

# 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

+98 21 4044 3580

##### Email address

hmoslemi71@gmail.com

##### 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

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

##### **Street address**

Arabi St., Yemen St , Shahid Chamran Highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985711151

##### **Phone**

+98 21 2243 9982

##### **Email**

hmoslemi71@gmail.com

#### **2**

#### **Recruitment center**

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

Imam Hossein Hospital

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

Hamidreza Moslemi

##### **Street address**

Imam Hossein Hospital, Shahid Madani St.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1617763141

##### **Phone**

+98 21 7343 0000

##### **Email**

hmoslemi71@gmail.com

### **Sponsors / Funding sources**

#### **1**

#### **Sponsor**

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

Shahid Beheshti University of Medical Sciences

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

Azita Tehrani

##### **Street address**

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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1983963113

##### **Phone**

+98 21 2242 1814

##### **Email**

info@sbmu.ac.ir

#### **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

#### Street address

Department of Oral and Maxillofacial Surgery, Shahid Beheshti School of Dentistry, Danshjo BLVD, Velenjak, Shahid Chamran Highway

#### City

Tehran

#### Province

Tehran

#### Postal code

1983963113

#### Phone

+98 21 4044 3580

#### Fax

#### Email

hmoslemi71@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Reza Tabrizi

#### Position

Associate Professor in Department of Oral and Maxillofacial Surgery

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

#### Street address

Shahid Beheshti School of Dentistry, Danshjo BLVD, Velenjak, Shahid Chamran Highway, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1983963113

#### Phone

+98 21 4044 3580

#### Email

tabmed@gmail.com

## Person responsible for updating data

### 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

#### Street address

Department of Oral and Maxillofacial Surgery, Shahid Beheshti School of Dentistry, Danshjo BLVD, Velenjak, Shahid Chamran Highway

#### City

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#### Province

Tehran

#### Postal code

1983963113

#### Phone

+98 21 4044 3580

#### Fax

#### Email

hmoslemi71@gmail.com

## 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**