

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The comparison of the efficacy *Foeniculum vulgare* and placebo on bone density and lipid profile in postmenopausal women

Protocol summary

Summary

The goal of this study is to assess the effects of *Foeniculum vulgare* on bone density and lipid profile. This study was a double-blind, randomized, placebo-controlled trial, which studied sixty eligible postmenopausal women, who were recruited in Imam Reza Hospital in Mashhad. Then, they were randomly assigned to fennel and placebo groups. Lipid profiles including total, low density lipoprotein (LDL) and HDL cholesterol as well as triacylglycerol were measured. The dual energy X-ray absorptiometry was utilized to measure bone mineral density (BMD) and bone mineral content (BMC) of the spine, femoral neck, Intertrochanter, and Trochanter at baseline and after three months. Inclusion criteria are as follows: postmenopausal status which was defined as aged over 40 years with no vaginal bleeding for 1 year; no regular ingestion of phytoestrogen or soy-based products; having a normal mammogram in the last year. The exclusion criteria were: use of any fluoride or bisphosphonates; diseases or medications affecting bone metabolism; Currently (or in the past 6 months) using estrogen or calcitonin; medication for lowering lipids or blood pressure; diabetes mellitus; no regular physical exercise or allergy to *Foeniculum vulgare*

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070428789N1**
Registration date: **2016-10-02, 1395/07/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-02, 1395/07/11

Registrant information

Name

Masumeh Ghazanfarpour

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences, Mashhad, Iran
Mashhad, Iran

Expected recruitment start date

2015-07-31, 1394/05/09

Expected recruitment end date

2016-04-08, 1395/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy *Foeniculum vulgare* and placebo on bone density and lipid profile in postmenopausal women

Public title

Foeniculum vulgare on bone and lipid profile

Purpose

Treatment

Inclusion/Exclusion criteria

postmenopausal status, which was defined as aged between 45-65 with no vaginal bleeding for 1 year no regular ingestion of phytoestrogen or soy-based products

; having a normal mammogram in the last year. The exclusion criteria were : use of any fluoride or bisphosphonates; diseases or medications affecting bone metabolism; Currently (or in the past 6 months) using estrogen or calcitonin; medication for lowering lipids or blood pressure diabetes mellitus; no regular physical exercise or allergy to

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Street address

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

City

Mashhad

Postal code**Approval date**

2015-04-15, 1394/01/26

Ethics committee reference number

IR.MUMS.ir.ac.1392.151

Health conditions studied**1****Description of health condition studied**

menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes**1****Description**

High density lipoprotein (HDL)

Timepoint

before and 90 days after treatment

Method of measurement

biochemical test

2**Description**

Osteoporosis

Timepoint

before intervention and 90 days after intervention

Method of measurement

the dual energy X-ray absorptiometry was utilized to measure bone mineral density (BMD)

3**Description**

low density lipoprotein (LDL)

Timepoint

before and after treatment

Method of measurement

biochemical test

4**Description**

Total cholesterol

Timepoint

before and 90 days after treatment

Method of measurement

biochemical test

5**Description**

Triglycerides

Timepoint

Before and after 90 days treatment

Method of measurement

biochemical test

Secondary outcomes

empty

Intervention groups**1****Description**

Foeniculum vulgare 30 mg soft capsule, three times a day, 12 week

Category

Treatment - Drugs

2

Description

placebo capsule 30 mg soft capsule, three times a day, 12 week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic of Emam Reza

Full name of responsible person

Maliheh Afiat

Street address

Gynecology Clinic, Emam Reza Hospital, Ebn-e Sina Street, Mashhad, Khorasan-e-Razavi,

City

mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Mohsen Tafaghodi

Street address

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

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korasan Razavi

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences, Vice chancellor for research

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, Vice chancellor for research

Full name of responsible person

Mohsen Tafaghodi

Position

Vice chancellor for research

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

PhD candidate of Reproductive Health

Other areas of specialty/work

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Position

PhD candidate of Reproductive Health

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