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

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

Sexual performance, quality of sexual life, satisfaction with treatment

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
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Postal code
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+98 917 664 8896
Email
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2

Recruitment center
Name of recruitment center
Martyr Civil Health Center, Akbarabad, Yasouj
Full name of responsible person
Sara Nikkhah
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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
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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 updating data

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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