Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of fennel (Foeniculum Vulgar) oral capsules on quality of life and sexual function in postmenopausal women: Triple blind randomized clinical trial

Protocol summary

Summary

The triple-blind randomized controlled clinical trial will be conducted to assess the effect of fennel(Foeniculum Vulgar) on quality of life and sexual function in postmenopause women. Inclusion criteria: women aged between 45-60 years; married women; women in the first 1-5 years of their post menopausal period; women with at least a sexual relationship per month; Negative history of physical and psychological diseases; Negative history of breast cancer; Negative history of hormone therapy and complementary medicine for menopausel symptoms; Negative history of Allergy to herbal medicine; Negative history of sedative and anti depressant drugs usage; Negative history of addiction and smoking; women with at least the ability to read and write. exclusion criteria: allergy to foeniculum vulgare during the intervention; worsening the disease during the intervention; poor cooperation during the intervention; stop using foeniculum vulgare/placebo for at least 6 days; using of other remedies for menopausal symptoms during the study; women without at least a sexual relationship per month during the study. Following approval of proposed study design, the study sample of 90 women, attending clinics affiliated to Tehran University of Medical Sciences, will be assigned randomly into two groups (intervention / control group) and they will receive two capsules of fennel (100mg fennel soft capsules) or placebo (100mg sunflower oil soft capsules) daily for 8 weeks. The primary outcomes (quality of life and sexual function in postmenopausal women) will be assessed by sabbatsberg questionnaire (for sexual function in postmenopausal women) and Menopause quality of life questionnaire (MENQOL) before intervention and at 4th and 8th week of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081927788N3**
Registration date: **2016-08-27, 1395/06/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-27, 1395/06/06

Registrant information

Name

Parvin Golzareh

Name of organization / entity

Nursing and Midwifery Faculty, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 937 821 4212

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of fennel (Foeniculum Vulgar) oral capsules on quality of life and sexual function in postmenopausal women: Triple blind randomized clinical trial

Public title

The effect of fennel (Foeniculum Vulgar) oral capsules on quality of life and sexual function in postmenopausal women: Triple blind randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women aged between 45-60 years; married women; women in the first 1-5 years of their post menopausal period; women with at least a sexual relationship per month; Negative history of physical and psychological diseases; Negative history of breast cancer; Negative history of hormone therapy and complementary medicine for menopausel symptoms; Negative history of Allergy to herbal medicine; Negative history of sedative and anti depressant drugs usage; Negative history of addiction and smoking; women with at least the ability to read and write. exclusion criteria: allergy to foeniculum vulgare during the intervention; worsening the disease during the intervention; poor cooperation during the intervention; stop using foeniculum vulgare/placebo for at least 6 days; using of other remedies for menopausal symptoms during the study; women without at least a sexual relationship per month during the intervention.

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, participants will be assigned to test and control groups using Random Number Table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee name 1 Ethics committee of Tehran University of Medical Sciences

Street address

Iran, tehran, Enghelab street, Ghods street

City

T

Postal code

1417614411

Approval date

2016-08-15, 1395/05/25

Ethics committee reference number

IR.TUMS.VCR.REC.1395.456

Health conditions studied

1

Description of health condition studied

quality of life in postmenopausal women

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

2

Description of health condition studied

sexual function in postmenopausal women

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dyfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

sexual function in postmenopause women

Timepoint

before intervention and at 4th and 8th week of the intervention.

Method of measurement

sabbatsberg questionnaire (for sexual function in postmenopausal women)

2

Description

quality of life in postmenopause women

Timepoint

before intervention and at 4th and 8th week of the intervention

Method of measurement

Menopause quality of life questionnaire (MENQOL)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group : 100mg fennel oral capsules, twice a day for 8 week.
Category
Treatment - Drugs

2

Description
Control group: 100mg sunflower oil oral capsule, twice a day for 8 week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farmanfarmayian clinic
Full name of responsible person
Seyedeh Effat Ramezaninejad, Bachelor of Scinence in Nursing
Street address
Between Golshan and Bastan street, Azarbayejan street, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Esmat Karimi
Street address
No23, Dameshgh Street, Valiasr Avenue
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty