclusion criteria. Prior to the initiation of any trial-related procedures, the principal investigator will provide

participants or their legally authorized representatives, with comprehensive information regarding the study.

Diagnostic criteria

Presence of at least 3 common symptoms of GSM i.e., Yoniraukshya, Yonikandu, Mutrakruccha, Mutradaha, Yonivedana, Yonidaha (vaginal dryness, vaginal itching, dysuria, burning micturition, dyspareunia, burning sensation per vagina).

Per speculum examination findings, vaginal atrophy (thinning, dryness, loss of elasticity). External vulvar changes (thinning of skin, loss of elasticity). Vaginal pH testing: Elevated pH after menopause (>4.5)

Allocation

The sequence generation for participant allocation in this study will be performed using computer-generated randomization to ensure unbiased distribution between the intervention and control groups. Since the study is open-label, there will be no blinding or masking of the participants or researchers. As a result, both the participants and the investigators will be aware of the treatment assigned, making allocation concealment unnecessary (NA). This approach is designed to maintain transparency throughout the trial, although it may introduce potential biases due to the lack of blinding.

Study procedure

This will be communicated both verbally and through printed documentation. The investigator will ensure that each participant is fully informed about the study's objectives, methodologies, potential discomforts and anticipated benefits. It is imperative to emphasize that participation in the trial is entirely voluntary and individuals reserve the right to withdraw from the study at any point without any repercussions. Following the screening process, eligible participants will be formally enrolled upon signing the informed consent document. Necessary diagnostic assessments will be conducted and Enrolment will be confirmed based on investigative findings. The day of Enrolment will be designated as Visit 1, also referred to as the baseline visit. The therapeutic intervention will commence only after all requisite formalities have been duly completed in accordance with the established protocol.

Data collection methods

Data will be collected by the scholar in a specially designed case report form which includes assessment criteria as well as laboratory investigations and symptomatic improvement.

Laboratory tests

All patients enrolled in the study will undergo a series of investigative assessments to ensure accurate diagnosis and monitoring of their health status For the purpose of assessing the general condition of the patient and excluding other pathologies, the following investigations will be carried out before the treatment: biochemical investigations including random blood sugar, liver profile (total bilirubin, direct and indirect bilirubin, ALP, AST, ALT) and renal profile (serum urea and serum creatinine) and serological tests such as HIV, HBsAg, VDRL and HCV. Additionally, the following investigations will be conducted both before and after treatment: routine haematological investigations including complete blood count and erythrocyte sedimentation rate (ESR); urine analysis comprising routine and microscopic analysis and urine culture if required. Special investigations will include vaginal maturity index assessed by Pap smear, serum estradiol levels (measured in randomly selected 20 patients from each group—every 2nd patient) and ultrasonography (TAS/TVS) to evaluate endometrial thickness in all patients.

Criteria for assessment

Subjective Assessment Criteria: The overall effect of the therapy will be assessed on the basis of relief in cardinal symptoms of GSM. A special proforma adopted from the standard symptoms scoring tool like Vaginal maturation Index (VMI), Female sexual health index, UTISA questionnaire incorporating the signs and symptoms of GSM.

Symptoms of genitourinary syndrome will be observed at baseline, during treatment at interval of 30 days, 60 days, 90 days. Changes in gradation of each symptom will be recorded before and after treatment and will be assessed in regards to baseline score.

Objective assesement criteria

Vaginal Atrophy will be assessed by VHI and the VMI before and after treatment. VMI is a non-invasive method used to assess the severity of vaginal atrophy. It involves a microscopic examination of a vaginal smear to determine the cellular composition of the vaginal epithelium. pre- and post-treatment VMI scores are compared to assess the efficacy of trial intervention.

Data management

Data will be entered in digital format in MS excel in form of master chart.

Data safety and monitoring

The study will be conducted under the supervision of the Institutional Ethics Committee (IEC), Institutional Review Committee (IRC) and Departmental Review Committee (DRC). All necessary approvals will be obtained prior to initiation. Regular monitoring will ensure participant safety, protocol compliance and data integrity. Any serious adverse events (SAEs) or protocol deviations will be reported promptly to the IEC. At the

end of the trial, the data will be disclosed to the IEC, IRC, DRC and relevant regulatory authorities as required.

Data analysis

The information gathered based on the observation made about various parameters will be subjected to statistical analysis in terms of Mean, Standard Deviation (SD) and Standard Error (SE). General data will be subjected to suitable statistical analysis such as descriptive statistics for demographic data, Chi-square test or normal variate Z test will be used for testing associations of the baseline data. Paired t-test for paired continuous data i.e., within the groups and unpaired t-test will be applied for between groups continuous data. Wilcoxon Signed-Rank Test will be used for non-parametric data within the groups and Mann-Whitney U Test for comparing between groups with non-parametric data. The data generated in the clinical study will be analyzed by applying appropriate statistical method also. After preparing the master chart of all the required data in a Microsoft Excel worksheet, statistical calculations will have made with the help of Sigma stat 3.5 software and in stat 3 software. The results will have interpreted as significant $p<0.05$, highly significant $p<0.01$, very highly significant $p<0.001$, insignificant $p>0.05$.

