

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Teriparatide, Alendronate, Zoledronic Acid, and combined effect of Teriparatide and Alendronate treatment of primary osteoporosis: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Teriparatide, Alendronate, Zoledronic Acid, and combined effect of Teriparatide and Alendronate treatment of primary osteoporosis. Design: a randomized clinical trial. Setting and conduct: The eligible patients with primary osteoporosis who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: primary osteoporosis; T-score less than -2.5 in the lumbar spine or femoral neck; female; age of 44 to 99 years. Exclusion criteria: secondary osteoporosis; using prednisolone more than 3 months; rheumatologic disease; malignancy; hypothyroidism; renal failure; history of surgery of parathyroid gland. Intervention group 1: Teriparatide 20 mcg daily subcutaneously for one year. Intervention group 2: Alendronate 70 mg weekly orally for one year. Intervention group 3: Zoledronic Acid 4 mg subcutaneously at the beginning of treatment and 6 months later. Intervention group 4: Teriparatide 20 mcg daily subcutaneously for 6 months and then Alendronate 70 mg weekly orally for 6 months. Control group: No control group. Primary outcome: Assessing the bone density before treatment and one year later using Dual X-ray Absorptiometry. Secondary outcome: Assessing the bone density before treatment and one year later using T-score. Randomization: Random assignment of the patients to the intervention and control groups using random number table. Blinding: Not blinding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605169014N99**

Registration date: **2016-05-20, 1395/02/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-20, 1395/02/31

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2006-06-05, 1385/03/15

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Teriparatide, Alendronate, Zoledronic Acid, and combined effect of Teriparatide and Alendronate treatment of primary osteoporosis: a randomized clinical trial

Public title

Effect of Teriparatide, Alendronate, Zoledronic Acid, and combined effect of Teriparatide and Alendronate treatment of primary osteoporosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primary osteoporosis; T-score less than -2.5 in the lumbar spine or femoral neck; female; age of 44 to 99 years. Exclusion criteria: secondary osteoporosis; using prednisolone more than 3 months; rheumatologic disease; malignancy; hypothyroidism; renal failure; history of surgery of parathyroid gland.

Age

From **44 years** old to **99 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups using random number table. Blinding: Not blinding.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.UMSHA.REC.1395.42

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

Assessing the bone density

Timepoint

before treatment and one year later

Method of measurement

using Dual X-ray Absorptiometry

Secondary outcomes

1

Description

Assessing the bone density

Timepoint

before treatment and one year later

Method of measurement

using T-score

Intervention groups

1

Description

Intervention group 1: Teriparatide 20 mcg daily subcutaneously for one year.

Category

Treatment - Drugs

2

Description

Intervention group 2: Alendronate 70 mg weekly orally for one year.

Category

Treatment - Drugs

3

Description

Intervention group 3: Zoledronic Acid 4 mg subcutaneously at the beginning of treatment and 6 months later.

Category

Treatment - Drugs

4

Description

Intervention group 4: Teriparatide 20 mcg daily subcutaneously for 6 months and then Alendronate 70 mg weekly orally for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Reza Fatahi

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the Technology, Hamadan
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

Farshchian Hospital

Full name of responsible person

Dr Reza Fatahi

Position

Internal Medicine Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

Dr Ahmad Tahamoli Roodsari

Position

Rheumatologist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

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