

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of bone density changes before and after administration of at least one year of danozoomab in patients referred to Imam Reza Hospital

Protocol summary

Study aim

Assessment of the effect of Denosumab in the improvement of bone mineral densitometry (BMD) in osteoporotic postmenopausal women

Design

Clinical trial without a control group, non-blind, non-randomized, in phase 3 on 202 patients.

Settings and conduct

This clinical trial will be performed to determine the effectiveness of the denosumab drug on the bone density in osteoporosis patients. patients referred to Imam Reza Hospital (501 Army) in Tehran, after bone density testing, if confirmed by osteoporosis by a physician and conscious consent, intervened and received a 60 mg dose of denosumab subcutaneously at baseline and 6 months later. People will return after 6 month and have a bone density test again.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Postmenopausal women (aged 45 to 75 years old) diagnosed with osteoporosis by densitometry via DEXA (dual-energy X-ray absorptiometry). Exclusion criteria include: Lack of consent for being in the trial Having hypersensitivity to denosumab or any component in the formulation Malabsorption syndrome History of thyroid surgery, parathyroid surgery or intestinal resection which has been caused, malabsorption Patient

Intervention groups

After performing a bone density test and assuring osteoporosis, the person will receive a 60 mg dose of denosumab subcutaneously at baseline and 6 months later. 6 month after the injection, the person will have a bone resuscitation test and the effectiveness of the denosumab will be checked.

Main outcome variables

T score, Percentage change in Bone mineral density (BMD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210803052067N1**

Registration date: **2021-09-21, 1400/06/30**

Registration timing: **retrospective**

Last update: **2021-09-21, 1400/06/30**

Update count: **0**

Registration date

2021-09-21, 1400/06/30

Registrant information

Name

Atie Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2205 2496

Email address

dr.kazemiatie@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of bone density changes before and after administration of at least one year of danozomab in patients referred to Imam Reza Hospital

Public title
Bone density changes before and after administration of danozomab

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Postmenopausal women (aged 45 to 75 years old) diagnosed with osteoporosis by densitometry via DEXA (dual energy X-ray absorptiometry).
Exclusion criteria:
Lack of consent for being in the trial Having hypersensitivity to denosumab or any component in the formulation Malabsorption syndrome History of thyroid surgery, parathyroid surgery or intestinal resection which has been caused malabsorption Patient

Age
From **45 years** old to **75 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **202**

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 Tehran University of Medical Science

Street address

First floor, NO 21, Dameshgh st, Felestin st. Keshavar Blv

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.AJAUMS.REC.1399.058

Health conditions studied

1

Description of health condition studied

Osteoporosis

ICD-10 code

M80

ICD-10 code description

Osteoporosis with current pathological fracture

Primary outcomes

1

Description

Percentage change in Bone mineral density (BMD) at the lumbar spine (L1-L4), femoral neck, and total hip

Timepoint

Baseline and at 12th month of the study

Method of measurement

BMD by dual-energy x-ray absorptiometry Hologic 4500 or higher

Secondary outcomes

1

Description

(T score)

Timepoint

At the beginning of the study and 12 months later

Method of measurement

Bone densitometry

Intervention groups

1

Description

Intervention group: After performing a bone density test and assuring osteoporosis, the person will receive a 60 mg dose of denosumab (Xgeva®, produced by Amgen) subcutaneously at baseline and 6 months later. 6 months after the injection, the person will have a bone resuscitation test and the effectiveness of the denosumab will be checked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital (501 Artesh)
Full name of responsible person
Dr. Mohsen Ghasemzadeh Soroush
Street address
Emam Reza hospital (501 Artesh), Shahid
Etemadzade St, west Fatemi AV, Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mojtaba yousefi zoshk
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West Fatemi Street - the end of Etemadzadeh Street
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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

Artesh 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

Artesh University of Medical Sciences
Full name of responsible person
Dr. Mohsen Ghasemzadeh Soroush
Position
Rheumatologist
Latest degree
Subspecialist
Other areas of specialty/work
Rheumatology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
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Internist resident
Latest degree
Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A portion of the data that represents the final outcome

When the data will become available and for how long

Access will be 6 months after the results are printed.

To whom data/document is available

All physicians and residents of the field of medical sciences

Under which criteria data/document could be used

After obtaining permission from the deputy research group

From where data/document is obtainable

The person responsible for scientific accountability study

What processes are involved for a request to access data/document

First approved by the Research Vice-President

Comments