

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### A study on the effect of vaginal aloe vera cream on the sexual function and sexual satisfaction of Post- menopausal women

#### Protocol summary

##### Study aim

Determining the effect of vaginal aloe vera cream on function and sexual satisfaction of postmenopausal women

##### Design

This clinical trial has a control group, three-blind, randomized, phase 3 on 100 patients, and randomization will be done in a simple way using Excel software and random number function.

##### Settings and conduct

In this study, 100 menopausal women, aged 45-65 years, will be selected from among those who refer to health care centers under the supervision of Alborz University of Medical Sciences, and will be divided into two intervention and control groups. None of the participants And the researcher and the data analyst will not know which group is the intervention and which is the control. In the intervention group, the study samples will consume aloe vera vaginal cream, and in the control group, they will consume placebo (vaginal cream without any active pharmaceutical ingredients) according to the instructions. The personal and demographic information form before the start of the study and questionnaires for women's sexual function index and sexual satisfaction questionnaire will be completed by the research samples before the start of the intervention, 4 weeks after the start of the intervention and 8 weeks after the start of the intervention.

##### Participants/Inclusion and exclusion criteria

- Age 45-65 years -Experience of at least 12 months of amenorrhea -Having a husband and having sex with him -Having symptoms of vaginal dryness, dyspareunia and itching

##### Intervention groups

In the intervention group: vaginal aloe vera cream will be used every night in the first two weeks and three nights a week in the next 6 weeks and during sexual intercourse, and in the control group: placebo (vaginal cream without any active pharmaceutical ingredients)

will be consumed in the same way.

##### Main outcome variables

sexual function; sexual satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240214061006N1**

Registration date: **2024-02-29, 1402/12/10**

Registration timing: **prospective**

Last update: **2024-02-29, 1402/12/10**

Update count: **0**

##### Registration date

2024-02-29, 1402/12/10

##### Registrant information

##### Name

neda khalaji

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3431 8371

##### Email address

nedakhalaji@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-02, 1403/01/14

##### Expected recruitment end date

2024-09-04, 1403/06/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
A study on the effect of vaginal aloe vera cream on the sexual function and sexual satisfaction of Postmenopausal women

**Public title**  
A study on the effect of vaginal aloe vera cream on the sexual function and sexual satisfaction of Postmenopausal women

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 45-65 years Experience of at least 12 months of amenorrhea Natural menopause (absence of menopause following surgery, absence of premature menopause (at the age of less than 40)) Postmenopausal women who are in their first 10 years of menopause. Having a husband and having sex with her Lack of sexual impotence in the husband (according to the woman) Having symptoms of vaginal dryness, dyspareunia and itching Not taking herbal hormonal drugs containing phytoestrogens or hormonal supplements in any form Being literate in reading and writing Not using herbal or chemical drugs affecting sexual function No history of hysterectomy and mastectomy A maximum of five natural births Not having genital infections (according to the woman) BMI less than 30 No stressful event has occurred in the last 6 months (death or illness of close relatives, major change in living situation) in any of the couples. According to the wife, there are no mental problems (illness under observation or treatment by a doctor) in any of the couples. Absence of disease affecting sexual function  
**Exclusion criteria:**

**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: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The research units will be divided into two intervention and control groups in a simple random manner using Excel software and random number function. The list of people will be determined before the start of the study and people will be placed in each of the groups in order of entry. In this way, the researcher will be unaware of the type of group of each person before starting the

intervention.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
In this research, the researcher, the participants and the data analyst will not know which group (intervention or control) each participant is in (at the beginning of the research, the participant will be informed that he may be in any of the intervention or control groups). be controlled), so that with simple random method and random number function, it will be determined that according to the participant number (which will be assigned according to the order of entry into the research) that participant will be placed in which group A or B, but Until the end of the research, it will not be clear which group A or B is intervention or control.

**Placebo**  
Used

**Assignment**  
Other

**Other design features**  
Research units will be divided into intervention and control groups. The intervention group will use aloe vera vaginal cream and the control group will use placebo for 2 months.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

research ethics committess of school of pharmacy and nursing and midwifery--shahid beheshti universi

##### Street address

Tehran, Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Shahid Rajaei Heart Hospital, Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835119

#### Approval date

2024-02-11, 1402/11/22

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.259

## Health conditions studied

### 1

#### Description of health condition studied

sexual function

#### ICD-10 code

#### ICD-10 code description

## 2

### **Description of health condition studied**

sexual satisfaction

### **ICD-10 code**

### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Sexual function score in females sexual function index questionnaire

#### **Timepoint**

At the beginning of the study and 4 and 8 weeks after starting to use vaginal aloe vera cream

#### **Method of measurement**

females sexual function index questionnaire

### 2

#### **Description**

Sexual satisfaction score in Hudson's sexual satisfaction questionnaire

#### **Timepoint**

At the beginning of the study and 4 and 8 weeks after starting to use vaginal aloe vera cream

#### **Method of measurement**

Hudson's sexual satisfaction questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In this research, aloe vera plant will be prepared from the greenhouse around Tehran and after confirming the scientific name, at the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences and Health Services, its leaves will be separated and extracted with ethanol. It is inserted into the base of the vaginal cream and it will be prepared in the form of aloe vera vaginal cream, and it will be autoclaved after preparation. which will be consumed vaginally by the research samples for 2 weeks, every night and then for the next 6 weeks, three nights a week and during sexual intercourse, 7 grams each time with an applicator.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: In this research, the vaginal cream placebo will be based on vaginal cream without any effective ingredients (including cetostearyl alcohol, petroleum gel, glycerin, water, mineral oil, protective

and antioxidant substances, etc.) Shahid Beheshti's health care services have been prepared and after preparation, it will be autoclaved, which in terms of shape, smell, color, size and amount is completely similar to vaginal aloe vera cream, which is applied every night for 2 weeks and then three nights a week for the next 6 weeks. And during sexual intercourse, 7 grams will be taken vaginally with an applicator.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Health care centers under Alborz University of Medical Sciences

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

neda khalaji

##### **Street address**

Gohardasht, Moazn Blvd, Pirozi shomali Ave, Bostan19, number15

##### **City**

karaj

##### **Province**

Alborz

##### **Postal code**

3147834579

##### **Phone**

+98 26 3431 8371

##### **Email**

khalajineda3@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shahid Beheshti University of Medical Sciences

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

dr.Masoumeh simbar

##### **Street address**

Tehran, Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Shahid Rajaei Heart Hospital, Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1996835119

##### **Phone**

+98 21 8865 5367

##### **Email**

msimar@yahoo.com

#### **Grant name**

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

#### **Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Neda Khalaji

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Gohardasht, moazen blvd, north pirozi ave, bostan19, number15

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**Fax****Email**

khalajineda3@gmail.com

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

dr.Masoumeh simbar

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Vali Asr St., intersection of Ayat A... Hashemi Rafsanjani Highway, in front of Shahid Rajae Heart Hospital, Faculty of Nursing and Midwifery, Shahid

Beheshti University of Medical Sciences

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**Province**

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Neda Khalaji

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Gohardasht, moazen blvd, north pirozi ave, bostan19, number15

**City**

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Alborz

**Postal code**

3147834579

**Phone**

+98 26 3431 8371

**Fax****Email**

khalajineda3@gmail.com

**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