Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Platelet-rich plasma and ozone gas injection in patients with temporomandibular joint disorders

Protocol summary

Study aim
Comparison of the effect of Platelet-rich plasma and ozone gas injection in patients with temporomandibular joint disorders

Design
double blinded randomized clinical trial with two intervention groups and 20 patients in each group. Random sequencing is done by simple random allocation method using random number table.

Settings and conduct
The study is performed in the Department of Oral and Maxillofacial Surgery, School of Dentistry, Shahid Sadoughi University of Medical Sciences, Yazd. In one group, the patients' own blood was taken and after centrifugation, the obtained PRP was mixed with 2% lidocaine and 3 cc of this solution was injected in 3 different places in each painful joint. In the other group, 3 ml of ozone gas with a concentration of 10 µg/ml (after anesthesia with 1 ml of lidocaine 2%), is injected in the upper space of the painful joint. Injections will be performed on days 0 and 14 for PRP group and days 0, 7 and 14 for ozone group and patients' follow-up will be performed on days 0, 14, 30, 60.

Participants/Inclusion and exclusion criteria
Patients with unilateral or bilateral temporomandibular joint disorders are included in the study. All of these patients have a history of at least 3 months of joint pain, or decreased mouth opening or joint clicking sound, and have undergone conservative treatment such as medication, occlusal splints, and physiotherapy but have not recovered. patients who do not cooperate for follow-up, have an hypersensitivity reaction or have problems during the injection such as excessive bleeding and swelling are excluded from the study.

Intervention groups
In one group, PRP taken from the patients' own blood is injected into the temporomandibular joint. In the other group, ozone gas is injected in the temporomandibular joint.

Main outcome variables
Pain, The amount of mouth opening and joint clicking on days 0, 14, 30 and 60

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210306050604N3**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date
2022-02-19, 1400/11/30

Registrant information

Name
Mohsen Barzegar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 8342

Email address
m.barzegar@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-03-20, 1400/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Platelet-rich plasma and ozone gas injection in patients with temporomandibular joint disorders

Public title

Comparison of the effect of Platelet-rich plasma and ozone gas injection in patients with temporomandibular joint disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A history of chronic temporomandibular joint pain and a clicking sound in one or both sides and decreased mouth opening that started at least 3 months ago and has not responded to conservative treatment No evidence of intra-articular pathological problems on open and closed-mouth dynamic MRI Do not have inflammatory connective tissue disease, neurological disorders, severe anemia, thrombocytopenia or malignant diseases of the head and neck Do not have masticatory muscles problems and muscle tenderness and a previous history of open surgery of tmj Do not have problems with dental origin in panoramic

Exclusion criteria:

Patients who do not agree with the injection protocol

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using Random allocation software version 1.0 under Windows, we generate a random sequence by simple random allocation method. In this table, we specify from one to 40 and each number is assigned to an intervention group (A or B). . The first qualified person is assigned number 1, the second person is assigned number 2 and so on up to 40 patient. In order to blind the random allocation of clients by a third person who is unaware of the interventions, they are placed in intervention groups (A or B) by this table. When the eligible patient presents, based on the patient's number, the intervention group is asked by telephone from a third person

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient does not see the type of injectable material. Also, the outcome assessor does not know the type of injected substance.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadouqi School of Yazd Dentistry

Street address

Dahe Fajr Ave, Shahid Sadouqi School of Dentistry of Yazd

City

Yazd

Province

Yazd

Postal code

8914881167

Approval date

2022-02-05, 1400/11/16

Ethics committee reference number

IR.SSU.REC.1400.003

Health conditions studied

1

Description of health condition studied

Temporomandibular joint disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient pain in temporomandibular joint

Timepoint

Days 0 (before the start of the study), 14, 30, 60

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Maximum mouth opening rate

Timepoint

Days 0 (before the start of the study), 14, 30, 60

Method of measurement

millimeter

3

Description
Joint clicking sound
Timepoint
Days 0 (before the start of the study), 14, 30, 60
Method of measurement
0: No sound- 1: Subjective sound / can be heard with a stethoscope- 2: A sound that can be heard without a stethoscope

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1: For each joint, 10 cc of blood is taken from the patient's antecubital vein and transferred to sterile test tubes (BD Company-made in USA) containing sodium citrate, and after transferring the tubes to the laboratory in the shortest possible time, Centrifuge for 1 minute at 1500 rpm and 50 Hz frequency (High speed Universal - PIT320), the amount of 1.5 cc of PRP obtained is mixed with 1.5 cc of 2% lidocaine. In each painful joint, 3 cc of this solution is injected in 3 different places. Injections are done in 2 stages on days 0 and 14
Category
Treatment - Drugs

2

Description
Intervention group: For the preparation of ozone gas, herrmann Medozon Germany ozone machine made in Germany is used. We place the injection syringe on the output of the ozone maker device to insert ozone gas into it. In this study, we used 3 ml of ozone gas with a concentration of 10 µg/ml (after anesthesia with 1 ml of lidocaine 2%), which is the injection site in the upper joint space. Ozone injection for the patient will be three times the injection on days 0, 7 and 14 and the patient will be evaluated on days 0, 14, 30, 60.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadouqi School of Dentistry of Yazd
Full name of responsible person
Mohsen Barzegar
Street address
Dahe Fajr Ave
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3621 3870
Email
m.eslami2060@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Maryam kazemipoor
Street address
Dahe Fajr Ave
City
YAZD
Province
Yazd
Postal code
8914881167
Phone
+98 35 3621 3870
Email
m.eslami2060@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mohsen Barzegar
Position
Assistant professor
Latest degree

Specialist
Other areas of specialty/work
Dentistry
Street address
Non121 bahar ave Javan blvd
City
Yazd
Province
Yazd
Postal code
8916698436
Phone
+98 35 3820 8342
Email
m.Barzegar@ssu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mohsen Barzegar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Non121 bahar ave Javan blvd
City
yazd
Province
Yazd
Postal code
8916698436
Phone
+98 35 3820 8342
Email
m.Barzegar@ssu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Mohsen Barzegar
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Non121 bahar ave Javan blvd
City
yazd
Province
Yazd
Postal code
8916698436
Phone
+98 35 3820 8342
Email
m.Barzegar@ssu.ac.ir

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