

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Calcium -Vitamin D and Alendronate on serum Dickkopf-1(Dkk-1) and Osteoprotegerin(OPG) in women with osteoporosis

Protocol summary

Summary

The aim of this study is evaluation of the effect of Calcium -Vitamin D and Alendronate on serum Dickkopf-1(Dkk-1) and Osteoprotegerin(OPG) in women with osteoporosis.Study will be done without placebo.The study population includes menopause women referred to specialty clinics of Tabriz University of Medical Sciences.Sample size in this study is 72 people.36 people with normal bone density is intended to determine the relation of serum levels of OPG and Dkk-1 with bone density in women with osteoporosis and without osteoporosis. 36 people with osteoporosis are intervention group. Inclusion criteria for intervention: menopause women that on the basis of the results obtained in densitometry according to the WHO criteria,have osteoporosis (Tscore below -2.5)at least in one of the two site(hip and spine).Exclusion criteria:Use of glucocorticoids and medications that affect bone metabolism and density ,previous treatment with calcium or vit D or both,osteoporosis secondary to disease,history of malignant disease and presence of advanced osteoarthritis in physical examination.Women with osteoporosis will be treat with Calcium-Vit D 1000 mg daily and Alendronate 70 mg once a week for 4 months,prior to initiating therapy and 4 months later serum levels of OPG and Dkk-1 will be evaluate. The primary outcome measures are serum levels of Dickkopf-1 and Osteoprotegerin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201238809N1**

Registration date: **2012-03-01, 1390/12/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-01, 1390/12/11

Registrant information

Name

Bahareh Amanifar

Name of organization / entity

tabriz university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research vice chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Calcium -Vitamin D and Alendronate on serum Dickkopf-1(Dkk-1) and Osteoprotegerin(OPG) in women with osteoporosis

Public title

Effect of Calcium -Vitamin D and Alendronate on serum Dickkopf-1(Dkk-1) and Osteoprotegerin(OPG) in women with osteoporosis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Menopause women that on the basis of the results obtained in densitometry according to the WHO criteria, have osteoporosis (Tscore below -2.5) at least in one of the two sites (hip and spine). Exclusion criteria: 1. Use of glucocorticoids or other medications that affect bone metabolism and density (cytotoxic drugs and anticoagulants). 2. Patients treated with Calcium or Vit D or both. 3. History of malignant disease. 4. Disease that cause secondary osteoporosis, such as intestinal, hepatic, hematologic, kidney disease; rheumatologic disease (such as RA, SLE) and endocrine disease (such as Cushing syndrome, hypogonadism). 5. Presence of advanced osteoarthritis in physical examination.

Age

From **45 years** old to **100 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Ethics committee, Research vice chancellor, Faculty of medicine, Tabriz University of Medical Sciences

City

Tabriz

Postal code

5166614766

Approval date

2011-12-28, 1390/10/07

Ethics committee reference number

7699/4/5

Health conditions studied

1

Description of health condition studied

osteoporosis

ICD-10 code

M81.5

ICD-10 code description

idiopathic osteoporosis

Primary outcomes

1

Description

Dickkopf-1

Timepoint

prior to initiating therapy and 4 months later

Method of measurement

ELISA method

2

Description

Osteoprotegerin

Timepoint

prior to initiating therapy and 4 months later

Method of measurement

ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Alendronate, 70 mg tab, once a week, for 4 months + Calcium-D, 500 mg tab, twice daily, for 4 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialty clinics of Tabriz University of Medical Sciences

Full name of responsible person

Mehrzaad Hajjalilo

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Vice chancellor for research, Faculty of medicine, Tabriz University of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research vice chancellor of Tabriz University of Medical Sciences

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

Tabriz University of Medical Sciences

Full name of responsible person

Mehrzad Hajjalilo

Position

Assistant professor of medicine, Rheumatologist

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