Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Foeniculum Vulgare and placebo for sleep quality and quality of life in menopausal women

Protocol summary

Summary

The goal of this study is to assess the effects of Foeniculum vulgare on quality of life and quality of sleep. This was a double-blind, randomized, placebo-controlled trial, single center study, which studied fifty eligible postmenopausal women, who were recruited in Ghaem Hospital in Mashhad. Then, they were randomly assigned to Foeniculum vulgare and placebo group. Quality of life, quality of sleep, depression, anxiety and attitude toward menopause were measured at baseline and after three months. Inclusion criteria: postmenopausal status which was defined as aged aged 45 to 65 with no vaginal bleeding for 1 year; a normal mammogram. The exclusion criteria: use of systemic and tropical estrogen in past six months. Primary outcome included quality of sleep and quality of life and secondary outcome include attitude toward menopause and anxiety and depression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092828789N3**
Registration date: **2017-06-15, 1396/03/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-15, 1396/03/25

Registrant information

Name

Masumeh Ghazanfarpour

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 4230 9487

Email address

ghazanfarpm901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad Unversity of Medical Sceince

Expected recruitment start date

2015-06-14, 1394/03/24

Expected recruitment end date

2016-10-05, 1395/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Foeniculum Vulgare and placebo for sleep quality and quality of life in menopausal women

Public title

the effect of fennel on quality of life and sleep quality

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy postmenopausal women aged 45 to 65 with no vaginal bleeding for one year; a normal mammogram in the last year Exclusion criteria: use of systemic and tropical estrogen in past six months.

Age

From **44 years** old to **64 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

randamation was accomplished using a computerized random number

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Biomedical research, Mashhad University of Medical Sciences- IR.MUMS.REC

Street address

Mashhad Khorasan Razavi Iran, Islamic Republic Of

City

Korsan Razavi

Postal code

Approval date

2014-07-23, 1393/05/01

Ethics committee reference number

Ir.mums. Res. 1393.42

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

Quality of life

ICD-10 code

G47.9

ICD-10 code description

Sleep Disorder, Unspecified

Primary outcomes

1

Description

Attitude toward to menopause questionnaire

Timepoint

before intervention and 90 days after intervention

Method of measurement

Attitude toward to menopause questionnaire

2

Description

Anxiety and depression

Timepoint

before intervention and 90 days after intervention

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

3

Description

sleep quality

Timepoint

before intervention and 90 days after intervention

Method of measurement

Pittsburgh Sleep Quality Index

4

Description

The Menopause-Specific Quality of Life (MENQOL)

Timepoint

before intervention and 90 days after intervention

Method of measurement

The Menopause-Specific Quality of Life (MENQOL) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

100-mg soft capsules containing 30% fennel (Standardized to 21-27 mg anethole), three times a day, for three months

Category

Treatment - Drugs

2

Description

100-mg soft capsules containing sunflower oil, three times a day, for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gynecology Clinic of Ghem

Full name of responsible person
Maliheh Afiat

Street address

City
Korsan RAZAVI

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Ghoreishi building, Daneshgah street, Khorasan Razavi , Mashhad, Islamic Republic Of Iran

City
Mashhad

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, Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Position
Vice chancellor for research, Mashhad University of Medical Sciences

Other areas of specialty/work

Street address
Ghoreishi building, Daneshgah street, Khorasan Razavi , Mashhad, Islamic Republic Of Iran

City
Mashhad

Postal code
13944-91388

Phone
+98 51 3843 7840

Fax

Email
Tafaghodim@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University Of Medical Science

Full name of responsible person
Masumeh Ghazanfarpour

Position
PhD candidate of Reproductive Health

Other areas of specialty/work

Street address
Department of Midwifery, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Ebn-e Sina St, Mashhad, Iran

City
Mashhad

Postal code
13944-91388

Phone
+98 513053152455

Fax

Email
Ghazanfarpm901@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Science

Full name of responsible person
Masumeh Ghazanfarpour

Position
PhD candidate of Reproductive Health

Other areas of specialty/work

Street address
Department of Midwifery, School of Nursing and Midwifery, Mashhad University of Medical Sciences, Ebn-e Sina St, Mashhad, Iran

City
Mashhad

Postal code
13944-91388

Phone
00

Fax

Email
Masumeh.Ghazanfarpour@yahoo.com

Web page address

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