Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of low-level laser therapy in preventing Osteonecrosis of the jaws in patients with a history of taking Bisphosphonate and Denosumab drugs after tooth extraction

Protocol summary

Study aim
prevention of MRONJ in patients with history of Bisphosphonate or Denusomab after extraction of hopeless teeth using Low Level Laser Therapy(LLL)

Design
clinical trial without control group and single, non randomized for 30 patients with specific condition of systemic health and dental problem

Settings and conduct
tooth extraction will be done under local anesthetic in Atraumatic surgery by oral and maxillofacial residents in operation room of Imam Husein Hospital or department of oral maxillofacial surgery ,college of dentistry of Shahid Beheshti university

Participants/Inclusion and exclusion criteria
Patients must have normal systemic conditions for tooth extraction under local anesthesia. Given this issue and the fact that a large number of specific patient which enter have cancer, clearance from the patient's oncologist is essential. The target population of this study is 2 categories: 1- Patients who have been taking oral bisphosphonates for more than three years due to osteoporosis or have used the injectable form of denosumab 2- Specific patients who are undergoing intravenous bisphosphonate treatment by an oncologist due to bone metastases or bone marrow cancer such as multiple myeloma.

Intervention groups
The effect of low-level laser applied to the tooth socket before and after tooth extraction and the status of soft and hard tissue repair and the healing process of the tooth socket in specific patients taking bisphosphonates or denosumab are being studied.

Main outcome variables
Soft tissue closure of extracted tooth socket Bone repair of tooth socket without clinical signs of inflammation and infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260515069406N1**
Registration date: **2026-06-18, 1405/03/28**
Registration timing: **prospective**

Last update: **2026-06-18, 1405/03/28**
Update count: **0**

Registration date
2026-06-18, 1405/03/28

Registrant information

Name
Hoda Movafagh Moghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2026-09-21, 1405/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of low-level laser therapy in preventing Osteonecrosis of the jaws in patients with a history of taking Bisphosphonate and Denosumab drugs after tooth extraction

Public title
Effect of low level laser therapy in prevention of MRONJ after tooth extraction
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
patient with history of Bisphosphonate therapy (orally or parenteral) in need of extraction of hopeless tooth
Exclusion criteria:
severe systemic problem which prevents tooth extraction and causes exclusion of patient from laser therapy and tooth extraction
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **1**
unrestorable teeth in patients of the study which should be extracted which can be more than one
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 Shahid Beheshti University of Medical Science
Street address
No.36, East Sonbol alley,South Golestan ave,Ferdos blvd, 2nd Sadeghiyeh SQ
City
Tehran
Province
Tehran
Postal code
1481754553
Approval date
2025-07-26, 1404/05/04
Ethics committee reference number
IR.SBMU.DRC.REC.1404.030

Health conditions studied

1

Description of health condition studied
Medication Related Osteonecrosis Of Jaws (MRONJ)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
soft tissue healing and wound closure over the extracted dental socket
Timepoint
Weekly clinical examination until complete healing of soft tissue
Method of measurement
Weekly clinical observation and examination and recording by camera photography

Secondary outcomes

1

Description
hard tissue healing in extracted dental socket
Timepoint
Radiographic examination 4 months after tooth extraction
Method of measurement
Panoramic or periapical radiographic examination

Intervention groups

1

Description
Intervention group: The target population of this study is divided into two groups:1- Patients who have been taking oral bisphosphonates (sodium Alendronate) for more than three years due to osteoporosis or who have used the injectable form of denosumab (Prolia or Xgeva) .2- Specific patients who are undergoing intravenous bisphosphonate (Zoledronic acid) or Denosumab treatment by an oncologist due to bone metastases or bone marrow cancer such as multiple myeloma even one single dose.These patients undergo a low-level laser protocol before and after extraction of non-retainable teeth, and the process of soft and hard tissue repair is

studied.A drug holiday of at least two months is also considered in patients. The patient will take oral antibiotic amoxicillin 500 mg every eight hours from three days before tooth extraction until soft tissue recovery. The patient will also use 0.2% chlorhexidine mouthwash for a period of time. At least two laser therapy sessions before extraction and then eight post-extraction laser therapy sessions continue in the dental socket in the laser department of faculty , as sessions twice a week. If the patient requires additional sessions, additional sessions can be continued until the soft tissue is fully recovered.The Diode laser available in the Faculty of Dentistry has a wavelength of 808 nm and a power of 0.4 watts (LAMBDA Scientifica Company under the trade name Doctor Smile) with a continuous radiation mode for 60 seconds from the buccal, lingual (palatal) and occlusal areas on the surface of the tooth or tooth socket in a non-contact manner. The photosensitizer methylene blue is used in this study to utilize photodynamic therapy to reduce bacterial load. The patient is visited by residents every week after laser therapy and photographs of the socket are taken to check the healing process, meaning the patient is followed up from one week after extraction to one month later. Then, a 4-month follow-up with appropriate radiographs is also performed to check for bone healing.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of oral and Maxillofacial surgery, college of Dentistry,Shahid Beheshti University

Full name of responsible person
Hoda Movafagh Moghadam

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No 36, East Sonbol Alley, South Golestan ave. Ferdos Blvd, 2nd Sadeghiyeh SQ

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Zarghi afshin

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hoda Movafagh Moghadam

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Position
Resident

Latest degree
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Person responsible for updating data

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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
The type of illness of the person and the history of the medication used, drug holiday , and photography of the extracted socket that show the healing process on a weekly basis until complete healing, can be published.

When the data will become available and for how long
Access begins 6 months after results are published.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
For better results and broader research in the field of MRONJ, anyone who has research on the prevention and treatment of this disease, which is a complication after tooth extraction in patients taking certain drugs such as bisphosphonates and denosumab, can request access to the data.

From where data/document is obtainable
Hoda Movafagh Moghadam Tehran, Oral and Maxillofacial Surgery Department, College of Dentistry, Shahid Beheshti University EMAIL: hoda. movafagh63@gmail.com

What processes are involved for a request to access data/document
This research is the subject of my thesis for my specialization course, a copy of which will be available at Shahid Beheshti Dental School after the defense. The applicant should first submit the request to me via email, and then coordination will be provided for access.

Comments