

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Garlic tablet on Pro-Inflammatory Cytokines in Post-menopause Osteoporotic Women

Protocol summary

Summary

The aim of this randomized double blind clinical trial study is examination the effect of garlic tablet on pro-inflammatory cytokines in post-menopause osteoporotic women. Subjects are post-menopause osteoporotic women in neck femur and lumbar spine aged 45-65 years who were randomly selected from Yazd Bone Mass Densitometry. Women with Heart disease, Hypertension or Hyperlipidemia that take Aspirin, Captopril, lipid lowering drug or women with peptic ulcer and sensitive to garlic are excluded from this study. Sample size is 22 cases in each group (intervention – placebo). Subjects in intervention group take two 570mg tablets of garlic per day for 1 month and those in placebo group take 2 placebos per day for 1 month. Blood specimens are obtained before and after intervention and serum is separated and cytokines measure by ELISA kits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811183273N1**

Registration date: **2010-04-24, 1389/02/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Hamideh Hesabgar

Name of organization / entity

Shahid Sadughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Sadughi University of Medical Sciences and Health Services

Expected recruitment start date

2010-03-06, 1388/12/15

Expected recruitment end date

2010-04-04, 1389/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Garlic tablet on Pro-Inflammatory Cytokines in Post-menopause Osteoporotic Women

Public title

The effect of garlic tablet in prevention of osteoporosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: post-menopause osteoporotic women in lumbar spine or neck femur, Exclusion criteria: Subjects with heart diseases & Hypertension that take Aspirin, Captopril or other Anti-coagulant drugs, hyperlipidemic patients that take lipid lowering drugs and people with Peptic Ulcer and hypersensitivity to Garlic

Age

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

Gender

Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: 45

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

Shahid Sadughi University of Medical Sciences and Health Services

Street address

Second Central Building of Shahid Sadughi University of Medical Sciences and Health Services, Shahid Bahonar square, Yazd, Iran

City

Yazd

Postal code

Approval date

2010-03-10, 1388/12/19

Ethics committee reference number

1/116334/پ

Health conditions studied

1

Description of health condition studied

osteoporosis

ICD-10 code

M81.1

ICD-10 code description

Postmenopausal osteoporosis

Primary outcomes

1

Description

The rate of cytokines involved in osteoporosis

Timepoint

Before and after intervention

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Garlic, 2 tablets (570mg) per day for 1 month

Category

Treatment - Drugs

2

Description

Placebo 2 tablets (570mg) per day for 1 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Bone Mass Densitometry

Full name of responsible person

Street address

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadughi University of Medical Sciences and Health Services

Full name of responsible person

Hassan Mozaffari

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadughi University of Medical Sciences and Health Services

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**

Shahid Sadughi University of Medical Sciences and Health Services

Full name of responsible person

Dr Hassan Mozaffari

Position

PhD

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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*