

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 groups 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; using 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

Before 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 University of 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 University of 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

Street address

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

City

Mashhad

Postal code

Phone

+98 51 1859 1511

Fax

Email

parnana901@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid golmakani

Position

Masters, Faculty member

Other areas of specialty/work

Street address

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

City

Mashhad

Postal code

Phone

+98 51 1859 1511

Fax

Email

Golmakanin@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Aazam Prnan Emamverdikhan

Position

Postgraduate student

Other areas of specialty/work

Street address

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

City

Mashhad

Postal code

Phone

+98 51 1341 5848

Fax

Email

Web page address

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