

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of using Prolia drug on bone density in hemodialysis patients

Protocol summary

Study aim

Determining the effectiveness of prolia drug usage on bone density in hemodialysis patients

Design

Clinical trials have an intervention group, non-blinding, non-random, phase 3 in 120 patients

Settings and conduct

This clinical trial will be performed to determine the effectiveness of the prolia drug on the bone density of hemodialysis patients. Hemodialysis patients referred to Alborz clinic, after bone density testing, if confirmed by osteoporosis by a physician and conscious consent, intervened and received a 60 mg dose of prolia (Denosumab) subcutaneously. People will return after a month and have a bone density test again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patient has a medical diagnosis of osteoporosis; undergoing hemodialysis courses.

Exclusion criteria: previous history of fracture; the patient does not have osteoporosis.

Intervention groups

After performing a bone density test and assuring osteoporosis, the person will receive a 60 mg dose of prolia (Denosumab) subcutaneously. One month after the injection, the person will have a bone resuscitation test and the effectiveness of the prolia will be checked.

Main outcome variables

Bone density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045282N1**

Registration date: **2020-06-12, 1399/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**

Update count: **0**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Elahe Dolatshahi

Name of organization / entity

Alborz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 26 3457 0030

Email address

e.dolatshahi@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of using Prolia drug on bone density in hemodialysis patients

Public title

The effectiveness of using Prolia drug on bone density

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient should have informed consent to participate in the intervention The patient should be undergone hemodialysis courses The patient has a medical diagnosis of osteoporosis

Exclusion criteria:

The patient does not have conscious consent to participate in the intervention The patient does not have a medical diagnosis of osteoporosis The patient has a history of previous fractures

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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 Alborz University of Medical Sciences

Street address

Deputy of research and technology, Safarian Ave., Golshahr, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2020-03-08, 1398/12/18

Ethics committee reference number

IR.ABZUMS.REC.1398.151

Health conditions studied

1

Description of health condition studied

Bone density

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bone density

Timepoint

The amount of bone density will be measured before the intervention and one month after the subcutaneous injection of the prolia drug.

Method of measurement

Bone density measurement test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: These people will intervene after a bone density measurement test and confirmation of osteoporosis, if there is conscious consent, Individuals receive subcutaneous doses of 60 mg of prolia (Denosumab).one month after the injection, people will return and have a bone density test again.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz Subspecialty Clinic

Full name of responsible person

Elahe Dolatshahipirooz

Street address

Mahdiye Ave, Tohid Sq

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3221 0484

Email

e.dolatshahi@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research and technology of Alborz university of medical sciences

Full name of responsible person

Mohammad Noorisepehr

Street address

Safarian Ave ,Golshahr,Deputy of research and technology

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3705

Email

e.dolatshahi@abzums.ac.ir

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

Yes

Title of funding source

Deputy of research and technology of Alborz 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**

Alborz University of Medical Sciences

Full name of responsible person

Elahe Dolatshahipirooz

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

Street address

Shahid Rajaei Hospital, Rajaei Ave., Hesarak, Shahidbeheshti Ave.

City

Karaj

Province

Alborz

Postal code

3197635141

Phone

+98 26 3457 0030

Email

e.dolatshahi@abzums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Alborz University of Medical Sciences

Full name of responsible person

Elahe Dolatshahipirooz

Position

Associate professor

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3197635141

Phone

+98 26 3457 0030

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e.dolatshahi@abzums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Alborz University of Medical Sciences

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Elahe Dolatshahipirooz

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3197635141

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable