

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of *Foeniculum vulgare* seed powder on estrogen levels, menopausal symptoms and sexual desire in menopausal women

Protocol summary

Summary

The aim of this randomized controlled trial (double blind) is to determine the effect of *Foeniculum vulgare* seed powder on estrogen levels, menopausal symptoms and sexual desire in menopausal women. We will recruit 70 cases of post menopausal women 45-60 years old at selected health care centers in gachsaran/Iran. Inclusion criteria inclusive the during the past 12 months have not been menstrual periods; with minimum score of 15 in Kupperman Index. After getting written informed consent, participants will complete the demographic characteristics.Kupperman Index and Hullbert Index of Sexual Desire.Then we will randomly allocate them into intervention and control groups using permuted block randomization. One group receive fennel capsule (500mg for QID) and the other one receive placebo capsule for 8 weeks. The Kupperman Index and Hullbert Index of Sexual Desire (HISD) is evaluated before and after 4, 8 weeks treatment again. Before and after the intervention by taking blood samples from participants to determine their estrogen levels.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022125566N4**

Registration date: **2016-03-23, 1395/01/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-23, 1395/01/04

Registrant information

Name

Maryam Hosseinik

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 1334 6079

Email address

hosseinik.maryam@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Foeniculum vulgare* seed powder on estrogen levels, menopausal symptoms and sexual desire in menopausal women

Public title

Effect of *Foeniculum vulgare* seed powder on menopausal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being married and between 40 and 60 years old ; During the past minimum of 12 months and maximum of 5 years have not been menstrual periods; With minimum score of 15 in Kupperman Index; Did not recognize diagnosed with mental retardation and hearing

and vision problems cognitive; Not received hormone therapy and diet or herbal treatment during the last 6 months ; Lack of chronic diseases (especially epilepsy) Exclusion criteria: Migration;Chronic diseases that have an affected on outcome variables, Consumes less than 80 percent of the drugs in a month

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: **70**

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

Yasuj University of Medical Science Yasuj

Street address

Motahary boulevard, Vice chancellor for research

City

Yasuj

Postal code

Approval date

2015-04-22, 1394/02/02

Ethics committee reference number

ir.yums.rec.1394.6

Health conditions studied

1

Description of health condition studied

Menopausal

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climactric states

Primary outcomes

1

Description

Estrogen levels

Timepoint

Before the intervention and Two months after the beginning intervention

Method of measurement

According ng / mL by ELISA sensitivity

2

Description

Symptoms of menopausal

Timepoint

Before the intervention, Four and eight weeks after the beginning intervention

Method of measurement

Kupperman index

3

Description

Sexual desire

Timepoint

Before the intervention, Four and eight weeks after the beginning intervention

Method of measurement

Hullbert Index of Sexual Desire (HISD)

Secondary outcomes

1

Description

Vasomotor symptoms

Timepoint

Before the intervention, Four and eight weeks after the beginning intervention

Method of measurement

Before the intervention, Four and eight weeks after the beginning intervention

Intervention groups

1

Description

4 caps of placebo, Every 6 Hours for 8 weeks

Category

Placebo

2

Description

4 500mg-caps of fennel, Every 6 Hours for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
health care centers in gachsaran
Full name of responsible person
Street address
City
gachsaran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Yasuj University of
Medical Sciences
Full name of responsible person
Dr Abdul Mohammad Mousavi
Street address
Motahary boulevard, Vice chancellor for research,
Yasuj University of Medical Science
City
Yasuj
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,Yasuj 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
Yasuj University of Medical Science
Full name of responsible person
Dr Nazafarin Hosseini
Position
Assistant Professor
Other areas of specialty/work
Street address
Near the Imam Sajjad (AS), Campus Yasuj of Medical
Science, the third floor, School of Nursing and
Midwifery (R)
City

Yasuj
Postal code
Phone
+98 74 3223 4115
Fax
Email
hosseinichenar@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yasuj University of Medical Science
Full name of responsible person
Dr Nazafarin Hosseini Affiliated Organization name
Position
Assistant Professor
Other areas of specialty/work
Street address
Near the Imam Sajjad (AS), Campus Yasuj of Medical
Science, the third floor, School of Nursing and
Midwifery (R)
City
Yasuj
Postal code
Phone
+98 74 3223 4115
Fax
Email
hosseinichenar@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Yasuj University of Medical Science
Full name of responsible person
Maryam Hosseininik
Position
Master Student in Public Health Tendency
Other areas of specialty/work
Street address
Near the Imam Sajjad (AS), Campus Yasuj of Medical
Science, the third floor, School of Nursing and
Midwifery (R)
City
Yasuj
Postal code
Phone
00
Fax
Email
m.hosseinin@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