

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of combined vaginal gel of *Quercus brantii* and fennel (*Foeniculum vulgare*) on the sexual function and quality of sexual life of menopausal women

#### Protocol summary

Sexual performance, quality of sexual life, satisfaction with treatment

##### Study aim

Investigating the effect of combined gel of oak placenta and fennel on sexual performance and quality of sexual life of postmenopausal women

##### Design

A clinical trial with a control group/parallel/double-blind/randomized on 80 people/simple randomization, using a table of random numbers

##### Settings and conduct

Refer to the selected health centers, collect the list of eligible women, voluntary participation of people in the study, fully explain the method of conducting the study to the people, divide the samples into two intervention and control groups, give tubes containing gel and placebo for 8 weeks. Observing people during this period by making phone calls and referrals, completing questionnaires before and after starting treatment and then interpreting the results. The researcher and the patient do not know about the type of prescription and it is double-blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: One year has passed since the last menstrual period or FSH >40 Age 45-65 years Having sex and monogamy Non-entry criteria: Vaginal infection Genital abnormality Hormone therapy 8 weeks before the study Use of vaginal drugs 15 days before the study Smoking breast disease uterine bleeding Abundant consumption of phytoestrogen for the past month BMI>30 Liver, kidney, thromboembolism and high blood pressure disorders

##### Intervention groups

\Both the intervention and control groups will be given a 50 gram tube to consume for 8 weeks. The intervention group tube contains gel and the control group tube contains placebo. Questionnaires will be completed by people before and after consumption.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240506061682N1**

Registration date: **2024-06-19, 1403/03/30**

Registration timing: **prospective**

Last update: **2024-06-19, 1403/03/30**

Update count: **0**

##### Registration date

2024-06-19, 1403/03/30

##### Registrant information

##### Name

Sara Nikkhah

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 841 6273

##### Email address

saranik358@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-07-20, 1403/04/30

##### Expected recruitment end date

2024-09-20, 1403/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of combined vaginal gel of Quercus brantii and fennel (Foeniculum vulgare) on the sexual function and quality of sexual life of menopausal women

**Public title**  
Investigating the effect of combined vaginal gel of oak placenta and fennel on sexual function and quality of sexual life of postmenopausal women

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Passing at least one year since the last menstruation, having a hormone test with an FSH level greater than 40 international units age range of 45-65 years having sex and being monogamous  
**Exclusion criteria:**

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

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **80**

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

**Randomization description**  
First, people will be randomly assigned to two groups of herbal gel and placebo by Computer Random Generation method. The tubes will be coded by the pharmacist using a table of random numbers and noted by the pharmacist, so that each tube has a unique code. Only the pharmacist knows which tube contains gel and which tube contains placebo. Researchers or volunteers participating in the project are covered.

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

**Blinding description**  
Both the menopausal women participating in the project and the researcher related to them are unaware of the exposure received, the tube and box of gel and placebo are offered in a completely similar appearance and packaging, and each has its own code, which is only the pharmacist of the mentioned items. knows

**Placebo**  
Used

**Assignment**  
Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Yasouj University of Medical Sciences

##### Street address

Qorani Blvd./ Shahid Dehrabpur St./ Corner of Jhanbazan 8

##### City

yasuj

##### Province

Kohgilouyeh-va-Boyrahmad

##### Postal code

7591396661

#### Approval date

2024-04-27, 1403/02/08

#### Ethics committee reference number

IR.YUMS.REC.1403.005

## Health conditions studied

### 1

#### Description of health condition studied

Quality of sexual life and sexual performance

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Questionnaire score of sexual performance

#### Timepoint

At the beginning of the study and before drug administration and 8 weeks after the start of treatment

#### Method of measurement

Postmenopausal Women's Sexual Performance Questionnaire (FSFI)

### 2

#### Description

quality of sexual life of menopausal women

#### Timepoint

At the beginning of the study and before drug administration and 8 weeks after the start of treatment

#### Method of measurement

Women's Quality of Life Questionnaire (SQOL-F)

## Secondary outcomes

### 1

**Description**

sexual desire

**Timepoint**

At the beginning of the study before drug administration and also after treatment

