

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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)

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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

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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

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Madani st. , Imam ali exp.

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2

Recruitment center

Name of recruitment center

Vali-e-Asr hospital

Full name of responsible person

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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

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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

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Contact

Name of organization / entity
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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