Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluate the effectiveness of ozone therapy on recuperation of patient suffering from Medication-related osteonecrosis of the jaw

Protocol summary

Study aim
Evaluation of the effect of ozone therapy on the recovery of patients with drug-induced jaw osteonecrosis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 0 on 28 patients. Sealed envelopes will be used for randomization.

Settings and conduct
The mentioned plan will be performed on 28 patients in Imam Reza and Ghaem hospitals in Mashhad. The mentioned plan is double-blind.

Participants/Inclusion and exclusion criteria
In this study, 20 patients who are in Stage up to 3 categories related to Medication-related osteonecrosis of the jaw according to the American Society of Oral and Maxillofacial Surgeons are included and randomly divided into two groups.

Intervention groups
fourteen patients randomly selected patients initially between 3 to 10 sessions depending on the stage of the disease or the patient's response to treatment (for 3 consecutive days per week for 3 weeks and one session in the fourth week) (2 syringes of 10 c per day C with a concentration of 25% at the lesion site with a distance of at least 2 cm and a maximum of 4 cm apart. The day after the last ozone treatment session, surgery is performed for the patient. All surgeries and injections are performed by the main executor of the project.

Main outcome variables
The rate of improvement of clinical symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201201049555N1**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **registered_while_recruiting**
Last update: **2020-12-06, 1399/09/16**
Update count: **0**

Registration date
2020-12-06, 1399/09/16

Registrant information

Name
Majid Eshghpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3841 3492

Email address
eshghpourm@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-13, 1398/08/22

Expected recruitment end date
2021-10-23, 1400/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluate the effectiveness of ozone therapy on recuperation of patient suffering from Medication-related osteonecrosis of the jaw

Public title
Evaluate the effectiveness of ozone therapy on recuperation of patient suffering from Medication-related osteonecrosis of the jaw

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Exposed bone or bone that can be probed through an intraoral or extraoral fistula that remains in the maxillofacial region for more than 8 weeks. No history of radiotherapy Possibility of frequent visits for ozone therapy sessions

Exclusion criteria:

Existence of pathological fractures while entering the study Pregnant patients Poor prognosis of cancer (with five-year SR less than 10%) Incidence of pathological fractures in the jaw in the affected area Perform radiotherapy during the treatment process

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. A random sequence is used after using the convenience sampling method. The questionnaire is filled for all referring people on different days of the week until completion the sample size. Then we name the groups A and B, then we put a questionnaire in group A and one in the group .

Blinding (investigator's opinion)

Double blinded

Blinding description

The statistical analyst and the Investigator is different from the surgeon and does not know how to treat (check the recovery rate and clinical symptoms) will be unaware of the intervention and control groups.

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 Sciences

Street address

Ghaem Hospital, Ahmad Abad AVE

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Approval date

2019-11-13, 1398/08/22

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.117

Health conditions studied

1

Description of health condition studied

Osteonecrosis

ICD-10 code

M87.1

ICD-10 code description

Osteonecrosis due to drugs

Primary outcomes

1

Description

Tenderness pain

Timepoint

After intervention

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ozone therapy with surgery for patients with drug-induced osteonecrosis of the jaw

Category

Treatment - Drugs

2

Description

Control group: Traditional debridement and surgery for patients with drug-induced jaw osteonecrosis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person
Majid Eshghpour
Street address
Ghaem Hospital, Ahmad Abad AVE
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3841 3492
Email
eshghpourm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Ghoreishi building, Daneshgah AVE
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3841 2081
Email
ramresearch@mums.ac.ir
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
Farnaz Dehabadi
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Ghaem Hospital, Ahmad Abad AVE
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3841 3492
Email
eshghpourm@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farnaz Dehabadi
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Ghaem Hospital, Ahmad Abad AVE
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3841 3492
Email
DehabadiF961@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farnaz Dehabadi
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Ear, Nose, and Throat
Street address
Ghaem Hospital, Ahmad Abad AVE
City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3841 3492

Email

DehabadiF961@mums.ac.ir

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

email

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

email

Under which criteria data/document could be used

researchers

From where data/document is obtainable

email

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

Sending files via email

Comments