

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effectiveness of Vaginal cream *Artemisia absinthium* on Sexual function and sexual satisfaction and quality of sexual life of postmenopausal women.

#### Protocol summary

##### Study aim

Determining the effect of wormwood vaginal cream on sexual performance and satisfaction and quality of sexual life of postmenopausal women

##### Design

This study is a randomized clinical trial two groups (drug and placebo), three-blinds, phase 3, which will be performed on 112 women with inclusion criteria. Random allocation sequences are performed using random allocation software and block size two.

##### Settings and conduct

The study site is the gynecology clinic of Imam Reza (AS), Ghaem (AS) hospitals and health centers of Mashhad. At the beginning and end of the intervention, the female sexual function index, Larson sexual satisfaction and quality of sexual life and depression are completed by two groups. The researcher, participants, and data analyzer are blinded so that the creams are given to participants in the same packaging as the pharmacist consultant.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included age range 45-65 years, married women, having a hormonal test with FSH above 40, one year or more after the last menstrual period, having sexual activity at least twice during the month of intervention and sexual function score below 28 of the Female Sexual Function Index questionnaire and sexual satisfaction score below 75 of the Larson sexual satisfaction questionnaire. Exclusion criteria include the use of phytoestrogens such as soy, flaxseed, clover sprouts and alfalfa in the diet, infection or vaginal bleeding of unknown cause.

##### Intervention groups

The intervention group will use one application of wormwood cream vaginally for 4 weeks and 3 times a week. The placebo group will use the same foundation cream without wormwood extract according to the

mentioned instructions.

##### Main outcome variables

Performance and satisfaction and quality of sexual life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210223050471N2**

Registration date: **2022-01-13, 1400/10/23**

Registration timing: **prospective**

Last update: **2022-01-13, 1400/10/23**

Update count: **0**

##### Registration date

2022-01-13, 1400/10/23

##### Registrant information

##### Name

niloofar Hajatpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3686 1224

##### Email address

hajatpourn982@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-05-22, 1401/03/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of Vaginal cream Artemisia absinthium on Sexual function and sexual satisfaction and quality of sexual life of postmenopausal women.

**Public title**

The effectiveness of cream Artemisia absinthium on Sexual function and sexual satisfaction and quality of sexual life .

**Purpose**

Treatment

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

Age ranges 45-65 years Married women Having a hormonal test with an FSH level above 40 One year or more after the last menstrual period Having sexual activity at least twice during a month of intervention time No liver, kidney, heart, thromboembolic and psychological problems No history of chemotherapy or radiation therapy to the pelvis or the whole body Lack of consumption psychiatric drugs, fluoxetine, vitamin E, propranolol and other chemical or herbal medicines that affect the symptoms of menopause Lack of consumption hormone replacement therapy Lack of consumption tobacco, alcohol or drugs Lack of depression (depression score 21 and above), no anxiety (anxiety score 15 and above), no stress (stress score 26 and above) of DASS-21 questionnaire Sexual performance score below 28 of the Female Sexual Function Index questionnaire and sexual satisfaction score below 75 of the Larson Sexual Satisfaction Questionnaire

**Exclusion criteria:**

Use phytoestrogens in the diet such as soy, flaxseed, clover germ and alfalfa Infection or vaginal bleeding of unknown cause

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **112**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the permutation block method is used to generate a sequence of random allocation of individuals to the study groups. Random allocation sequences are performed using random allocation software and block size two. The permutation block method is one of the random allocation methods in which each block is

selected according to the number of groups studied.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this research, the researcher, participants and statistical analyst are blinded. In this way, the drugs that are placed in the same boxes and named by the pharmacist consultant (no one in the study except the pharmacist consultant knows the contents of the boxes) the boxes are given to the group of participants.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics Committee of the School of Nursing and Midwifery - Mashhad University of Medical Sciences

**Street address**

University St., Qureshi Building, Mashhad University of Medical Sciences, Vice Chancellor for Research

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

13944-91388

**Approval date**

2021-11-30, 1400/09/09

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1400.077

**Health conditions studied****1****Description of health condition studied**

Sexual function, sexual satisfaction, quality of sexual life

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Sexual Performance Score

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

Female Sexual Function Index (FSFI)

## 2

### **Description**

Sexual satisfaction score

### **Timepoint**

Before intervention and 4 weeks after intervention

### **Method of measurement**

Larson Sexual Satisfaction Questionnaire(LSSQ)

## 3

### **Description**

Sexual quality of life score

### **Timepoint**

Before intervention and 4 weeks after intervention

### **Method of measurement**

Female Sexual Quality of Life Questionnaire(SQOL-F)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

For 4 weeks and 3 times a week (before going to bed) and if you are intercourse during these 3 times 30 minutes before sexual intercourse, an applicator of 5% wormwood herbal cream will be used vaginally. In 4 weeks, 12 applicators of the cream should be used. Each applicator is equivalent to 250 mg of wormwood extract.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: The same cream without wormwood extract for 4 weeks and 3 times a week (before bedtime) and if you have intercourse in these three times, 30 minutes before, an applicator of the cream will be used vaginally. In 4 weeks, 12 applicators of the cream should be used.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Ghaem Hospital

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

Dr. Fatemeh Tara

##### **Street address**

Ahmadabad St., Ghaem Hospital

##### **City**

Mashhad

##### **Province**

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##### **Phone**

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##### **Email**

b.ghaem@mums.ac.ir

## 2

#### **Recruitment center**

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

Imam Reza Hospital of Mashhad

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

Dr. Ali Khorsand Vakilzadeh

##### **Street address**

Imam Reza Hospital, University Street

##### **City**

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9137913316

##### **Phone**

+98 51 3854 3031

##### **Email**

Emamreza@mums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Mashhad University of Medical Sciences

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

Dr. Mohsen Tafqadi

##### **Street address**

University Street, Mashhad University of Medical Sciences

##### **City**

Mashhad

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##### **Email**

Tafaghodim@mums.ac.ir

#### **Grant name**

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

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

Yes

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

Mashhad University of Medical Sciences

#### **Proportion provided by this source**

70

#### **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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Raheleh Babazadeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

PhD in Reproductive Health

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Raheleh Babazadeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

PhD in Reproductive Health

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Niloufar Hajatpour

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

University Street, School of Nursing and Midwifery

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**Email**

HajatpourN982@mums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

The data will be shared after it becomes unrecognizable

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

6 months after recording the results

**To whom data/document is available**

All researchers

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

All postmenopausal women have dysfunction and sexual satisfaction and low quality of sex life

**From where data/document is obtainable**

Email niloofarhajatpoor@gmail.com Library of Mashhad School of Nursing to Mashhad, Daneshgah St.

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

First, send a requested email and if you do not respond within a week, you can refer to the library of Mashhad School of Nursing.

**Comments**