

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation the effect of Fennel extract in the treatment of menopausal symptoms compared with placebo

Protocol summary

Summary

Objective: The current research seeks to compare the effect of fennel extract and placebo on the improvement of menopausal symptoms. Design: The research is a randomized clinical, double-blind, and placebo- control trial. Set up: the intervention period lasts eight weeks. First, demographic and green inventories are filled out by the participants. The samples are randomly divided into two distinct categories. Participants: The samples are comprised of 50 menopausal women aged 45 to 60 years old. Inclusion criteria: the women ranging from 45 to 65 years old; menstrual period is elapsed minimally one year and maximally three years; the number of their hot flushes is at least 2 times a day. Exclusion criteria: smoking; undergoing hormone; antibiotics therapy for a period of 3 months at least; systemic diseases such as kidney disease; blood pressure; diabetes; blood fat; depression and anxiety (anxiety and depression diagnosis based on diagnostic criteria DSM5 by psychiatrist); taking anti-thyroid drugs; gabapentin; SSRI; sulfonamides; methotrexate; Tryamtryn; sulfasalazine; estrogen; uptake of traditional medicines such as drug-induced flushing. Intervention: One group takes fennel extract capsules twice a day, and another group uptakes placebo twice a day for 8 weeks. At the end of the 2nd, 4th, and 8th weeks, the participants fill out the questionnaires again. Outcome: The final outcome of the current research is an improvement in menopausal symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120528967N4**

Registration date: **2017-02-13, 1395/11/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-13, 1395/11/25

Registrant information

Name

Safora Salemi

Name of organization / entity

Shahid Chamran University of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 83 3821 1001

Email address

e.mahmoudi@cobeldarou.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-01-05, 1395/10/16

Expected recruitment end date

2017-10-09, 1396/07/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Fennel extract in the treatment of menopausal symptoms compared with placebo

Public title

Comparing the effect of Fennel extract and placebo on menopausal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the women ranging from 45 to 65 years old; menstrual period is elapsed minimally one year and maximally three years; the number of their hot flushes is at least 2 times a day. Exclusion criteria: smoking; undergoing hormone; antibiotics therapy for a period of 3 months at least; systemic diseases such as kidney disease; blood pressure; diabetes; blood fat; depression and anxiety (anxiety and depression diagnosis based on diagnostic criteria DSM5 by psychiatrist); taking anti-thyroid drugs; gabapentin; SSRI; sulfonamides; methotrexate; Tryamtryn; sulfasalazine; estrogen; uptake of traditional medicines such as drug-induced flushing.

Age

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

Gender

Female

Phase

2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

kums.rec.1395.449

Health conditions studied

1

Description of health condition studied

menopausal symptoms

ICD-10 code

o95

ICD-10 code description

Symptoms such as flushing, sleeplessness, headache, lack of concentration, associated with menopause

Primary outcomes

1

Description

Vasomotor

Timepoint

before intervention-2 weeks later- 4 weeks later- 8 weeks later

Method of measurement

Green questionnaire

2

Description

Depression

Timepoint

before intervention-2 weeks later- 4 weeks later- 8 weeks later

Method of measurement

Green questionnaire

3

Description

Sexual Function

Timepoint

before intervention-2 weeks later- 4 weeks later- 8 weeks later

Method of measurement

Green questionnaire

4

Description

Anxiety

Timepoint

before intervention-2 weeks later- 4 weeks later- 8 weeks later

Method of measurement

Green questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First group will be given fennel extract, 2 times daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Second group will be given placebo, 2 time daily for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Red Crescent clinics

Full name of responsible person

Ali Rahmani

Street address

Shahid Beheshti Blvd, Red Crescent clinics

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Korosh Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

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, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Vahid Farnia

Position

Psychiatrist

Other areas of specialty/work

Street address

Isar square, Farabi Hospital

City

Kermanshah

Postal code

Phone

+98 833826451

Fax

Email

vfarnia@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical

Full name of responsible person

Safora Salemi

Position

Psychologist

Other areas of specialty/work

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Phone

+98 83 3821 1001

Fax

Email

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