

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

+98 34 4230 9487

##### Email address

ghazanfarpm901@mums.ac.ir

#### 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

##### City

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

#### Street address

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## 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

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## 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

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**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*