

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Assessing of the use of platelet-rich plasma (PRP) in improving function and healing in the treatment of mandibular condyle fractures by the closed reduction In traumatized patients

#### Protocol summary

##### Study aim

evaluation of PRP in improvement of function and haling in closed reduction of condylar fractures

##### Design

two arm parallel group randomised trial with double blinded on 64 pateints. randomization is performed with random allocation software

##### Settings and conduct

the patients with condylar fractures who referred to Imam Hossein or Vali-e-asr hospitals will divided in two groups. maximum mouth opening and laterusive movement of jaw is measured. Arch bar is placed in patients in both groups under general anesthesia. in study group, 10cc blood is taken from peripheral vein and centrifuged twice to extracted PRP. then, PRP is injected into the fracture area. MMF is performed in both groups. pain evaluate with visual analogue scale after surgery and immediately after MMF removal. maximum mouth opening and laterusive movement is measured immediately after MMF removal and 2 weeks after that in both groups. patients and evaluators do not have any information about injection or not injection of PRP.

##### Participants/Inclusion and exclusion criteria

patients who had condylar fractures in Imam Hosein and Vali-e- asr hospitals and underwent closed reduction, at least 18 years old, with repeatable and stable occlusion. patients should be have not any history of bone metabolism disorders or use of medications that affect on bone metabolism.

##### Intervention groups

in study group, after arch bar insertion, PRP is extracted from peripheral vein blood with centrifuge; and is injected into the fracture area

##### Main outcome variables

pain based on VAS, maximum mouth opening, laterusive movement of jaw

#### General information

##### Reason for update

##### Acronym

PRP

##### IRCT registration information

IRCT registration number: **IRCT20190429043413N2**

Registration date: **2023-08-29, 1402/06/07**

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

Last update: **2023-08-29, 1402/06/07**

Update count: **0**

##### Registration date

2023-08-29, 1402/06/07

##### Registrant information

##### Name

Pedram Bakhshaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2258 8141

##### Email address

bakhshaei.pedram@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-08, 1402/04/17

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Assessing of the use of platelet-rich plasma (PRP) in improving function and healing in the treatment of mandibular condyle fractures by the closed reduction In traumatized patients

**Public title**  
platelet-rich plasma (PRP) in mandibular condyle fractures

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
patients with at least 18 years old patients who need close reduction of condylar fractures stable and repeatable occlusion for maxillomandibular fixation(MMF) patients without any bone disorders like arthritis no history of bisphosphonate use  
**Exclusion criteria:**  
unstable occlusion for MMF condylar displacement into cranial fossa extracapsular displacement contraindication for MMF like seizure of intolerance of patients metabolic bone disorders or arthritis use of medications that affect on bone metabolism open reduction and internal fixation of fractures inability to follow up the patients growing patients history of jaw or condylar surgery

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **64**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
in this study, random allocation software was used for simple randomization. after allocation in 2 groups with 32 persons, concealed in sequentially numbered, sealed, opaque envelopes.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participants , after choose of one sealed envelopes, place on one of groups and because of doing procedure under general anesthesia, they don't have any information about PRP injection into the fracture site. Also, evaluators don't know what is the group of any patient and PRP injection. Data analyzer analysis data without any information about groups.

**Placebo**  
Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of directorate of health, rescue and treatment of police headquarter of Iran  
**Street address**  
Edward Brown st. ,North Kargar st. , Enghelab sq.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417944661  
**Approval date**  
2023-07-06, 1402/04/15  
**Ethics committee reference number**  
IR.SBMU.TEB.POLICE.REC.1402.013

## Health conditions studied

**1**

**Description of health condition studied**  
mandibular condyle fracture  
**ICD-10 code**  
S02.6  
**ICD-10 code description**  
Fracture of mandible

## Primary outcomes

**1**

**Description**  
pain assessment  
**Timepoint**  
the day after surgery, immediately after MMF removal  
**Method of measurement**  
based on visual analogue scale (VAS)

**2**

**Description**  
maximum mouth opening  
**Timepoint**  
before treatment, immediately after MMF removal, 2 weeks after MMF removal  
**Method of measurement**  
inter incisal distance in millimeters

### 3

#### **Description**

laterusive movement of jaw

#### **Timepoint**

before treatment, immediately after MMF removal, 2 weeks after MMF removal

#### **Method of measurement**

maxillary and mandibular dental midline displacement in laterusive movement in millimeters

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

Intervention group: in this group, PRP is injected into the fracture area. Patients in intervention group, underwent arch bar insertion under general anesthesia. then, 10cc venal blood is taken and PRP is extracted. About 2 cc of PRP is injected into the fracture area( palpitation of joint for detect the injection position). for 2-4 weeks, patients have MMF.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Control group: no intervention, just usual fracture treatment. Under general anesthesia, arch bar is inserted and then for 2-4 weeks patients have MMF

##### **Category**

N/A

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Imam Hossein Hospital

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

Pedram Bakhshaei

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

Madani st. , Imam ali exp.

###### **City**

Tehran

###### **Province**

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### 2

##### **Recruitment center**

###### **Name of recruitment center**

Vali-e-Asr hospital

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

Pedram Bakhshaei

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

opposite Zafar st. , Vali Asr st.

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tebbehdad@gmail.com

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

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

directorate of Health, Rescue and Treatment of Police  
Headquarter of Islamic Republic of Iran

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

Reza Mohammadi

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

opposite Zafar st. , Vali asr st.

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##### **Grant name**

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

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

Yes

##### **Title of funding source**

directorate of Health, Rescue and Treatment of Police  
Headquarter of Islamic Republic of Iran

##### **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**

Other

## Person responsible for general inquiries

bakhshaei.pedram@gmail.com

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Pedram Bakhshaei

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

oral & maxillofacial surgery

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Position**

assistant professor

**Latest degree**

Specialist

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## Person responsible for updating data

### Contact

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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