

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of fennel (*Foeniculum Vulgar*) oral capsules on menopausal symptoms 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 menopausal symptoms 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; achieving a minimum score of 9 by women according to Menopause Rating Scale questionnaire (middle severity of menopausal symptoms); Negative history of physical and psychological diseases; Negative history of hormone therapy and complementary medicine for menopause 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. 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 outcome (Severity of Menopausal Symptoms score) will be assessed by Menopause Rating Scale questionnaire (MRS) questionnaire before intervention and at 4th,8th and 10th week of the intervention. Secondary outcomes (Severity score of physical symptoms ,Severity score of psychological symptoms, Severity score of urogenital symptoms) will be assessed by MRS questionnaire (physical symptoms, psychological symptoms and urogenital symptoms parts)

at the same time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050827788N1**

Registration date: **2016-05-26, 1395/03/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-26, 1395/03/06

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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saharreziaie1980@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2016-08-10, 1395/05/20

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 menopausal symptoms in postmenopausal women: Triple blind randomized clinical trial

Public title
The effect of fennel(Foeniculum Vulgar) oral capsules on menopausal symptoms

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; achieving a minimum score of 9 by women according to Menopause Rating Scale questionnaire (middle severity of menopausal symptoms); Negative history of physical and psychological diseases; Negative history of hormone therapy and complementary medicine for menopause 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

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 of Tehran University of Medical Sciences

Street address

Iran, tehran, Enghelab street, Ghods street

City

Tehran

Postal code

1417614411

Approval date

2016-02-15, 1394/11/26

Ethics committee reference number

IR.TUMS.REC.1394.1973

Health conditions studied

1

Description of health condition studied

menopausal symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Severity score of Menopausal Symptoms

Timepoint

Before intervention, at the end of 4th, 8th and 10th week of intervention.

Method of measurement

Menopause Rating Scale questionnaire

Secondary outcomes

1

Description

Severity score of physical symptoms, Severity score of psychological symptoms, Severity score of urogenital symptoms

Timepoint

Before intervention, at the end of 4th, 8th and 10th week of intervention.

Method of measurement

MRS questionnaire

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, Azarbajejan street, Tehran

City

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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, Valiasr Avenue, Dameshgh Street

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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

Nursing and Midwifery Faculty, Tehran University of Medical Sciences

Full name of responsible person

Parvin Golzareh

Position

MS student in Midwifery Education

Other areas of specialty/work

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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