# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effect of combination of surgery, Low-Level Laser, vitamin E and Pentoxifylline on treatment of medication Related Osteonecrosis of Jaw

### Protocol summary

**Study aim**
Treatment of Medication-related osteonecrosis of the jaw

**Design**
This study is an interventional study with a comparison of patients before and after. Sampling was done through census and, based on the number of visits, it will include all patients who visit the Maxillofacial Surgery Clinic of Al-Zahra Educational and Medical Center during the study period.

**Settings and conduct**
This study is an interventional study with a comparison of patients before and after. Sampling was done through census and, based on the number of visits, it will include all patients who visit the Maxillofacial Surgery Clinic of Al-Zahra Educational and Medical Center during the study period.

**Participants/Inclusion and exclusion criteria**
inclusion criteria: Patients who are diagnosed with stage 1 and 2 drug-related osteonecrosis of the jaw based on their history and clinical symptoms (individuals who have not improved for more than 8 weeks after identification of exposed bone, have a history of taking bisphosphonates or similar drugs, and have not undergone radiotherapy). Have a history of bisphosphonate/denosumab use. The patient has not received surgical treatment to improve their lesion in the previous 6 months. exclusion criteria:Failure to visit regularly for treatment protocol The patient's malignancy is in an active stage Unwillingness to continue treatment Intolerance to medication Patients with stage 3 drug-induced osteonecrosis of the jaw based on history and clinical symptoms Death Stage III patients due to differences in type of surgery and treatment algorithm

**Intervention groups**
Patients undergo surgical intervention along with low-level laser and vitamin E and pentoxifylline supplementation.

**Main outcome variables**
Treatment of Medication-related osteonecrosis of the jaw

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20221108056446N11**
Registration date: **2025-01-02, 1403/10/13**
Registration timing: **prospective**

Last update: **2025-01-02, 1403/10/13**
Update count: **0**

**Registration date**
2025-01-02, 1403/10/13

**Registrant information**

**Name**
Mehdi Mahmoodkhani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 913 686 3733

**Email address**
mahmoodkhani@med.mui.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-01-20, 1403/11/01

**Expected recruitment end date**
2025-06-22, 1404/04/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Effect of combination of surgery, Low-Level Laser, vitamin E and Pentoxifylline on treatment of medication Related Osteonecrosis of Jaw

**Public title**
surgery, Low-Level Laser, vitamin E and Pentoxifylline on treatment of medication Related Osteonecrosis of Jaw
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients who are diagnosed with stage 1 and 2 drug-related osteonecrosis of the jaw based on their history and clinical symptoms (individuals who have not improved for more than 8 weeks after identification of exposed bone, have a history of taking bisphosphonates or similar drugs, and have not undergone radiotherapy). Have a history of bisphosphonate/denosumab use. The patient has not received surgical treatment to improve their lesion in the previous 6 months.
**Exclusion criteria:**
Failure to visit regularly for treatment protocol The patient's malignancy is in an active stage Unwillingness to continue treatment Intolerance to medication Patients with stage 3 drug-induced osteonecrosis of the jaw based on history and clinical symptoms Death Stage III patients due to differences in type of surgery and treatment algorithm
**Age**
No age limit
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **16**
**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 Isfahan University of Medical Sciences
**Street address**
Hazar Jarib Street, Azadi Square
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Approval date**
2024-10-14, 1403/07/23
**Ethics committee reference number**
IR.MUI.DHMT.REC.1403.125

## Health conditions studied

**1**

**Description of health condition studied**
medication related osteonecrosis of the jaw
**ICD-10 code**
M87.1
**ICD-10 code description**
Osteonecrosis due to drugs

## Primary outcomes

**1**

**Description**
Wound healing
**Timepoint**
Twice a week for three months after surgery
**Method of measurement**
Patient examination

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Antibiotics co-amoxiclav 625 mg three times a day and metronidazole 250 mg three times a day are prescribed from two days before surgery to 7 days after. Then low-level laser two sessions per week and a series of 8 sessions after surgery, chlorhexidine mouthwash 0.2% twice a day for two weeks after surgery, vitamin E 400 units twice a day for three months, pentoxifylline 400 mg twice a day for three months
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Al-zahra Hospital
**Full name of responsible person**
Bizhan Movahedian Atar
**Street address**
Al-Zahra Hospital, Safa Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675731
**Phone**
+98 913 267 1849
**Email**
Ghoraani_h@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Gholamreza Asgari
**Street address**
Hazar Jarib Street, Azadi Square
**City**
Isfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Phone**
+98 31 3668 0048
**Email**
mui@mui.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan University of Medical Sciences
**Proportion provided by this source**
1
**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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Bizhan Movahedian Atar
**Position**
Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Dentistry
**Street address**
Al-Zahra Hospital, Safa Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675731
**Phone**
+98 913 267 1849
**Email**
Ghoraani_h@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Bizhan Movahedian Atar
**Position**
Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Dentistry
**Street address**
Al-Zahra Hospital, Safa Street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675731
**Phone**
+98 913 267 1849
**Email**
Ghoraani_h@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Bizhan Movahedian Atar
**Position**
Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Dentistry
**Street address**

Al-Zahra Hospital, Safa Street

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8174675731

**Phone**

+98 913 267 1849

**Email**

Ghoraani_h@yahoo.com

## 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**

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

**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**

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

**Data Dictionary**

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