

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluating the complementary treatment effect of low-level laser versus ozone in patients with MRONJ (Medication-related osteonecrosis of the jaw) who were treated with debridement surgery and PRF (Platelet-rich fibrin)

Protocol summary

Study aim

Evaluating the complementary treatments of ozone therapy and PRF placement compared to laser therapy and PRF placement

Design

A clinical trial with a control group, with parallel groups, single-blinded, randomized, phase 3 on 30 patients. The outcome assessor will not be aware of the study groups. Block randomization will be done by the computer software "Random Allocation Software".

Settings and conduct

Oral and maxillofacial surgery department of Qaem hospital, Mashhad. The outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria

The inclusion criteria includes: 1. All patients with Medication-related osteonecrosis of the jaw, MRONJ stage 2, with pain and pus discharge 2. No history of previous MRONJ treatment 3. Absence of pathological fracture during study entry; The Exclusion criteria includes: 1. Pregnant patients 2. The impossibility of frequent visits for complementary treatment sessions (ozone or laser) 3. Radiotherapy during the treatment process 4. Occurrence of pathological fracture in the jaw in the affected area 5. Dissatisfaction with continuing the study.

Intervention groups

Control group: Patients receive the usual and standard debridement surgery along with PRF (Platelet-rich fibrin). Intervention group 1: In patients who have been treated with surgical debridement and PRF placement, in 10 sessions (3 days a week for 3 weeks and one session in the fourth week) will be subjected to ozone therapy with sedecal Ozone model serial number Ozt1077 made in Spain. Intervention group 2: In patients who have been treated with surgical debridement and PRF placement, in 10 sessions (2 days a week for 5 weeks) laser therapy is

performed with a THOR diode laser made in England and a power of 200 milliwatts.

Main outcome variables

Amount of jaw pain in the specified time period; Soft tissue healing; Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022697N13**

Registration date: **2023-03-05, 1401/12/14**

Registration timing: **prospective**

Last update: **2023-03-05, 1401/12/14**

Update count: **0**

Registration date

2023-03-05, 1401/12/14

Registrant information

Name

Sahand Samiee rad

Name of organization / entity

mashhad dental school,oral and maxillofacial department

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 7289

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the complementary treatment effect of low-level laser versus ozone in patients with MRONJ (Medication-related osteonecrosis of the jaw) who were treated with debridement surgery and PRF (Platelet-rich fibrin)

Public title

Evaluating the effect of low-level laser versus ozone in patients with Medication-related osteonecrosis of the jaw who were treated with debridement surgery and Platelet-rich fibrin

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with Medication-related osteonecrosis of the jaw, MRONJ stage 2, with pain and pus discharge No history of previous MRONJ treatment Absence of pathological fracture during study entry

Exclusion criteria:

Pregnant patients The impossibility of frequent visits for complementary treatment sessions (ozone or laser) Radiotherapy during the treatment process Occurrence of pathological fracture in the jaw in the affected area Dissatisfaction with continuing the study

AgeFrom **18 years** old to **80 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **30****Randomization (investigator's opinion)**

Randomized

Randomization description

Since the three groups are supposed to have the same sample size, the restricted randomization method and permuted block randomization will be used in this study. Random block units will usually be used to balance the number of samples assigned to each of the groups studied. The size of blocks will be selected randomly and there is an equal number of each group in each block. Creating a random sequence will be performed by computer software " Random Allocation Software". Random allocation concealment will be done using sequentially numbered, sealed, opaque envelopes by an

independent person who does not know the study process

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor will not be aware of the study groups. The assessor, the operator who delivers the checklist to the patient and completes the study checklist is not aware of the group assignment to prevent the complications.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Science

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Ghoreishi building, Daneshgah avenue

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Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2023-02-13, 1401/11/24

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1401.138

Health conditions studied**1****Description of health condition studied**

Osteonecrosis

ICD-10 code

M87.1

ICD-10 code description

Osteonecrosis due to drugs

2**Description of health condition studied**

Pain in jaw

ICD-10 code

K10.9

ICD-10 code description

Disease of jaws, unspecified

3

Description of health condition studied

Soft tissue dehiscence

ICD-10 code

M79.9

ICD-10 code description

Soft tissue disorder, unspecified

Primary outcomes

1

Description

Amount of jaw pain in the specified time period

Timepoint

1, 3, 6 and 12 months after the intervention

Method of measurement

Visual Analogue Scale (VAS) in checklist

2

Description

Soft tissue healing

Timepoint

1, 3, 6 and 12 months after the intervention

Method of measurement

Appropriate soft tissue healing was defined when no dehiscence occurred

Secondary outcomes

1

Description

Infection

Timepoint

1, 3, 6 and 12 months after the intervention

Method of measurement

Any sign of pus or fistula tract in treatment area

Intervention groups

1

Description

Control group: Patients receive the usual and standard debridement surgery along with PRF (Platelet-rich fibrin)

Category

Treatment - Surgery

2

Description

Intervention group 1: In patients who have been treated with surgical debridement and PRF placement, in 10 sessions (3 days a week for 3 weeks and one session in the fourth week), (each session 2 syringes of 10 cc with a concentration of 25% in the lesion site with minimum distance of 2 cm and maximum of 4 cm from each other) will be subjected to ozone therapy with sedecal Ozone model serial number Ozt1077 made in Spain

Category

Treatment - Drugs

3

Description

Intervention group 2: In patients who have been treated with surgical debridement and PRF placement, in 10 sessions (2 days a week for 5 weeks), (each session with a wavelength of 660 nm, 8 continuous points on the buccal surface and 8 continuous points on the lingual surface, each point will be irradiated for 15 seconds, then this process is repeated with a wavelength of 810 nm) laser therapy is performed with a THOR diode laser made in England and a power of 200 milliwatts

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and maxillofacial surgery department of Qaem hospital, Mashhad

Full name of responsible person

Sahand Samieerad

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Ahmadabad bouvar, Mashhad Qaem hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sahand Samieerad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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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

All collected data would be shared for all researchers after the participants were unidentified.

When the data will become available and for how long

The access to data will be started 6 months after publication.

To whom data/document is available

The data would only be available for people working in academic institutions.

Under which criteria data/document could be used

It is allowed to use the data for meta-analysis and systematic reviews.

From where data/document is obtainable

The data can be obtained via email, from the corresponding researcher (Dr Sahand Samieerad). E-mail: samieerads@mums.ac.ir

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

The new research proposal and the processes details should be e-mailed to corresponding researcher in order to get the access permission.

Comments