

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluating the effects of pine bark extract supplementation on the bone turnover, as well as the possible mechanisms OPG/RANKL signaling in postmenopausal osteopenic women

Protocol summary

Summary

Objectives: This study aims to determine the effects of Pine Bark Extract supplementation on bone turnover in postmenopausal osteopenic women **Design:** The present study was designed as a randomized, double-blind, clinical trial **Setting and Conduct:** 44 postmenopausal women with osteopenia referring to Shariati Hospital were invited based on inclusion criteria, after obtaining written consent and completing the general questionnaire, will be evaluated for the serum levels of their bone turnover markers. Then we randomly place them in two groups of supplement and placebo recipients and then we supplemented them for 12 weeks. At the end of 12 weeks, the tests will be performed again. **Participants including major eligibility:** Participants in this study were selected from osteopenic postmenopausal women referring to Shariati Hospital in Tehran. **Intervention:** will include pine bark extract supplementation (250 mg / day) or placebo for 12 weeks. **Main outcome measures:** The main outcome measures will be included changes in bone turnover markers, and bone alkaline phosphatase and RANKL/OPG.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071123153N1**
Registration date: **2017-07-21, 1396/04/30**
Registration timing: **na**

Last update:

Update count: **0**

Registration date

2017-07-21, 1396/04/30

Registrant information

Name

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Name of organization / entity

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Recruitment status

Not enough for processing

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-08-21, 1396/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of pine bark extract supplementation on the bone turnover, as well as the possible mechanisms OPG/RANKL signaling in postmenopausal osteopenic women

Public title

Evaluating the effects of pine bark extract supplementation in postmenopausal osteopenic women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Postmenopausal women; Age: between 50-65 years; With a diagnosis of osteopenia. Osteopenia

was defined as bone mineral density T-score at the spine and/or hip between 1 to 2.5 SD below the young normal ex-matched areal BMD of the reference database (According to the WHO); Normal function of thyroid, liver, and kidney. Exclusion criteria: Report of fractures during the study; unwilling to continue participate in the project; Any visible side effects of supplements; The history of bone disease (Paget's disease, osteomalacia, etc.); History of chronic diseases, including cancer, diabetes, kidney failure, liver disease, systemic inflammatory disease, degenerative joint diseases and rheumatologic disorders;

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

The ethics committee of Tehran University of Medical Sciences

Street address

4th Floor, No. 23, before Pour Sina St. - 16th Azad St.
- Keshavarz Blvd

City

Tehran

Postal code

Approval date

2017-01-07, 1395/10/18

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1408

Health conditions studied

1

Description of health condition studied

Osteopenia

ICD-10 code

M81.0

ICD-10 code description

Postmenopausal osteoporosis

Primary outcomes

1

Description

Procollagen type I N-terminal propeptide (PINP)

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

ELISA

2

Description

Cross-Linked Carboxy-Terminal Telopeptide of Type I Collagen

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

ELISA

3

Description

Bone alkaline phosphatase (BAP)

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

ELISA

4

Description

Receptor activator of nuclear factor kappa-B ligand (RANKL)

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

ELISA

5

Description

Osteoprotegerin (OPG)

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Weight

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

digital scale

Intervention groups

1

Description

Intervention group: Daily intake of 5 Oligopin capsules for 12 weeks (2 with breakfast, 2 with lunch, 1 with dinner) (Each capsule contains 50 mg of French pine bark extract)

Category

Treatment - Drugs

2

Description

Control group: Daily intake of 5 capsules containing water for 12 weeks (2 with breakfast, 2 with lunch, 1 with dinner) (quite similar to pine bark extract capsule)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Osteoporosis Research Center of Shariati Hospital of Tehran University of Medical Sciences

Full name of responsible person

Seyed Bahman Panahande

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Vice Chancellor of Research, International Campus

Full name of responsible person

Dr Mohammad Reza Hadiyan, Deputy Unit

Street address

Tehran University of Medical Sciences Office of Vice-President for Research Affairs, Number 124 , Baradaran-e-Mozaffar St., Dameshgh St., Vali-e Asr

Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences, Vice Chancellor of Research, International Campus

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

Department of Clinical Nutrition, School of Nutritional Sciences and Dietetics, Tehran University of

Full name of responsible person

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Position

PhD Candidate in Nutritional Sciences

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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyed Bahman Panahande

Position

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