Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effect of two different doses of Alendronate on the treatment of osteopenia based on fracture risk assessment (FRAX) in menopauses women who referred to Alzahra hospital during 2014-17

Protocol summary

Study aim
Comparison of the efficacy of 35 mg weekly versus 70 mg weekly Alendronate for the treatment of osteopenia based on FRAX (Fracture risk assessment) index in menopaused females

Design
Randomized clinical trail, with parellel group, single blinded, with 70 participants in each group

Settings and conduct
Menopause females referring to Rheumatology outpatient clinic of Alzahra Hospital with the diagnosis osteopenia based on FRAX assessment will be included through simple sampling and then allocated to each group of either 35 mg weekly Alendronate use or 70 mg weekly Alendronate use for 2 years. FRAX assessment will be reevaluated at the end of the study

Participants/Inclusion and exclusion criteria
Inclusion: - Menopausal state - Osteopenia (hip or spine T-score -2.5 to -1) - Normal serum levels of vitamin D, Calcium, Phosphorus, Alkaline phosphatase - Lacking history of pathological or traumatic fractures - Lacking the diagnosis of malignancy Unmet criteria: - The impossibility to determine FRAX index due to any reason - Osteoprosis (T-score worse than -2.5) - Osteopenia (hip or spine T-score -2.5 to -1) plus pathological fracture

Intervention groups
1) Treatment with 70 mg weekly Alendronate (Osteophus; CIPLA; India) for two years 2) Treatment with 35 mg weekly Alendronate (Osteophus; CIPLA; India) for two years

Main outcome variables
FRAX Hip T-score Spine T-score Hip Z-score Spine Z-score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043111N1**
Registration date: **2019-10-28, 1398/08/06**
Registration timing: **retrospective**

Last update: **2019-10-28, 1398/08/06**
Update count: **0**

Registration date
2019-10-28, 1398/08/06

Registrant information

Name
Negar Botlani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3641 4877

Email address
negarbotlani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2014-04-04, 1393/01/15

Expected recruitment end date
2017-12-20, 1396/09/29

Actual recruitment start date
2015-04-04, 1394/01/15

Actual recruitment end date
2018-02-25, 1396/12/06

Trial completion date
2018-05-29, 1397/03/08

Scientific title
The effect of two different doses of Alendronate on the

treatment of osteopenia based on fracture risk assessment (FRAX) in menopauses women who referred to Alzahra hospital during 2014-17

Public title
Assessment of two doses of Alendronate on the treament of osteopenia on menopaused females
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Menopausal state Osteopenia (hip or spine T-score -2.5 to -1) Normal serum levels of vitamin D, Calcium, Phosphorus, Alkaline phosphatase Lacking history of pathological or traumatic fractures Lacking the diagnosis of malignancy
Exclusion criteria:
The impossibility to determine FRAX index due to any reason Osteoprosis (T-score worse than -2.5) Osteopenia (hip or spine T-score -2.5 to -1) plus pathological fracture
Age
From **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **140**
Actual sample size reached: **152**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization; individual; using Random allocation software as those with odd number are allocated to one and with even number to the other group
Blinding (investigator's opinion)
Single blinded
Blinding description
The clinical investigator who evaluates FRAX index will be blinded
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezarjarib Street, Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
7346181746
Approval date
2017-05-26, 1396/03/05
Ethics committee reference number
IR.MUI.REC.1396.3.639

Health conditions studied

1

Description of health condition studied
Osteopenia
ICD-10 code
N95
ICD-10 code description
Menopausal and other perimenopausal disorders

Primary outcomes

1

Description
Hip FRAX
Timepoint
Immediately before intervention and within 2 years following intervention
Method of measurement
Bone mineral densitometry

2

Description
Spine FRAX
Timepoint
Immediately before intervention and within 2 years following intervention
Method of measurement
Bone mineral densitometry

3

Description
Hip T-score
Timepoint
Immediately before intervention and within 2 years following intervention
Method of measurement
Bone mineral densitometry

4

Description
Spine T-score
Timepoint

Immediately before intervention and within 2 years following intervention

Method of measurement

Bone mineral densitometry

Secondary outcomes

1

Description

Hip Z-score

Timepoint

Immediately before intervention and within 2 years following intervention

Method of measurement

Bone mineral densitometry

2

Description

Spine Z-score

Timepoint

Immediately before intervention and within 2 years following intervention

Method of measurement

Bone mineral densitometry

Intervention groups

1

Description

Intervention group: Treatment with 70 mg weekly Alendronate for 2 years

Category

Treatment - Drugs

2

Description

Intervention group: Treatment with 35 mg weekly Alendronate for 2 years

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology outpatient clinic of Alzahra Hospital

Full name of responsible person

Mansour Karimifar

Street address

Hezarjarib Street

City

Isfahan

Province

Isfehan

Postal code

ۀ8174673461

Phone

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Email

karimifar@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Karimifar

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Karimifar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Rheumatology
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Person responsible for updating data

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karimifar@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, patients' densitometry is recorded and they would be followed for two years. Then as they will be followed for a longer duration, the patients'records will be provided only following the connection to the study responsible rheumatologist.
When the data will become available and for how long
The data accessibility due to the long-term follow-up is not possible.
To whom data/document is available
Rheumatologist professors
Under which criteria data/document could be used
For long-term follow-up study by the permission of rheumatologist responsible for the study
From where data/document is obtainable
The rheumatologist responsible for the study
What processes are involved for a request to access data/document
It should be connected to the rheumatologist responsible for the study
Comments