

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A randomized, double-blind, placebo-controlled pilot study of the efficacy of alendronate on the prevention of bone loss in patients with early ankylosing spondylitis

Protocol summary

Summary

Objectives: The aim of this study is the considering the efficacy of alendronate on the prevention of bone loss in the patients with early ankylosing spondylitis. **Design, setting and conduct:** In a randomized double blind placebo controlled study in the Emam Reza hospital of Tabriz University of Medical Sciences, patients with early ankylosing spondylitis which diagnosed by the (ASAS) after explaining the study aims and obtaining written informed consent will be recruited to the study. The early ankylosing spondylitis criteria are: Schober index $\geq$ 5; Normal hip joint in the pelvic radiography; Absence or rarity of syndesmophytes in the spine radiography (Taylor index $\leq$ 1). They will be randomized and allocated with the Randlist software to the treatment and control groups. **Participants:** Early ankylosing spondylitis patients according to the Assessment of SpondyloArthritis international Society (ASAS) criteria **Exclusion criteria:** 1. Using of drugs which increase bone density like bisphosphonates; 2. Using of steroids and biological agents; 3. Coexistence of other disease which decreases bone density: including hyperparathyroidism, diabetes, hyper and hypothyroidism, osteomalacia, liver failure, renal failure. **Intervention:** A group of patients will receive alendronate sodium 70 mg tablet (Ostomod, Modava company) 70mg/week (one tablet at week) for 12 months and another group will receive placebo. Alendronate tablets and placebo tablets were overencapsulated to look similar. Before intervention and 12 months after intervention densitometry will be performed by the dual energy X-ray absorptiometry method with Hologic QDR model instrument from lumbar and pelvic area. Patients, assessing physicians and densitometry technicians are blind. Both groups will receive calcium 1000mg/d and vitamin D 400mg/d supplements. For control of the inflammatory symptoms standard treatment including one non steroidal anti-

inflammatory drug (NSAID) with anti-inflammatory dose will be started. Main outcome measures: Bone density which will be measured by the dual energy X-ray absorptiometry method with Hologic QDR model instrument from the lumbar and pelvic area and data will be entered in a questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212206975N3**

Registration date: **2013-01-31, 1391/11/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-01-31, 1391/11/12

Registrant information

Name

Alireza Khabbazi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01
Expected recruitment end date
 2013-07-21, 1392/04/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 A randomized, double-blind, placebo-controlled pilot study of the efficacy of alendronate on the prevention of bone loss in patients with early ankylosing spondylitis

Public title
 Alendronate for the prevention of osteoporosis in ankylosing spondylitis

Purpose
 Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: Schober index $\geq$ 5; Normal hip joint in the pelvic radiography; Absence or rarity of syndesmophyte in the spine radiography (Taylor index $\leq$ 1); Normal bone density or mild osteopenia (T-score $\geq$ -1.5) Exclusion criteria: Use of drugs which increase bone density like bisphosphonates; Use of steroids and biological agents; Coexistence of other disease which decreases bone density: including hyperparathyroidism, diabetes, hyper and hypothyroidism, osteomalasia, liver failure, renal failure

Age
 No age limit

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: 20

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 For elimination of the possibility of any probable bias due to the knowledge of patients and assessing physicians about the type of treatment we will perform a double blind study. Alendronate and placebo will be encapsulated and for this reason patients and assessing physicians do not have any knowledge about the type of treatment. Randomization will be performed by the Randlist software and every patient will be entered in the treatment or placebo groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tabriz University of Medical Sciences

Street address

Ethic committee, Vice chancellor for research, 4th floor, Faculty of medicine, Tabriz University of Medical Sciences

City

Tabriz

Postal code

5166614766

Approval date

2012-11-27, 1391/09/07

Ethics committee reference number

7939.4.5

Health conditions studied

1

Description of health condition studied

Ankylosing spondylitis

ICD-10 code

M45

ICD-10 code description

Ankylosing spondylitis

Primary outcomes

1

Description

Bone density

Timepoint

12 months after intervention (at the end of study)

Method of measurement

Bone mineral density measurement as gram/cm² by the DEXA method with Hologic QRD model instrument from lumbar and pelvic area

Secondary outcomes

1

Description

Osteoporotic fracture

Timepoint

Every 3 months until 12 months

Method of measurement

History, physical examination, and radiography

Intervention groups

1

Description

Control group will receive placebo for 12 months.

Category

Treatment - Drugs

2

Description

Treatment group will receive alendronate sodium 70 mg tablet (Ostomod, Modava company) with 70mg/week (one tablet at week)dose orally for 12 months. Alendronate is a bisphosphonate which binds to the hydroxyapatite in bone and act as a inhibitor of the resorption of bone. Chemically, it is described as bisphosphonic acid monosodium salt trihydrate. It should be taken alone on an empty stomach first thing in the morning with at least 240 mL of water. After administration, the patient should not have food, drink, medications, or supplements for at least one-half hour.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Research Team, Tabriz University of Medical Sciences

Full name of responsible person

Alireza khabbazi

Street address

Rheumatology Research Team, 4th floor, Emam Reza hospital, University street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

Vice chancellor for research, 4th floor, Faculty of Medicine, Tabriz University of Medical Sciences

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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, 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 Hajialilo

Position

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Person responsible for scientific inquiries

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Contact

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Assistant professor of medicine/Rheumatologist

Other areas of specialty/work

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Phone

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