

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation effect of Viola odorata vaginal suppository on the treatment of vaginal atrophy in post menopausal women

#### Protocol summary

Treatment of vaginal atrophy, improvement of complications caused by vaginal atrophy

#### Study aim

Evaluation the effect of Viola odorata vaginal suppository on the treatment of vaginal atrophy in postmenopausal women.

#### Design

A randomized, three-blind control clinical trial with parallel group in 3 phase of trial on 60 postmenopausal women. Randomisation is centralised and computerised with Free Random Generator.

#### Settings and conduct

This study is conducted for 8 weeks on postmenopausal women who refer to the Health School of Behesht Traditional Medicine in Tehran. First, the checklist of vaginal mucosa atrophy is completed by the researcher. Then a sample of vaginal mucosa cells is taken from the lateral and posterior fornix of the vagina and then fix in a liquid smear. Vaginal pH is also measured by a litmus detector. People are randomly assigned to one of two intervention groups (Viola odorata suppository) and control group (glycerin suppository). and take one suppository at night for 8 weeks. Symptoms of vaginal atrophy are evaluated by 4-point Likert self-assessment scale in three periods, before treatment, 4 and 8 weeks after treatment. Also, PH and maturation of vaginal value are evaluated before and after treatment.

#### Participants/Inclusion and exclusion criteria

women who had natural menopause confirmed by amenorrhea for one year or increased follicle stimulation hormone (FSH)  $\geq 40$  IU/l, women who lived with their husband and were sexually active, having at least two symptoms of descriptive evaluation table of vaginal epithelium and Women with vaginal bleeding or moderate to severe infection, women who were receiving hormone therapy and women who used phytoestrogen, are excluded from the study

#### Intervention groups

The intervention group is Viola odorata vaginal cream, the control group is glycerin suppository.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220814055687N1**

Registration date: **2022-09-04, 1401/06/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-09-04, 1401/06/13**

Update count: **0**

##### Registration date

2022-09-04, 1401/06/13

##### Registrant information

##### Name

Fataneh Amindehghan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7729 2107

##### Email address

f.amindehghan@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-24, 1401/06/02

##### Expected recruitment end date

2022-12-21, 1401/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation effect of Viola odorata vaginal suppository on the treatment of vaginal atrophy in post menopausal women

**Public title**

Evaluation effect of Viola odorata vaginal suppository on the treatment of vaginal atrophy in post menopausal women

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women who had natural menopause confirmed by amenorrhea for one year or increased follicle stimulation hormone FSH>40 IU/l Having at least two symptoms from the descriptive evaluation table of the vaginal mucosa Women who are sexually active being married Women who are literate Phone number for follow up

**Exclusion criteria:****Age**

No age limit

**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**

This study is a three-blind controlled randomized clinical trial on 60 postmenopausal women. Free Random Number Generator computer software is used for randomization. In this way, a table of random numbers is obtained. Two groups are defined in this software. Group A is the intervention group and Group B is the control group. Then the numbers obtained from this software are recorded by the pharmacist of the group on the medicine box, and the eligible women are assigned to one of the two treatment groups, 30 people on the fragrant violet shelf and 30 people on the placebo suppository based on these numbers.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

This study is triple-blind type. It means that the researchers, patients and information evaluators are completely unaware of whether the vaginal suppositories are medicines or placebos. The medicines are produced by the pharmacist and the codes are generated by the software, are written on the packets by the pharmacist. Packets and suppositories of Viola odorata and placebo are completely similar to each other in

shape, size, color and smell. In this study, the evaluators including: the doctor as the first evaluator of the patients' atrophy, the pathologist as the second evaluator of the cytological information and the evaluator of the statistical information as the third person are kept blind.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Ardabil University of Medical Sciences

**Street address**

Daneshgah Ave, The northern side of the administrative complex of Ardabil University of Medical Sciences

**City**

Ardabil

**Province**

Ardabil

**Postal code**

56189-85991

**Approval date**

2022-08-14, 1401/05/23

**Ethics committee reference number**

IR.ARUMS.REC.1401.111

**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**

Subjective symptoms of vaginal atrophy

**Timepoint**

Before intervention. 4 and 8 weeks after the treatment

**Method of measurement**

Likert self-assessment scale

## 2

### **Description**

Vaginal Maturation Value

### **Timepoint**

Before intervention and 8 weeks after treatment

### **Method of measurement**

Vaginal smear

## 3

### **Description**

Vaginal PH

### **Timepoint**

Before intervention, 8 weeks after treatment

### **Method of measurement**

Litmus paper

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Viola odorata vaginal suppository ,one suppository every night for 8 weeks.This suppository contains flavonoids, mucilage, saponin and a protein called cyclotide. The drug is standardized according to the amount of total flavonoid. 12.9% of total flavonoid in terms of catechin per milliliter.Tabsem Knowledge and Treatment Company

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Glycerin suppository, one supp every night for 8 weeks.Each suppository contains 2 grams of glycerin, Abu Rihan Pharmaceutical Company

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Behesht School of Traditional Medicine

##### **Full name of responsible person**

Fataneh Amindehghan

##### **Street address**

No 847,Behesht Ave,Vahdat e Eslami Ave, Hasan Abad Square

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ardabil University of Medical Sciences

##### **Full name of responsible person**

Fataneh Amindehghan

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Daneshgah Ave,Administrative complex of Ardabil University of Medical Sciences

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info@arums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

##### **Full name of responsible person**

Fataneh Amindehghan

##### **Position**

M.Sc Std of Midwifery

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

### Title and more details about the data/document

0

### When the data will become available and for how long

0000000

### To whom data/document is available

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### Under which criteria data/document could be used

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### From where data/document is obtainable

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

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### Comments