Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the therapeutic effect of conjugated estrogen vaginal cream with vitamin D and E combination vaginal cream in the treatment of postmenopausal genital syndrome

Protocol summary

Study aim

Comparison of the therapeutic effect of conjugated estrogen vaginal cream with vitamin D and E combination vaginal cream in the treatment of postmenopausal genital syndrome

Design

Phase 3 Randomized Clinical trial on 64 patients. samples will be randomly assigned to two intervention and control groups.

Settings and conduct

This double blind study will be conducted in Fatemieh Hospital affiliated to Hamadan University of Medical Sciences. In this study, the coverage of the ointments will be made in different colors, the prescribing physician and the patient will be unaware of the content inside them.

Participants/Inclusion and exclusion criteria

Participants are postmenopausal women with genital urinary syndrome include vaginal dryness, burning and itching of the vagina, dyspareunia, and urinary symptoms of burning and frequent urination. Conditions for not entering the study include: definitive or suspected endometrial or breast cancer, abnormal vaginal bleeding or vaginal infection, a history of diabetes, CKD, arthritis, cardiovascular disease and active hepatobiliary disease, sensitivity to vitamin E, D or estrogen. women who have had hormone therapy for the past 12 weeks and women whose husbands have a sexual dysfunction.

Intervention groups

In the intervention group, patients will be treated with a combination vaginal cream containing Vitamin D 1000 IU / dose and Vitamin E 100 IU / dose with daily once a day for 2 weeks and then three times a week for 10 weeks. In the control group, patients will be treated with 0.625 g / dose estrogen conjugated vaginal cream (1 g of estromarin produced by Abu Reihan Pharmaceutical Company, equivalent to a quarter of a 4 g applicator) once a day for 2 weeks, followed by three times a week for 10 weeks.

Main outcome variables

Primary outcome of study will be changes in genital urinary symptoms and secondary outcome patients' marital quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N10**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **prospective**

Last update: **2020-06-22, 1399/04/02**
Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-21, 1399/04/31

Expected recruitment end date
2022-07-21, 1401/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the therapeutic effect of conjugated estrogen vaginal cream with vitamin D and E combination vaginal cream in the treatment of postmenopausal genital syndrome

Public title
Treatment of postmenopausal genital syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
postmenopausal women Has urinary-genital symptoms: vaginal itching, burning, dryness, dyspareunia, urination frequency and burning
Exclusion criteria:
Definitely or suspected of having endometrial or breast cancer Women with abnormal vaginal bleeding or vaginal infection Women with Diabetes, CKD, Arthritis, Cardiovascular Disease and Active Hepatobiliary Disease Sensitivity to vitamin E, D or vaginal estrogen Women have spouses with sexual dysfunction Women who have been on hormone therapy for the past 12 weeks
Age
From **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
We made 64 cards and write letter I on 32 for Intervention and on the other 32 letter C for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and will be opened, based on selected letter (I or C) patients will be assigned to intervention or control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Vaginal creams will be in prepared in two different colors.Neither the patients nor the prescribing physician will be aware of the active ingredient in the cream.When analyzing data, group code is revealed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan Univercity of Medical Science
Street address
Shahid Fahmideh Avenue
City
Hamedan
Province
Hamadan
Postal code
6517838697
Approval date
2020-05-22, 1399/03/02
Ethics committee reference number
IR.UMSHA.REC.1399.220

Health conditions studied

1

Description of health condition studied
Genital urinary syndrome in postmenopausal women
ICD-10 code
N95
ICD-10 code description
Menopausal and other perimenopausal disorders

Primary outcomes

1

Description
Changes in urinary-genital symptoms
Timepoint
Week 4, 12 and 16 after treatment onset
Method of measurement
Get a history and clinical examination

Secondary outcomes

1

Description
Marital Quality of life
Timepoint
16 weeks after treatment onset
Method of measurement

Women's Sexual Performance Index Questionnaire

Intervention groups

1

Description
Intervention group: This group will be treated with a combination vaginal cream containing Vitamin D 1000 IU / dose and Vitamin E 100 IU / dose once a day for 2 weeks and followed by three times a week for 10 weeks
Category
Treatment - Drugs

2

Description
Control group: Patients in this group will be treated with 0.625 g / dose estrogen conjugated vaginal cream (1 gram of estrogen produced by Abu Reihan Pharmaceutical Company, equivalent to a quarter of a 4 g applicator) once a day for 2 weeks and followed by three times a week for 10 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Nahid Radnia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Abbas Moradi
Position
Coach
Latest degree
Master
Other areas of specialty/work
Epidemiology
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Person responsible for scientific

inquiries

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Full name of responsible person
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Position
Associate Professor of Obstetrics and Gynecology

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable