# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Comparison of the effects of Persicaria hydropiper vaginal cream based on coconut oil and sesame oil with conjugated estrogen vaginal cream and placebo on vaginal atrophy and sexual function of postmenopausal women.

## Protocol summary


**Study aim**
To compare the effect of Persicaria hydropiper vaginal cream; conjugated estrogen vaginal cream and placebo on vaginal atrophy and sexual function of postmenopausal women.

**Design**
The clinical trial with two intervention and a control groups, parallel design, double-blind, randomized, phase 3 on 111 patients. The method of randomized permutation blocks with random block sizes of 6, 9 and 12 (using the table related to random permutations) is used for randomization.

**Settings and conduct**
Place of study: Health center number 12, Ahvaz city; Study population: menopausal women referring to health center number 12; Blinding: double blind, in which the tube of vaginal creams will be marked as A, B and C by the pharmacist.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Passing at least one year since the last menstruation; sexual function index score less than 26. Exclusion criteria: People with or suspected of endometrial and breast cancer; abnormal bleeding

**Intervention groups**
Intervention group 1: blue pepper vaginal cream based on coconut oil and sesame oil 0.5 g 5%, for 12 weeks; Intervention group 2: conjugated estrogen vaginal cream 0.625 milligram, one milligram, for 12 weeks; Control group: placebo vaginal cream, 12 weeks duration.

**Main outcome variables**
Overall score of objective and subjective assessment of vaginal atrophy; vaginal cell maturation index


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20240207060932N1**
Registration date: **2024-03-03, 1402/12/13**
Registration timing: **prospective**

Last update: **2024-03-03, 1402/12/13**
Update count: **0**

**Registration date**
2024-03-03, 1402/12/13


**Registrant information**
**Name**
Mahdieh GHorbani
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-04-08, 1403/01/20

**Expected recruitment end date**
2024-10-11, 1403/07/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Comparison of the effects of Persicaria hydropiper vaginal cream based on coconut oil and sesame oil with conjugated estrogen vaginal cream and placebo on vaginal atrophy and sexual function of postmenopausal women.

**Public title**

The effect of Persicaria hydropiper vaginal cream based on coconut oil and sesame oil on vaginal atrophy and sexual function

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women who have had at least one year since their last menstruation or have an FSH test of more than 40 international units Age range 45-65 years old Being sexually active (the participant and his wife) The ultrasound results of the uterus and ovaries are normal Sexual function index score less than 26.5 Having At least two signs of vaginal atrophy through objective evaluation of the vagina Normality of the results of clinical breast examination

**Exclusion criteria:**

People with or suspected of endometrial and breast cancer and undergoing chemotherapy Abnormal bleeding vaginal infection diabetes cardiovascular disease chronic kidney disease active hepatobiliary disease arthritis mental illness People under hormone therapy in the last 12 weeks People treated with non-hormonal drugs for vaginal atrophy during the last 8 weeks A history of unusual severe drug reactions to medicinal plants taking blood pressure drugs vaginal gels and lubricants thiazide diuretics antihistamines antidepressants lithium digoxin psychoactive drugs danazol benzodiazepines barbiturates

**Age**

From **45 years** old to **65 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **111**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of assigning the intervention to people is randomly and by the method of randomized permutation blocks with random block sizes of 6, 9 and 12 (using the table related to random permutations). The randomization list is prepared by a statistician. The intervention used in this research is allocated according to the randomized list by a person outside the study who is not aware of the research objectives and according to the corresponding codes in the sealed envelopes. Also, in order to reduce the creation of selection bias, allocation concealment will be done using unique codes allocated to individuals.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher and the participants in this research will be completely unaware of the type of treatment (Persicaria hydropiper vaginal cream, conjugated estrogen vaginal cream and placebo vaginal creams). In this way, the tube of vaginal creams will be marked as A, B and C in the same packaging by the pharmacist.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Associate Professor of Research and Information Technology, Ahvaz Jundishapur University of Medical Sciences, Daneshgahi town, Ahvaz

**City**

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**Province**

Khouzestan

**Postal code**

61357-15794

**Approval date**

2024-01-23, 1402/11/03

**Ethics committee reference number**

IR.AJUMS.REC.1402.560

## Health conditions studied

### 1

**Description of health condition studied**

Vaginal atrophy in postmenopausal women

**ICD-10 code**

N95.2

**ICD-10 code description**

Postmenopausal atrophic vaginitis

### 2

**Description of health condition studied**

sexual function of postmenopausal women

**ICD-10 code**

F52.0

**ICD-10 code description**
Hypoactive sexual desire disorder

## Primary outcomes

### 1

**Description**
Subjective, objective assessment of vaginal atrophy
**Timepoint**
At the beginning of the research, week 8 and week 12 during treatment, 4 weeks after treatment
**Method of measurement**
Questionnaire for subjective and objective evaluation of vaginal atrophy and experimental investigation

### 2

**Description**
Maturation percentage of vaginal cells
**Timepoint**
Before intervention, after intervention
**Method of measurement**
Based on Meisel's formula

### 3

**Description**
Vaginal acidity
**Timepoint**
Before intervention, after intervention
**Method of measurement**
PH gauge

## Secondary outcomes

### 1

**Description**
Sexual function
**Timepoint**
At the beginning of the research, week 8 and week 12 during treatment, 4 weeks after treatment
**Method of measurement**
Female Sexual Function Index-questionnaire

## Intervention groups

### 1

**Description**
Intervention group 1 (Standard treatment group): conjugated estrogen vaginal cream 0.625 mg, one mg for 12 weeks (the first two weeks every night and the next ten weeks twice a week), Luqman Pharmaceutical Company
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: Persicaria hydropiper vaginal cream based on coconut oil and sesame oil 5%, 0.5 g for 12 weeks (the first two weeks every night and the next ten weeks twice a week)
**Category**
Treatment - Drugs

### 3

**Description**
Control group: placebo vaginal cream, 0.5 g for 12 weeks (the first two weeks every night and the next ten weeks twice a week)
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
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**Full name of responsible person**
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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**
Ahvaz 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**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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