# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 refering 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**
Registration 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 commitee 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

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Islamic Azad University
**Full name of responsible person**
Farzin Sarkarat
**Street address**
No 5, 9thNeyestan 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, 9thNeyestan , Pasdaran Ave
**City**
Tehran
**Province**
Tehran
**Postal code**
1913633151
**Phone**
+98 21 2256 4571
**Email**
M_sezavar@dentaliau.ac.ir

## 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
**City**
Tehran
**Province**
Tehran
**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**
Tehran
**Postal code**
1913633151
**Phone**
+98 21 3331 1107
**Email**

M_sezavar@dentaliau.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