

# 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)

##### Phone

+98 51 3869 5550

##### Email address

kianita941@mums.ac.ir

##### 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

**Street address**

Omolbanin hospital, Behjat Blvd.

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Mashhad

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Razavi Khorasan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Honarvar

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Golestan University of Medical Sciences; Shastkola Road.

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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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Marzieh Gharaaty  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Alieh Kianitalaei  
**Position**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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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**