

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison Efficacy of platelet-rich fibrin membrane and melatonin on sensory recovery following mandibular fracture: a double-blind randomized trial

Protocol summary

Study aim

Determining and comparing the effect of platelet-rich fibrin membrane and melatonin on nerve recovery following mandibular fractures

Design

The clinical trial has a control group, with factorial groups, double-blind, randomized, phase 3 on 45 patients, and permutation blocks were used for randomization.

Settings and conduct

In group 1, after exposing the fracture area, in cases of involvement of the lower alveolar canal, PRF prepared from the patient's blood is placed inside the bone and on the canal, and then bone reduction and fixation are performed. In cases of exposure of the mental nerve, the fibrin membrane is placed directly on the nerve in the exit area of the foramen and is supported by an absorbable collagen membrane and absorbable suture. In group 2, 10 mg melatonin capsules were given to the patients the night before surgery and then one capsule every night until 21 days after surgery. Reduction and fixation of fracture lines will be done as in group 1. In group 3, reduction and fixation of fracture lines will be performed as the control group. In this study the examiner and the patient are blind to the type of intervention.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients with minimal displacement Fractures that require open mandibular fracture treatment Patients with no history of sensitivity to melatonin Non-entry conditions: Patients who have severed nerve fibers at the fracture site Patients who have soft tissue injuries in the lower lip and chin area.

Intervention groups

In group 1, patients are treated with platelet-rich fibrin membrane. In group 2, patients are treated with melatonin. In group 3 (control), reduction and fixation of

fracture lines will be performed.

Main outcome variables

Improving the para-esthesia of the lower lip and chin caused by mandibular fracture, using platelet-rich fibrin membrane or melatonin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230517058216N1**

Registration date: **2023-07-27, 1402/05/05**

Registration timing: **retrospective**

Last update: **2023-07-27, 1402/05/05**

Update count: **0**

Registration date

2023-07-27, 1402/05/05

Registrant information

Name

mohammad goodarzi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Efficacy of platelet-rich fibrin membrane and melatonin on sensory recovery following mandibular fracture: a double-blind randomized trial

Public title

Comparison Efficacy of platelet-rich fibrin membrane and melatonin on sensory recovery following mandibular fracture

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with no history of systemic diseases such as diabetes, kidney and liver problems Patients with no history of sensitivity to melatonin Patients who have informed consent to participate in the study Patients who have no history of previous mandibular surgery and nerve damage Patients with minimally displaced fractures that require open treatment of the mandible Patients with a level of GCS of 15, who are fully awake for examinations

Exclusion criteria:

Patients who have dissected nerve fibers at the fracture site Patients who have soft tissue injuries in the lower lip and chin area. Patients with mental retardation and psychotic disorders who do not cooperate for examinations Patients with blood and coagulation disorders

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **45****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be divided into three groups according to the permutation block randomization method. Based on the permutation blocks method, 5 blocks of 9 blocks are considered for randomizing the samples in three groups. The randomization method of permutation blocks is based on random blocks with the same size, and random allocation 1 software is used to create random blocks. Based on the output of the software, based on each block of size 9, a number from 1 to 9 that represents the block number is randomly selected and then according to the assigned groups in each block, randomization of the

samples in the order of entering The study is based on the specified intervention

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, and the examiner who performs the post-operative examinations and completes the checklist and the patient are blind to the type of intervention. For all patients, the study process, including how to prepare platelet-rich fibrin from the patient's blood sample in the first group, and the use of melatonin in the second group, are described. However, which group the patient will be placed in is determined during the sampling process and based on randomization.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Central Organization of Shahid Sadoughi University of Medical Sciences and Health Services, Shahid Bahonar square, Yazd

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Province

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8916978477

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.SSU.DENTISTRY.REC.1401.062

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

Lower lip and chin paresthesia due to mandibular fracture

ICD-10 code

R20

ICD-10 code description

Disturbances of skin sensation

Primary outcomes

1

Description

Improving the amount of lower lip paresthesia caused by mandibular fracture.

Timepoint

One week, one month and three months

Method of measurement

Two-point discrimination, brush direction detection and self-expression (Visual Analogue Scale) tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group 1, after exposing the fracture area, in cases of involvement of the lower alveolar canal, PRF prepared from the patient's blood is placed inside the bone and on the canal, and then bone reduction and fixation are performed by miniplates and mono-cortical screws. In cases of exposure of the mental nerve, the fibrin membrane is placed directly on the nerve in the exit area of the foramen and is supported by an absorbable collagen membrane and absorbable suture.

Category

Treatment - Drugs

2

Description

Intervention group: In group 2, 10 mg melatonin capsules (Galinos-Iran) were given to the patients the night before surgery and then one capsule every night until 21 days after surgery. Patients who undergo IMF after surgery dissolve the contents of the capsule in a glass of water and drink it. Reduction and fixation of fracture lines will be done as in group 1

Category

Treatment - Drugs

3

Description

Control group: In group 3, reduction and fixation of fracture lines will be performed as the control group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Maxillofacial Surgery Department, Shahid Rahnamoun Hospital

Full name of responsible person

Mohammad Goodarzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Yazd 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

Yazd University of Medical Sciences

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Mohammad Goodarzi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared transparently.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

All researchers and practitioners in related industry to the study title.

Under which criteria data/document could be used

Data use or analysis is permitted with the permission of the research investigators

From where data/document is obtainable

Mohammad Goodarzi E-mail
:m.goodarzi.omfs@gmail.com

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

By sending an email to the researcher, the documentation plan will be sent to them within a month.

Comments