

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of platelet-rich fibrin on neurosensory recovery of inferior alveolar nerve injury after mandibular body fracture

Protocol summary

Study aim

The effect of platelet-rich fibrin on neurosensory recovery of inferior alveolar nerve injury after mandibular body fracture

Design

Randomized Controlled clinical trial, two sided blinded on 13 patients. Randomization done by Excel application

Settings and conduct

The study was conducted on patients referring to the maxillofacial surgery ward in Taleghani and Imam Hossein hospitals. All patients will undergo CT-Scan imaging. An informed consent will be obtained from all patients. Demographic information of the patients will be recorded. Both patient and the examiner will be blind relative to the surgery. PRF will be derived from the patients' venous blood. During the reconstruction of the body fracture, the PRF will be put on the IAN of one side as the treatment group. But, the fixation on the other side will be performed without putting the PRF as the control group 6 and 12 months later, the patients will undergo the neurosensory evaluations.

Participants/Inclusion and exclusion criteria

Inclusion: The patients with bilateral mandibular body fracture with less than 5mm displacement, who are candidates for open reduction internal fixation (ORIF)

Exclusion: The patients with other types of fracture or those who are not a candidate for the ORIF treatment method, history of mandible genioplasty or orthognathic surgery, history of mandible trauma, history of mandibular fracture, apparent perioperative nerve injury, psychiatric medication, refusing to participate in the postoperative examinations, having systemic neuropathic diseases such as diabetes, and having no consent for participation in the study.

Intervention groups

PRF will be put on the IAN of one side as the treatment group. But, the fixation on the other side will be performed without putting the PRF as the control group

Main outcome variables

The two-point discrimination test, The brush directional stroke, Self-reported paresthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200922048799N2**

Registration date: **2022-01-10, 1400/10/20**

Registration timing: **prospective**

Last update: **2022-01-10, 1400/10/20**

Update count: **0**

Registration date

2022-01-10, 1400/10/20

Registrant information

Name

Hamidreza Moslemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-18, 1400/11/29

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of platelet-rich fibrin on neurosensory recovery of inferior alveolar nerve injury after mandibular body fracture

Public title

The effect of platelet-rich fibrin on neurosensory recovery of inferior alveolar nerve injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients with bilateral mandibular body fracture with less than 5mm displacement, who are candidates for open reduction-internal fixation (ORIF)

Exclusion criteria:

Patients with other types of fracture or those who are not a candidate for the ORIF treatment method History of mandible genioplasty or orthognathic surgery History of mandible trauma History of mandibular fracture Obvious perioperative nerve injury Psychiatric medication Refusing to participate in the postoperative examinations Having neuropathic systemic diseases such as diabetes Having no consent for participation in the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **13**

More than 1 sample in each individual

Number of samples in each individual: **2**

During the reconstruction of the body fracture, before the fixation of the fracture, the PRF will be put on the IAN of one side as the treatment group. But, the fixation on the other side will be performed without putting the PRF as the control group.

Randomization (investigator's opinion)

Randomized

Randomization description

During the reconstruction of the body fracture, before the fixation of the fracture, the PRF will be put on the IAN of one side as the treatment group. But, the fixation on the other side will be performed without putting the PRF as the control group. For this purpose, the right or left side will be selected randomly by a software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The neurosensory evaluations at three times including before the surgery (T0), 6 months after the surgery (T1), and 12 months after the surgery (T2) will be performed by an examiner who is unaware of the study groups and

surgical process

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Research institute of dental sciences Shahid beheshti university of me

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Shahid Beheshti School of Dentistry, Danshjoo BLVD, Velenjak, Shahid Chamran Highway

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Province

Tehran

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1983963113

Approval date

2021-12-13, 1400/09/22

Ethics committee reference number

IR.SBMU.DRC.REC.1400.095

Health conditions studied**1****Description of health condition studied**

Inferior Alveolar nerve neurosensory defect due to mandibular body fracture

ICD-10 code

S04.3

ICD-10 code description

Injury of trigeminal nerve

Primary outcomes**1****Description**

The two-point discrimination test (TPD)

Timepoint

before the surgery (T0), 6 months after the surgery (T1), and 12 months after the surgery (T2)

Method of measurement

the minimum distance of two discriminable points, which is created by a needle on the lower lip and the mental area.

2**Description**

The brush directional stroke discrimination test

Timepoint

before the surgery (T0), 6 months after the surgery (T1), and 12 months after the surgery (T2)

Method of measurement

performed by movement of a thin brush on the lower lip and the mental area and the patient must recognize the direction of the brush movement.

3

Description

Self reported paresthesia

Timepoint

before the surgery (T0), 6 months after the surgery (T1), and 12 months after the surgery (T2)

Method of measurement

using the visual analogue scale with a score range of (1-10) so that scores of (1 to 3), (4 to 6), and (7-10) are defined as mild, moderate, and severe, respectively.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before the fixation of the fracture, the PRF will be put on the IAN of one side as the treatment group.

Category

Treatment - Surgery

2

Description

Control group: The fixation of the fracture will be performed without putting the PRF

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Hamidreza Moslemi

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2

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Tehrani

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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

Shahid Beheshti University of Medical Sciences

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamidreza Moslemi

Position

DMD, Postgraduate student of Oral and Maxillofacial Surgery

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

all collected deidentified on demand

When the data will become available and for how long

Starting in April 2023

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

no more intervention or analysis allowed

From where data/document is obtainable

Email to Dr Hamidreza Moslemi hmoslemi71@gmail.com

What processes are involved for a request to access data/document

After the request was accepted by the authors, data will

be sent to them.

Comments