Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of vitamins D and E with conjugated estrogen vaginal cream on menopausal vulvovaginal symptoms

Protocol summary

Study aim
Comparison of the effect of vitamins D and E with conjugated estrogen vaginal cream on menopausal vulvovaginal symptoms

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 66 patients, randomization list through www.sealedenvelope.com/simple-randomiser/v1/lists

Settings and conduct
After referring to the clinic of Shahid Beheshti Hospital in Kashan, in the first visit, 22 people will be given vitamin D500000, 22 others will be given 400 IU vitamin E capsules and 22 others will be given conjugated estrogen vaginal cream. They will consume it daily for two months. The necessary instructions on how to use the drug daily in an applicator for 14 days and then twice a week, will be given deep inside the vagina before going to bed and the patient will be given a daily record of drug use. All three groups receive the same drugs in the same package, size and box. The codes remain with one of the research project colleagues and will be decoded at the end of the study. None of the administrators and patients know the type of codes of each patient until after analyzing the data

Participants/Inclusion and exclusion criteria
Postmenopausal women 45 to 65 years with vulvovaginal menopausal symptoms

Intervention groups
Three intervention groups have been identified: 1- Take vitamin D supplement - Perl 50,000 weekly 2- Receiving vitamin E supplement - IU400 capsule daily 3- Receiving conjugated vaginal cream - daily, one applicator for 14 days and then twice a week, deep inside the vagina

Main outcome variables
Vaginal dryness, vaginal irritation, vaginal itching, dyspareunia, abnormal vaginal discharge, vaginal cell maturity index and vitamin D levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054881N1**
Registration date: **2022-05-25, 1401/03/04**
Registration timing: **prospective**

Last update: **2022-05-25, 1401/03/04**
Update count: **0**

Registration date
2022-05-25, 1401/03/04

Registrant information

Name
Sayad Nazari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-30, 1401/03/09

Expected recruitment end date
2022-07-31, 1401/05/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of vitamins D and E with conjugated estrogen vaginal cream on menopausal vulvovaginal symptoms

Public title
Comparison of the effect of vitamins D and E with conjugated estrogen vaginal cream on menopausal vulvovaginal symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is menopausal Pap smears have been normal for the last 3 years She has symptoms of vaginal atrophy Vaginal maturity index should be less than or equal to 55 Vitamin D levels should be less than or equal to 30 The minimum entry age is 45 years and the maximum age is 65 years
Exclusion criteria:
She has a vaginal infection She has genital abnormalities She has a history of taking sex hormones during the 8 weeks before the study She may have vaginal bleeding of unknown cause She has a history of consuming a lot of phytoestrogens such as soy, red clover, fenugreek and Vitex in the past month
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method will be: first, the group receiving vitamin D with the letter A, the group receiving vitamin E with the letter B and the group receiving conjugated estrogen with the letter C, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists The randomization list will be prepared by selecting a sample size of 66 (3 groups of 22) and a balanced 6-part blocking method. Then, through the obtained randomization list, the enrolled people (in the order of enrollment time) will be assigned to one of the two groups A or B or C.
Blinding (investigator's opinion)
Double blinded
Blinding description
All three groups receive the same drugs in the same package, size and box. The codes remain with one of the research project colleagues and will be decoded at the end of the study. None of the administrators and patients have any information about the type of codes of each patient after analyzing the data. Thus, this study is performed in two blinds.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research, School of Medicine and Dentistry, Kashan University of Medical Science
Street address
Qutb Ravandi Boulevard - Kashan University of Medical Sciences
City
Kashan
Province
Isfehan
Postal code
8715973474
Approval date
2022-04-16, 1401/01/27
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1401.007

Health conditions studied

1

Description of health condition studied
Volvaginal symptoms of menopause
ICD-10 code
N95.2
ICD-10 code description
Postmenopausal atrophic vaginitis

Primary outcomes

1

Description
Vaginal cell maturation index
Timepoint
At the beginning of the study, 8 weeks after taking the drug
Method of measurement
Vaginal cytology

2

Description
Vitamin D levels
Timepoint
The beginning of the study
Method of measurement

Blood test

3

Description
Vaginal dryness
Timepoint
The beginning of the study, day 28 and day 56
Method of measurement
Questionnaire and Likert scale

4

Description
Vaginal burning
Timepoint
The beginning of the study, day 28 and day 56
Method of measurement
Questionnaire and Likert scale

5

Description
Vaginal itching
Timepoint
The beginning of the study, day 28 and day 56
Method of measurement
Questionnaire and Likert scale

6

Description
Disparony
Timepoint
The beginning of the study, day 28 and day 56
Method of measurement
Questionnaire and Likert scale

7

Description
Abnormal vaginal discharge
Timepoint
The beginning of the study, day 28 and day 56
Method of measurement
Questionnaire and Likert scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving pearl vitamin D with a dose of 50000 IU (Cholecalciferol) under the brand name D-vigel from Dana Pharma once a week for 8 weeks
Category
Treatment - Drugs

2

Description
Intervention group: Receiving vitamin E capsule (d alpha tocopheryl acetate) with IU400 dose under the brand name of Hakim Vitamin E from Hakim Pharmaceutical Company daily for 8 weeks
Category
Treatment - Drugs

3

Description
Control group: Apply conjugated estrogen vaginal cream 0.625 mg with the brand name Stromarin from Abu Reihan Pharmaceutical Company for one day daily for 14 days and then twice a week, deep inside the vagina before going to bed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan Shahid Beheshti Hospital Clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Sayad Nazari
Position
Resident
Latest degree
Medical doctor
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Person responsible for updating data

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

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