

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of effect of PRP on temporomandibular disorder( TMD)

#### Protocol summary

##### Study aim

Evaluation of PRP (platelet rich plasma)effect on Temporomandibular disorders(TMD)

##### Design

Two arm parallel group randomised trial

##### Settings and conduct

All the patients referring to maxillofacial surgery department of Azad Dental School and Bouali Hospital with:pain,limitation in movement,goint sounds,deviation of mandible in mouth opening

##### Participants/Inclusion and exclusion criteria

nclusion criteria:PainLimitation in movement,Joint sounds,Deviation of mandible in mouth opening Exlusion criteria:Systemic deases,Patients candidated for temporomandibular joint(TMJ) surgery,Disk displacement without reduction

##### Intervention groups

PRP injection in one side(TMJ) and the other side as witness

##### Main outcome variables

Decrease in pain,Limitation in movement,Joint sounds,Deviation of mandible in mouth opening of patients despite effectivness of PRP injection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180503039510N1**

Registration date: **2018-05-29, 1397/03/08**

Registratation timing: **registered\_while\_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

##### Registration date

2018-05-29, 1397/03/08

##### Registrant information

##### Name

Mehdi Sezavar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3331 1107

##### Email address

m\_sezavar@dental.iau.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-01-01, 1395/10/12

##### Expected recruitment end date

2018-08-01, 1397/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of effect of PRP on temporomandibular disorder( TMD)

##### Public title

Evaluation of effect of PRP on TMD

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Pain Limitation in movement Joint sounds Deviation of mandible in mouth opening

##### Exclusion criteria:

Systemic deases Patient candidate for tmj surgery Disk displacement without reduction

##### Age

No age limit

##### Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 20

More than 1 sample in each individual

Number of samples in each individual: 2

Right and left temporomandibular joint( TMJ)

## Randomization (investigator's opinion)

Not randomized

## Randomization description

Choosing one tmj as witness and the other one as case

## 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 Azad Dental School

##### Street address

No.5 ,9 th Neyestan Alley, Pasdaran Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1913633151

#### Approval date

2016-05-15, 1395/02/26

#### Ethics committee reference number

IR.IAU.DENTAL.REC.1395,50

## Health conditions studied

### 1

#### Description of health condition studied

Temporomandibular disorder(TMD)

#### ICD-10 code

M26.6

#### ICD-10 code description

Temporomandibular joint disorders

## Primary outcomes

### 1

#### Description

Temporomandibular jointPain

## Timepoint

At the begining of study and 2,4 and 6 month later

## Method of measurement

Visual Analogue Scale questionarie

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: PRP injection in temporomandibular joint of one side in included patients(20 patients are being studie)6CC of patients blood will be transfused into sterile tubes coated with anti coagulant made by CHOUKRON company and centrifuged for3 minutes with1600 r/min,after formation of 3 layers in the tube ,the middle layer including platelet rich plasma or PRP is extracted,then a line is drwn joining the tragus to the lateral canthus(in the side to be injected),0.6 ml is injected in the point 10mm anterior to tragus (in the drawn line) and 2mm below,soft diet until one week is suggested to patient . index including pain,mouth opening,joint souds and jaw deviation in opening will be registered just at the time of injection and 2,4 and 6 months later and documented in related forms.

#### Category

Treatment - Other

### 2

#### Description

Control group: The temporomandibular joint in the side which has not been injected PRP,whitout any additional procedure, is considered as control group,and the indexes pain, limitation in joint movement,joint sound and deviation of mandible in opening at the begining of study and 2,4 and six months later the as intervention side is registered and finally compared with intervention group.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Maxillofacial department of Bouali Hospital

##### Full name of responsible person

Mehdi Sezavar

##### Street address

Bouali Hospital ,Damavand Ave

##### City

Tehran

##### Province

Tehran

**Postal code**  
1711734365  
**Phone**  
+98 21 3331 1107  
**Email**  
M\_sezavar@dental.iau.ac.ir

**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1913633151  
**Phone**  
+98 21 2256 4571  
**Email**  
M\_sezavar@dentaliau.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Farzin Sarkarat  
**Street address**  
No 5, 9th Neyestan Alley, Pasdaran Ave  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1913633151  
**Phone**  
+98 21 2256 4571  
**Email**  
M\_sezavar@dentaliau.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Islamic Azad University  
**Proportion provided by this source**  
1  
**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**  
Islamic Azad University  
**Full name of responsible person**  
Mehdi Sezavar  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
No 5, 9th Neyestan , Pasdaran Ave

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Mehdi Sezavar  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
No 5, 9th Neyestan Alley, Pasdaran Ave  
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Tehran  
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**Postal code**  
1913633151  
**Phone**  
+98 21 3331 1107  
**Email**  
M\_sezavar@dentaliau.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Mehdi Sezavar  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
No 5, 9th Neyestan Alley, Pasdaran Ave  
**City**  
Tehran  
**Province**  
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**Postal code**  
1913633151  
**Phone**  
+98 21 3331 1107  
**Email**

## 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