Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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samieerads@mums.ac.ir

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
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target 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
Street address
Ghoreishi building, Daneshghah avenue
City
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 boulvar, Mashhad Qaem hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 scientific inquiries

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Person responsible for updating data

Contact
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Resident
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Medical doctor
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Dentistry
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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