

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Comparison of the effect of PRP and Prolotherapy on symptom control in patients with temporomandibular joint disorders

#### Protocol summary

##### Study aim

Comparison of the effect of PRP and Prolotherapy on the control of symptoms in patients with temporomandibular joint disorders

##### Design

Not 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, 50% dextrose serum is mixed with 2% lidocaine and normal saline to obtain 12.5% dextrose. In each painful joint, 3 cc of this solution is injected in 3 different places. The injections will be done in 2 stages on days 0 and 14 and the follow-up of patients will be done on days 0, 14, 30, 60, 90.

##### 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 is injected into the temporomandibular joint from patients' own blood. In the other group, 12.5% serum dextrose is injected into the temporomandibular joint.

#### Main outcome variables

Pain, rate of mouth opening and joint clicking on days 0, 14, 30, 60, 90

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210306050604N2**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

##### Registration date

2021-11-16, 1400/08/25

##### 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

2021-10-23, 1400/08/01

##### Expected recruitment end date

2021-11-22, 1400/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of PRP and Prolotherapy on symptom control in patients with temporomandibular joint disorders

**Public title**  
Comparison of the effect of PRP and Prolotherapy on symptom control 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 be allergic to corn Do not have inflammatory connective tissue disease, neurological disorders, severe anemia, thrombocytopenia or malignant diseases of the head and neck Do not have masticatory muscle problems and muscle tenderness and a previous history of open joint surgery Do not have problems with dental origin in OPG  
**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**  
*No information*

**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 by a third person

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**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

2021-11-03, 1400/08/12

##### Ethics committee reference number

IR.SSU.REC.1400.158

## Health conditions studied

### 1

#### Description of health condition studied

Temporomandibular joint disorders

#### ICD-10 code

M26.6

#### ICD-10 code description

Temporomandibular joint disorders

## Primary outcomes

### 1

#### Description

Patient pain in temporomandibular joint

#### Timepoint

Days 0 (before the start of the study), 14, 30, 60, 90

#### 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, 90

#### Method of measurement

millimetre

### 3

#### **Description**

Joint clicking sound

#### **Timepoint**

Days 0 (before the start of the study), 14, 30, 60, 90

#### **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 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 1: 0.75 ml of 50% dextrose (Shahid Ghazi Pharmaceutical CompanyMade in Iran) with 1.5 ml of 2% lidocaine (provided by Caspian Pharmaceutical Company)- Made in Iran) and 0.75 ml of normal saline are mixed and thus dextrose with a concentration of 12.5% is obtained. In patients with dextrose group, we inject 3 ml of this solution in each joint in 3 separate areas (1 ml per area). Injections are done in 2 stages on days 0 and 14

##### **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**

amir.mtmd@yahoo.com

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Yazd University of Medical Sciences

###### **Full name of responsible person**

Maryam Kazemipor

###### **Street address**

Dahe Fajr Ave

###### **City**

Yazd

###### **Province**

Yazd

###### **Postal code**

8914881167

###### **Phone**

+98 35 3621 3870

###### **Email**

amir.mtmd@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **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

**Fax**

**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

**Fax**

**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

**Fax**

**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