

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

nazari-s@kaums.ac.ir

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

Isfahan

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

Sayad Nazari

Street address

Qutb Ravandi Boulevard, Shahid Beheshti Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamidreza Banafsheh

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research@kaums.ac.ir

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

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

Zohreh Tabasi

Position

Associate Professor

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Specialist

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Gynecology and Obstetrics

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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