**Method of measurement**

Questionnaire of sexual function of postmenopausal women

### 2

**Description**

orgasm

**Timepoint**

At the beginning of the study before drug administration and also after treatment

**Method of measurement**

Questionnaire of sexual function of postmenopausal women

### 3

**Description**

Stimulation

**Timepoint**

At the beginning of the study before drug administration and also after treatment

**Method of measurement**

Questionnaire of sexual function of postmenopausal women

### 4

**Description**

get wet

**Timepoint**

At the beginning of the study before drug administration and also after treatment

**Method of measurement**

Questionnaire of sexual function of postmenopausal women

### 5

**Description**

satisfaction

**Timepoint**

At the beginning of the study before drug administration and also after treatment

**Method of measurement**

Questionnaire of sexual function of postmenopausal women

### 6

**Description**

the pain

**Timepoint**

At the beginning of the study before drug administration

and also after treatment

**Method of measurement**

Questionnaire of sexual function of postmenopausal women

## Intervention groups

### 1

**Description**

Intervention group: Each person received a 50-gram tube containing a combined herbal gel of oak (5.2%) and fennel (5%) with an applicator to be used for 8 weeks (one gram every night for the first two weeks, and the next six weeks every other night) will be given. Then the patient will be called to the health center through a phone call. The patient will be taught the duration of use and the follow-up times, and the patients will be asked to return for re-examination and follow-up in the eighth week from the start of treatment. The phone number of the patients will be taken and the method of use and follow-up times will be reminded and it will be emphasized that they should not use any hormonal drugs with other vaginal ingredients. In case of any complications (such as allergy ) after taking the medicine, the intervention will be stopped and complications will be reported. Questionnaires of the quality of sexual life and sexual performance are completed by people before and after the intervention.

**Category**

Rehabilitation

### 2

**Description**

Control group: Each person will be given a 50 gram tube containing placebo with an applicator to be consumed for 8 weeks (one gram every night for the first two weeks, and every other night for the next six weeks). Then the patient will be called to the health center through a phone call. The patient will be taught the duration of use and the follow-up times, and the patients will be asked to return for re-examination and follow-up in the eighth week from the start of treatment. The phone number of the patients will be taken and the method of use and follow-up times will be reminded and it will be emphasized that they should not use any hormonal drugs with other vaginal ingredients. In case of any complications (such as allergy ) after taking the medicine, the intervention will be stopped and complications will be reported. Questionnaires of the quality of sexual life and sexual performance are completed by people before and after the intervention.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahid Shafiei Yasouj Health Center  
**Full name of responsible person**  
Sara Nikkhah  
**Street address**  
Qorani Blvd., Shahid Dohrabpur Street, Janbazan  
Corner, 8  
**City**  
Yasuj  
**Province**  
Kohgilouyeh-va-Boyrahmad  
**Postal code**  
7591396661  
**Phone**  
+98 917 664 8896  
**Email**  
saranik358@gmail.com

## 2

**Recruitment center**  
**Name of recruitment center**  
Martyr Civil Health Center, Akbarabad, Yasouj  
**Full name of responsible person**  
Sara Nikkhah  
**Street address**  
Qorani Blvd., Shahid Dohrabpur Street, Janbazan  
Corner, 8  
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## **Sponsors / Funding sources**

### 1

**Sponsor**  
**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Seyyed Amin Hosseini Mutlaq  
**Street address**  
Motahari Boulevard  
**City**  
Yasuj  
**Province**  
Kohgilouyeh-va-Boyrahmad  
**Postal code**  
7591396661  
**Phone**  
+98 917 664 8896  
**Email**  
saranik358@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor**

**organization/entity?**  
Yes  
**Title of funding source**  
Yasouj 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**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
Sara Nikkhah  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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## **Person responsible for scientific inquiries**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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## 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 research results will be made available to everyone with honesty.

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

The research results will be made available to everyone with honesty.

### To whom data/document is available

The research results will be made available to everyone with honesty.

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

The research results will be made available to everyone with honesty.

### From where data/document is obtainable

The research results will be made available to everyone with honesty.

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

The research results will be made available to everyone with honesty.

### Comments