Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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+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.
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Tehran
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1617763141
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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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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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Email
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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

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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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