Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Investigation of the effect of Alcea vaginal suppository on the treatment of vaginal atrophy in postmenopausal women.

Protocol summary

Study aim
Investigation of the effect of Alcea vaginal suppository on the treatment of vaginal atrophy in postmenopausal women.

Design
Clinical trial with control group, with a parallel group design of 60 patients, double blinded, Permuted block randomization

Settings and conduct
The study is conducted randomly and double-blind at the women clinic of Ummol-Banin Hospital in Mashhad. The patient and the investigator are unaware of the type of treatment, but the clinical care provider is aware of the type of treatment with the Alcea suppository or placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women, and have sexual activity; Age between 40-65 years; Complaint of vaginal dryness; Amenorrhea for at least 12 months, or laboratory confirmation of menopause(FSH>40); Amenorrhea after surgery and Bilateral Oophorectomy; Exclusion criteria: Endometrial cancer or breast cancer or suspicion of it; Vaginal bleeding with unknown causes; Vaginal infection; History of sensitivity to Alcea; Chronic diseases; The history of consumption of hormonal products containing estrogen and progesterone in the last month; The history of vaginal use of stimulants that can cause chronic vaginal itching (scents, moisturizers, soaps)in the last month.

Intervention groups
Intervention group: Alcea vaginal suppository (5%) every night for 2 weeks, followed by every other night administration for a further 6 weeks. Control group: placebo, vaginal suppository every night for 2 weeks, followed by every other night administration for a further 6 weeks. All stages of suppository preparation, are carried out by the pharmacist professor at the Traditional Medicine Laboratory. The Alcea angulata is prepared from the Faculty of Agriculture (Voucher number (FUMH-E 1009). The standardization of the suppository is done by the Folin-Ciocalteu method.

Main outcome variables
symptoms of vaginal atrophy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180923041099N1**
Registration date: **2019-02-24, 1397/12/05**
Registration timing: **prospective**

Last update: **2019-02-24, 1397/12/05**
Update count: **0**

Registration date
2019-02-24, 1397/12/05

Registrant information

Name
Alieh Kiani Talaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3869 5550

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-02, 1397/12/11

Expected recruitment end date
2019-08-02, 1398/05/11

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of Alcea vaginal suppository on the treatment of vaginal atrophy in postmenopausal women.

Public title

Effect of Alcea in treatment of vaginal atrophy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women, and have sexual activity; Age between 40-65 years; Complaint of vaginal dryness; Amenorrhea for at least 12 months, or laboratory confirmation of menopause(FSH>40); Amenorrhea after surgery and Bilateral Oophorectomy;

Exclusion criteria:

Endometrial cancer or breast cancer or suspicion of it; Vaginal bleeding with unknown causes; Vaginal infection; History of sensitivity to the Alcea; Chronic diseases; The history of consumption of hormonal products containing estrogen and progesterone in the last month; The history of vaginal use of stimulants that can cause chronic vaginal itching (scents, moisturizers, soaps) in the last month;

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Permuted block randomization; Random unit: Individual; Randomization Tool: block; How to create a random sequence: From the four blocks, we select one, by accident (Roll of a die), and according to the order, assign the samples to two groups A and B, and so continue until the end we give. Allocation concealment:This is a double-blind, placebo-controlled study. As the patient and researcher of the project are not aware of the content of the treatment. In both groups, vaginal suppositories are identical in terms of shape, odor, size, and color.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is conducted randomly, double-blind, and controlled by placebo. Participants are randomly selected and divided into two groups of intervention and control. The intervention group, the Alcea vaginal suppository, and the control group, are given placebo suppositories that are uniform in shape, odor, size and color, so the participants are unaware of the type of treatment. The researcher will provide Alcea suppository and placebo to clinical care providers, and she distributes them according to the patient's condition. Therefore, only clinical care providers are aware of the type of treatment, and during the treatment, the investigator and the assessor of the outcome, are unaware.

Placebo

Used

Assignment

Parallel

Other design features

To both groups, life style modification of Traditional Persian Medicine, are offered.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences; Shastkola Road.

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2019-02-04, 1397/11/15

Ethics committee reference number

IR.GOUMS.REC.1397.230

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, Eight weeks after intervention

Method of measurement

The most bothersome symptom of vaginal mucosa with Visual Analogue Scale

2

Description

Vaginal superficial cells

Timepoint

Before intervention, Eight weeks after intervention

Method of measurement

vaginal maturation index

3

Description

Vaginal PH

Timepoint

Before intervention, Eight weeks after intervention

Method of measurement

PH meter

Secondary outcomes

1

Description

Sexual satisfaction

Timepoint

Before intervention, Eight weeks after intervention

Method of measurement

Standard Questionnaire for Assessment of Female Sexual function (FSFI)

Intervention groups

1

Description

Intervention group: Alcea vaginal suppository(5%) every night for 2 weeks, followed by every other night administration for a further 6 weeks. Duration of treatment is 8 weeks. All stages of construction of suppositories are carried out by the professor of pharmacy at the Traditional Medicine Laboratory of Mashhad. At first, the Alcea angulata dried with Voucher number (FUMH-E 1009) from the Faculty of Agriculture, Ferdowsi University of Mashhad, was prepared and extracted by soaking. Then, 5% of the extract was added to the suppository base (PEG). Standardization of suppositories takes place in Folin–Ciocalteu method in 3 steps.

Category

Treatment - Drugs

2

Description

Control group:placebo, vaginal suppository every night for 2 weeks, followed by every other night administration for a further 6 weeks. Duration of use is 8 weeks.The placebo suppository containing the suppository base (PEG) made by the professor of pharmacy at the Traditional Medicine Laboratory of Mashhad. These suppositories are very similar to the Alcea suppositories in terms of shape, size, color and smell.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women clinic of Omolbanin hospital

Full name of responsible person

Alieh Kiani Talaei

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Omolbanin hospital, Behjat Blvd.

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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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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
Alieh Kiani Talaei

Position
Ph.D student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because of ethical principles and assuring patients that their specifications are not disclosed

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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

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

Title and more details about the data/document
Statistical results

When the data will become available and for how long
2019

To whom data/document is available
Researchers

Under which criteria data/document could be used

Continue the research

From where data/document is obtainable

Golestan University of Medical Sciences

What processes are involved for a request to access data/document

Written request; University agreement; Delivery of information

Comments