Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

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

Protocol summary

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

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

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Iran (Islamic Republic of)

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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/I 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

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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
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No 847,Behesht Ave,Vahdat e Eslami Ave, Hasan Abad Square
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Sponsors / Funding sources

1

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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
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
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Latest degree
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Person responsible for updating data

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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
0ooooоo
To whom data/document is available
000000
Under which criteria data/document could be used
000000
From where data/document is obtainable
0
What processes are involved for a request to access data/document
000000
Comments