

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effects of alendronate and Vitamin K Combination versus Alendronate alone on bone mineral density of patients with postmenopausal osteoporosis

Protocol summary

Summary

The purpose of the present study is to investigate the potential effect of vitamin K on the Bone mineral density of patients with postmenopausal osteoporosis. This open, randomized, parallel study will be conducted on patients with osteoporosis according to WHO Criteria ($T \leq -2.5$) 2) who will attend to the rheumatology clinic of Imam Reza Hospital, Mashhad, Iran. Eligible patients are those who meet all the following criteria: 1) Osteoporosis according to WHO Criteria ($T \leq -2.5$) 2) Age: 45-65 years 3) postmenopausal women. Patients are not eligible if they have: 1) secondary osteoporosis 2) Taking anticoagulants 3) History of liver and kidney disorders 4) History of bisphosphonates side effects 5) People who have contraindications to take calcium and vitamin D 6) People who take other anti-osteoporotic medications and 7) People who needs to use Vitamin K in the group 1. The total number of patients will be fifty cases. The patients will randomly assign into two groups: group 1 ($n=25$) will receive calcium + vitamin D pills twice daily (Jalinous company, Tehran, Iran, each pill has 500 mg calcium and 200 IU vitamin D), 70 mg Alendronate orally per week (Alenate®; Dr. Abidi Company, Tehran, Iran). Group 2 ($n=25$) will receive the same combination plus vitamin K1 pills 10 mg daily (Pars Minoo Ind. Company, Tehran, Iran). The duration of treatment will be one year in both groups. The main outcome measure will be bone mineral density. At the end of the study, we will measure bone mineral density again for all of the patients by the same scanner.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504141479N3**
Registration date: **2015-08-17, 1394/05/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-17, 1394/05/26

Registrant information

Name

Mohammadhassan Jokar

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 8818

Email address

jokarmh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research vice president of Mashhad University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of alendronate and Vitamin K Combination versus Alendronate alone on bone mineral density of

patients with postmenopausal osteoporosis

Public title

The effects of alendronate and Vitamin K on postmenopausal osteoporosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Osteoporosis according to WHO Criteria 2-Age:45-65 years 3- Postmenopausal women
Exclusion criteria 1- Secondary Osteoporosis 2- Taking anticoagulants 3- History of liver and kidney disorders 4- History of Bisphosphonates side effects 5- People who have contraindications to take calcium and vitamin D 6- People who take other anti- osteoporotic medications 7- People who needs to use Vit.K in the alendronate group

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: via a random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical sciences, Daneshgah street

City

Mashhad

Postal code

9177899191

Approval date

2012-08-11, 1391/05/21

Ethics committee reference number

IR.MUMS.REC.1391.101

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M81.0

ICD-10 code description

postmenopausal osteoporosis

Primary outcomes

1

Description

Bone mineral density

Timepoint

Before the intervention and one year later

Method of measurement

By Densitometry with DXA method

Secondary outcomes

1

Description

Drug side effects

Timepoint

Every 2 months

Method of measurement

Taking history

Intervention groups

1

Description

Group 1 will receive calcium + vitamin D pills twice daily (Jalinos company, Tehran, Iran, each pill contains 500 mg calcium carbonate and 200 IU vitamin D) and 70mg alendronate orally per week (Alenate®; Dr. Abidi Company, Tehran, Iran). The duration of treatment will be one year.

Category

Treatment - Drugs

2

Description

Group 2 will receive calcium + vitamin D pills twice daily (Jalinos company, Tehran, Iran, each pill contains 500 mg calcium carbonate and 200 IU vitamin D), 70mg alendronate orally per week (Alenate®; Dr. Abidi Company, Tehran, Iran) and vitamin K1 pills 10 mg daily (Pars Minoo Ind. Company, Tehran, Iran). The duration of treatment will be one year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mohammad Hassan Jokar

Street address

Chamran street

City

Mashhad

City

Mashhad

Postal code

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Email

jokarmh@mums.ac.ir

Web page address

<http://my.mums.ac.ir/default.aspx>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice president for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Daneshgah street

City

Mshhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice president for research, Mashhad 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

Imam Reza Hospital

Full name of responsible person

Mohammad Hassan Jokar

Position

MD, Rheumatologist, Associated Professor

Other areas of specialty/work**Street address**

Internal medicine ward, Imam Reza Hospital, Chamran street

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Reza Hospital

Full name of responsible person

Mohammad Hassan Jokar

Position

Rheumatologist, Associated Professor

Other areas of specialty/work**Street address**

Chamran street

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Person responsible for updating data

Contact

Name of organization / entity

Imam Reza Hospital

Full name of responsible person

Mohammad Hassan Jokar

Position

Associated professor

Other areas of specialty/work**Street address**

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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