Safety monitoring in this study will be carried out through a comprehensive approach, which includes detailed physical examinations, regular monitoring of vital signs and periodic clinical assessments throughout the trial. This ensures that any potential health concerns are promptly identified and addressed. In addition, any adverse events (AEs) or serious adverse events (SAEs) that occur during the study will be thoroughly documented. These events will be reported to the Adverse Drug Reaction (ADR) Cell, which is the Pharmacovigilance Cell of ITRA, for further evaluation and management. This process ensures participant safety and adherence to regulatory requirements, while also providing an effective mechanism for managing any unforeseen risks associated with the interventions.

Ethics and dissemination

The study will commence only after obtaining approval from the Institutional Ethics Committee (IEC), ensuring that all ethical standards are met. Additionally, the study will be registered with the Clinical Trials Registry of India (CTRI) to maintain transparency and accountability. Written informed consent will be obtained from all participants in the local language, ensuring they fully understand the study's purpose, procedures and potential risks. To protect participants' privacy, all personal data will be anonymized and coded. The results of the study will be disseminated through publication in peer-reviewed scientific journals and presented at academic forums, allowing for broader sharing of findings within the scientific community. This approach ensures that the study adheres to ethical guidelines while promoting the transparency and accessibility of its outcomes.

DISCUSSION

Acharya Sushruta has mentioned that Kalakruta Jara must be managed by Bhojana, Pana and Rasayana.[9] So, management of GSM can be done by drugs which contains phytoestrogens, antioxidants and having rejuvenating properties. Shatavaryadi Kashaya is mentioned in Shahastrayoga in the treatment of Mutrakruccha. The combination of Shatavari, Vidarikanda, Gokshur, Musta and Sariva in Shatavaryadi Kashaya include polyphenols and coumaroylquinic acids. Shatavari, Vidarikanda and Gokshur are rich source of phytoestrogens.[10] It helps in reducing genitourinary atrophy as well as improves sexual function in post-menopausal women. The Shatavari Ghrita formulation mentioned in Bhaishjyaratnavali containing Shatavari with ghee and cow milk is known for its nourishing and rejuvenating effects.[11] Shatavari has Tikta, Madhura Rasa, Sheeta Virya and Madhura Vipaka. It is rich source of phytoestrogen which mimic the action of estrogen in the body by binding to estrogen receptors. In females, phytoestrogens have been particularly noted for their role in alleviating menopausal symptoms such as vaginal dryness, dysuria etc. offering a natural alternative to hormone replacement therapy (HRT).[12] But the evaluation of effect of Shatavaryadi Ghrita ointment and Shatavaryadi Kashaya on the management of genitourinary syndrome of menopause is not studied yet. Thus, the topic is significant for current research work.

This study exhibits several methodological strengths, notably its randomized design and the inclusion of a sufficiently large participant cohort, ensuring robust statistical power for subgroup analyses. Additionally, the study is standard control providing comparison of the result as well as effect of Shatavari Ghrita ointment effect on vaginal epithelium by monitoring of vaginal maturation index by Pap smear. Potential limitation of this study is the awareness of investigators regarding participants' group assignments, which introduces the possibility of bias favouring specific groups. Consequently, the risk of observer bias cannot be entirely eliminated, potentially influencing the interpretation of study outcomes.

Strengths

This study exhibits several methodological strengths, notably its randomized design and the inclusion of a sufficiently large participant cohort, ensuring robust statistical power for subgroup analyses. Additionally, the study is standard control providing comparison of the result as well as effect of Shatavari Ghrita ointment effect on vaginal epithelium by monitoring of vaginal maturation index by pap smear.

Limitations

Potential limitation of this study is the awareness of investigators regarding participants' group assignments, which introduces the possibility of bias favouring specific groups. Consequently, the risk of observer bias cannot be entirely eliminated, potentially influencing the interpretation of study outcomes.

CONCLUSION

This randomized, standard-controlled clinical trial is designed to scientifically evaluate an Ayurvedic, non-hormonal therapeutic approach for the management of Genitourinary Syndrome of Menopause (GSM), a chronic and often under-recognized condition significantly affecting postmenopausal women's quality of life. By combining oral administration of Shatavaryadi Kashaya with local per-vaginal application of Shatavari Ghrita ointment, the intervention aims to address both systemic and localized degenerative changes described in menopausal state while also targeting estrogen-deficiency–related urogenital alterations recognized in contemporary medicine. The study employs validated subjective and objective outcome measures, including vaginal health index, female sexual health index, UTISA and Vaginal Maturation Index assessed by Pap smear, ensuring methodological rigor and comparability with standard estrogen therapy. By addressing a clear research lacuna in Ayurvediya gynecology and exploring a novel localized application of Shatavari, this study may provide evidence for a safe, effective and patient-acceptable alternative for women who are unsuitable or unwilling to use hormonal treatments, thereby contributing to integrative and personalized menopause care.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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