Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Serum Levels of PTH, ALP, Calcium, and Phosphorus in Cancer Patients with and without Medication-Related Osteonecrosis of the Jaw (MRONJ) Receiving Denosumab

Protocol summary

Study aim

To compare serum levels of PTH, ALP, calcium, and phosphorus between cancer patients with and without denosumab-related MRONJ and evaluate their association with disease severity.

Design

A cross-sectional, comparative case-control study conducted on 70 patients (35 in the case group and 35 in the control group) using non-randomized convenience sampling, not blinded.

Settings and conduct

The study is conducted at the Oral and Maxillofacial Surgery Departments of Sina and Imam Khomeini Hospitals in Tehran. After clinical examination and staging of MRONJ (using AAOMS criteria and panoramic/CBCT imaging), 5 mL fasting venous blood samples are collected from patients between 8:00 and 10:00 AM. Serum levels of PTH (via ECLIA) and ALP, calcium, and phosphorus (via colorimetric/spectrophotometric methods) are measured in the hospital laboratory.

Participants/Inclusion and exclusion criteria

Inclusion: Cancer patients aged >=20; receiving denosumab >=1 year; MRONJ group (AAOMS criteria) vs control group (no MRONJ); informed consent. Exclusion: Head/neck radiation; metabolic bone diseases; maxillofacial surgery in past 3 months; oral infections.

Intervention groups

Case group: 35 cancer patients receiving denosumab who developed MRONJ. Control group: 35 cancer patients receiving denosumab without any signs or symptoms of MRONJ, matched for demographic variables.

Main outcome variables

Serum levels of parathyroid hormone (PTH); serum levels of alkaline phosphatase (ALP); serum calcium (Ca) concentration; serum phosphorus (P) concentration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260530069570N1**
Registration date: **2026-10-20, 1405/07/28**
Registration timing: **prospective**

Last update: **2026-10-20, 1405/07/28**
Update count: **0**

Registration date

2026-10-20, 1405/07/28

Registrant information

Name
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-11-06, 1405/08/15

Expected recruitment end date

2027-04-04, 1406/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Serum Levels of PTH, ALP, Calcium, and Phosphorus in Cancer Patients with and without Medication-Related Osteonecrosis of the Jaw (MRONJ) Receiving Denosumab

Public title
Evaluation of Bone Biomarkers in Denosumab-Induced Jaw Osteonecrosis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Cancer patients aged 20 years or older History of receiving high-dose Denosumab (Xgeva) for at least one year Patients diagnosed with MRONJ according to AAOMS 2020 criteria for the case group Patients receiving Denosumab without any clinical or radiographic evidence of MRONJ for the control group Willingness to participate and signing the written informed consent

Exclusion criteria:
History of radiation therapy to the head, neck, or maxillofacial region History of metabolic bone diseases unrelated to MRONJ History of maxillofacial surgery within the past 3 months Presence of active and acute oral or dental infections unrelated to MRONJ Refusal to continue participation at any stage of sampling

Age
From **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This observational case-control study evaluates serum levels of PTH, ALP, calcium, and phosphorus in 70 cancer patients treated with Denosumab (35 patients with MRONJ and 35 matched controls without MRONJ) to assess potential diagnostic and prognostic bone turnover biomarkers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Faculty of Dentistry, Islamic Azad University of Medical Sciences, Tehran

Street address
No. 4, 10th Neyestan St., Pasdaran Ave., Faculty of Dentistry

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Tehran

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Tehran

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1946853314

Approval date
2026-05-20, 1405/02/30

Ethics committee reference number
IR.IAU.DENTAL.REC.1405.022

Health conditions studied

1

Description of health condition studied
Medication-related osteonecrosis of the jaw (MRONJ)

ICD-10 code
M87.1

ICD-10 code description
Osteonecrosis due to drugs

Primary outcomes

1

Description
Serum alkaline phosphatase (ALP) activity level

Timepoint
At the time of patient enrollment following diagnosis and prior to any intervention

Method of measurement
Enzymatic colorimetric / photometric method according to IFCC protocol using Hitachi 902 autoanalyzer

2

Description
Serum intact parathyroid hormone (PTH) level

Timepoint
At the time of patient enrollment following diagnosis and prior to any intervention

Method of measurement
Chemiluminescence / electrochemiluminescence immunoassay (ECLIA) using Stat Fax 2600 analyzer

Secondary outcomes

1

Description
Serum calcium (Ca) and phosphorus (P) concentrations

Timepoint

At the time of patient enrollment following diagnosis and prior to any intervention

Method of measurement

Colorimetric enzymatic method (Arsenazo III/o-CPC) for calcium and photometric colorimetric method (Phosphomolybdate/UV) for phosphorus using BT-3500 biochemistry analyzer

Intervention groups

1

Description

Intervention group: 35 cancer patients receiving Denosumab (Xgeva) who developed medication-related osteonecrosis of the jaw (MRONJ) according to AAOMS 2020 criteria. Fasting venous blood samples (5 mL) are collected to measure serum levels of PTH, ALP, calcium, and phosphorus.

Category

Diagnosis

2

Description

Control group: 35 cancer patients receiving Denosumab (Xgeva) without any clinical or radiographic evidence of MRONJ, matched for age and sex. Fasting venous blood samples (5 mL) are collected to evaluate serum levels of PTH, ALP, calcium, and phosphorus.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital, Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Abbasi

Street address

Imam Khomeini Street, Hassan Abad Square, Sina Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Fatemeh Abbasi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Asieh Rahimi

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Person responsible for updating data

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Student

Latest degree
A Level or less

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
To protect participants' confidentiality and privacy, individual participant data will not be shared publicly.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable