Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of vitamin E vaginal suppository with conjugated estrogen vaginal cream on the treatment of atrophic vaginitis in menopausal women

Protocol summary

Summary

This study is a clinical trial to compare vitamin E vaginal suppository with conjugated estrogen vaginal cream on the treatment of atrophic vaginitis in menopausal women. Inclusion criteria consisted of: married, sexually active women aged 40-65 years old; amenorrhea for at least 12 months; having a normal Pap smear within the past 3 years; clinical atrophy of the vagina through a set of criteria that includes: PH Vagina> 5 and earn a score of 65 or higher (based on a visual analogue scale, VAS) for most bothersome symptoms (MBS) and superficial cells equal or less than 5% and at least two symptoms of Descriptive Assessment Table of Vaginal Mucosa. Exclusion criteria included abnormal vaginal bleeding; hypersensitivity to conjugated estrogen cream; hormone therapy 8 weeks before the study. 60 postmenopausal women with symptoms of vaginal atrophy were randomized in two group to take vaginal suppositories of 100 IU vitamin E (n=30) or 1/8 applicator of conjugated estrogen vaginal cream (n=30) for 12 weeks. The symptoms of vaginal atrophy were evaluated by a Descriptive Assessment of Vaginal Mucosa ; most bothersome symptoms (MBS); vaginal pH and maturation value before and 1, 2, 3 months after therapy will be measured and compared in both the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013060913611N1**
Registration date: **2013-07-14, 1392/04/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-14, 1392/04/23

Registrant information

Name

Azam parnan emamverdikhan

Name of organization / entity

School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 51 1341 5848

Email address

parnana901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-07-11, 1392/04/20

Expected recruitment end date

2014-01-10, 1392/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vitamin E vaginal suppository with conjugated estrogen vaginal cream on the treatment of atrophic vaginitis in menopausal women

Public title

Non-hormonal treatment of vaginal atrophy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 40-65 years old; amenorrhea for at least 12 months, or 6 months after the last menstrual them with FSH> 40; having a normal Pap smear within the past 3 years, or more than 6 weeks postsurgical bilateral oophorectomy with or without hysterectomy; clinical atrophy of the vagina through a set of criteria that includes: PH vagina> 5 and earn a score of 65 or higher (based on a visual analogue scale, VAS) for most bothersome symptoms (MBS) and superficial cells equal or less than 5% and at least two symptoms of Descriptive Assessment Table of Vaginal Mucosa. Exclusion criteria: existing breast or endometrial cancer or suspicion thereof, genital abnormalities; abnormal vaginal bleeding; cardiovascular disease (including coronary heart disease; cerebrovascular disease; thromboembolic disorders); active liver or gallbladder disease; diabetes and blood pressure-lowering drugs; vaginal infection; allergy to estrogen and vitamin E; hormone use during the 8 weeks before the study; the use of 40 to 60 grams phytoestrogens during the day; use of stimuli that can cause chronic itching in the vagina; useing less than 70% of the total number of drug (less than 24 times during the treatment period

Age
From **40 years** old to **65 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
School of Nursing and Midwifery, Ibn Sina Street, Doctors Crossroads

City
Mashhad

Postal code

Approval date
2013-06-08, 1392/03/18

Ethics committee reference number
research/911186/1/6

Health conditions studied

1

Description of health condition studied
vaginal atrophy

ICD-10 code
N95.2

ICD-10 code description
Postmenopausal Atrophic Vaginitis

Primary outcomes

1

Description
Symptoms of vaginal atrophy

Timepoint
Before intervention, 4, 8 and 12 weeks after intervention

Method of measurement
Description of the vaginal mucosa، vaginal maturation index, the most bothersome symptom of vaginal and vaginal pH

Secondary outcomes

1

Description
Superficial cells in the vagina

Timepoint
Befor the intervention، 4، 8 and 12 weeks after intervention

Method of measurement
Vaginal maturation index

Intervention groups

1

Description
Intervention 2: 12-week treatment period. Conjugated estrogen vaginal cream once daily for 2 weeks، followed by twice weekly administration for a further 10 weeks as a maintenance therapy

Category
Treatment - Drugs

2

Description
Intervention1: 12-week treatment period. Vitamin E vaginal suppositories once daily for 2 weeks ، followed by twice weekly administration for a further 10 weeks as a maintenance therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Womens clinic of Ghaem Hospital

Full name of responsible person
aazam parnan emamverdikhan

Street address
Mashhad، Ghaem Hospital

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad Universityof Medical Sciences

Full name of responsible person
Dr. Mohsen Tafaghodi

Street address
Mashhad, Vakil Abad Boulevard, University College, School of Pharmacy, Department of Pharmaceutics

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad Universityof Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Aazam Prnan Emamverdikhan

Position
Postgraduate students

Other areas of specialty/work

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Person responsible for scientific inquiries

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Masters،Faculty member

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty