Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Masumeh Ghazanfarpour
Name of organization / entity
Mashhad University of Medical Sciences
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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 vulgareon 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
beforer and after tratment

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 Reaza 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
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Person responsible for updating data

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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