Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 whit 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
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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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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
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Sponsors / Funding sources

1

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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

Full name of responsible person
Mohammad Goodarzi
Position
resident
Latest degree
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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