Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The effect of four flowers herbal vaginal gel and auriculotherapy in comparison with placebo on atrophic vaginitis in women referred to selected medical centers affiliated to Isfahan University of Medical Sciences in 2021

Protocol summary

Study aim
Evaluation of the effect of four flower herbal vaginal gel and auricular therapy in comparison with placebo on atrophic vaginitis in women

Design
A clinical trial consisting of two intervention groups and a control group, with parallel groups, three-blind, randomized, on 90 patients. For randomization, permutation blocks with blocks of volume 6 are used.

Settings and conduct
The researcher first completes the personal information form, the evaluation form of mental symptoms of vulvovaginal atrophy and the female sexual function index questionnaire and the questionnaire to assess the quality of life of postmenopausal women. Patients are then randomly assigned to three groups receiving four-flower vaginal gel, placebo, and uriculotherapy. In the two groups of herbal vaginal gel and placebo, 8 tubes of vaginal gel or placebo in 50 gram tubes, completely in shape and smell, are delivered to the patient for consumption for 8 weeks. In the case of the uriculotherapy group, from the beginning of the study, the patient visits once a week for uriculotherapy. At each visit, the points related to vaginal atrophy in the ear are identified first and then placed in the points related to Seyed Vakaria. Forms and questionnaires in the uriculotherapy group will be completed at the beginning of the intervention, the end of the fourth week and the end of the eighth week.

Participants/Inclusion and exclusion criteria
Age: 45 to 65 years old; 12 months have passed since menopause; symptoms of vaginal atrophy; patient consent to participate in the project; being married; natural Pap smear test result.

Intervention groups
Herbal vaginal gel group; placebo vaginal gel group; Auriculo therapy group

Main outcome variables
Mental symptoms of vulvovaginal atrophy; Women's sexual function index; Quality of life of postmenopausal women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211013052757N1**
Registration date: **2022-02-11, 1400/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-11, 1400/11/22**
Update count: **0**

Registration date
2022-02-11, 1400/11/22

Registrant information

Name
Elahe Naderiafshar

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-08-23, 1401/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of four flowers herbal vaginal gel and auriculotherapy in comparison with placebo on atrophic vaginitis in women referred to selected medical centers affiliated to Isfahan University of Medical Sciences in 2021

Public title
The effect of four flower herbal vaginal gel and auricular therapy on atrophic vaginitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 45 to 65 years old 12 months have passed since menopause Symptoms of vaginal atrophy Patient consent to participate in the project Being married Natural Pap smear in the past year
Exclusion criteria:
Breast or uterine cancer Abnormal vaginal bleeding Vaginal device abnormalities Taking oral hormonal medication 8 weeks before treatment Use of topical hormonal creams or topical lubricants in the last month
Age
From **45 years** old to **65 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
90 patients were eligible to enter the study randomly, using the random number table available at the site, in two age groups under 60 years and over 60 years, in three groups of uriculotherapy, herbal gel and placebo (A, B, C) Will be divided. Because there is no possibility of blinding the participant and the researcher in the oriculotherapy group, group C will be known as the oriculotherapy group from the very beginning.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Interventions in patients consuming vaginal gel and placebo are in the form of three blinds, so that the patient and the researcher are not aware that the patient is taking the drug or placebo.However, in the uriculotherapy group, due to the impossibility, blindness was not performed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2021-12-24, 1400/10/03
Ethics committee reference number
IR.MUI.MED.REC.1400.699

Health conditions studied

1

Description of health condition studied
Volvovaginal atrophy
ICD-10 code
N95.2
ICD-10 code description
Postmenopausal atrophic vaginitis

Primary outcomes

1

Description
Volvaginal Atrophy Mental Symptoms
Timepoint
Completion of Volvaginal Atrophy Mental Symptoms Questionnaire before intervention, end of week 4 and end of week 8 after intervention
Method of measurement
Volvaginal Atrophy Mental Symptoms Questionnaire

2

Description
Women's sexual function index
Timepoint
Completion of women's sexual function index questionnaire before the intervention, end of week 4 and end of week 8 after the intervention
Method of measurement
Women's sexual function index questionnaire

3

Description
Quality of life for postmenopausal women
Timepoint
Completion of quality of life evaluation questionnaire for postmenopausal women before the intervention, end of week 4 and end of week 8 after the intervention
Method of measurement
Quality of life evaluation questionnaire for postmenopausal women

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In the herbal vaginal gel group, in the first session after completing the forms, 4 tubes of vaginal gel in 30 gram tubes are delivered to the patient for consumption for four weeks. How to take the drug in the first 4 weeks: Every night before going to bed, use a 5-gram applicator inside the vagina and do not get up for a few hours to absorb the drug. And Women's Sexual Performance Index Questionnaire and Quality of Life Assessment Questionnaire will be completed for each.Then another 2 tubes are delivered to patients for consumption in the next 4 weeks. How to take the medicine in the second 4 weeks: One night before going to bed, use a 5 g applicator inside the vagina and do not get up for a few hours to absorb the medicine. At the end of 8 weeks of intervention, the forms will be completed again.
Category
Behavior

2

Description
Second intervention group: In the case of the uriculotherapy group, the patient visits for uricotherapy once a week from the beginning of the study.At each visit, the points related to vaginal atrophy in the ear were identified first and then placed on the points related to Seyed Vakaria. The patient is instructed to press each side for 1 minute every hour (except when the patient is asleep). There is no problem in taking a shower while the patient is sick.Forms and questionnaires in the uriculotherapy group will be completed at the beginning of the intervention, the end of the fourth week and the end of the eighth week.
Category
Behavior

3

Description
Control group: In the control group, in the first session after completing the forms, 4 tubes of placebo in 30 gram tubes in a completely uniform shape are delivered to the patient for consumption for four weeks. How to take the drug in the first 4 weeks: Every night before going to bed, use a 5-gram applicator inside the vagina and do not get up for a few hours to absorb the drug. And Women's Sexual Performance Index Questionnaire and Quality of Life Assessment Questionnaire will be completed for each.Then another 2 tubes are delivered to patients for consumption in the next 4 weeks. How to take the medicine in the second 4 weeks: One night before going to bed, use a 5 g applicator inside the vagina and do not get up for a few hours to absorb the medicine. At the end of 8 weeks of intervention, the forms will be completed again.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Elahe Naderi Afshar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
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Elahe Naderiafshar
Position
Student
Latest degree
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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
There is no more information
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