

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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)

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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

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

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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?

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

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Person responsible for updating data

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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