Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of placement of second miniplates as tension band unit in mandibular parasymphysis fractures

Protocol summary

Summary

In this study, the need for placing a second miniplate as a tension band in presence of lower arch bar is evaluated in mandibular parasymphysis fractures. 90 patients with mandibular parasymphysis fracture will be included in the study. They will be divided into two equal groups randomly. Arch bar will be placed for all patients. Then the first group will be treated with only one miniplate at the inferior border, but the second group will be treated with the same method and an additional miniplate will be placed 4 to 5 milimeters above the first miniplate. A follow-up after 6 months will be performed. The duration of surgery, incidences of occlusal discrepancy, infection, wound dehiscence, sensory changes and exposure of implants will be assessed. Then these parameters will be compared between the two group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052718946N6**
Registration date: **2017-06-17, 1396/03/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-17, 1396/03/27

Registrant information

Name
Reza Piri
Name of organization / entity
Emam Reza educational-medical center, Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of placement of second miniplates as tension band unit in mandibular parasymphysis fractures

Public title

Placement of second miniplates as tension band

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 65 years old; patients with mandibular parasymphysis fractures; filling written consent; patients with indication of surgical intervention.
Exclusion criteria: patients with accompanying fractures; patients with comorbidities.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Daneshgah street
City
Tabriz
Postal code
Approval date
2017-05-13, 1396/02/23
Ethics committee reference number
IR.TBZMED.REC.1396.96

Health conditions studied

1

Description of health condition studied
Fracture of mandible
ICD-10 code
S02.6
ICD-10 code description
Lower jaw (bone)

Primary outcomes

1

Description
Surgery duration
Timepoint
day 0
Method of measurement
Clock

2

Description
Occlusal discrepancy
Timepoint
Day 180
Method of measurement
Physical examination

3

Description
Wound infection
Timepoint
Day 180
Method of measurement
Physical examination

4

Description
Wound dehiscence
Timepoint
Day 180
Method of measurement
Physical examination

5

Description
Sensory changes
Timepoint
Day 180
Method of measurement
Physical examination

6

Description
Exposure of implants
Timepoint
Day 180
Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Control group: arch bar will be placed for all the patients and they wil be treated with only one miniplate at the inferior border of mandible.
Category
Treatment - Surgery

2

Description
Intervention group: Arch bar will be placed for all

patients and group is treated with a miniplate at the inferior border of mandible,then they will be treated with an additional miniplate placed 4 to 5 milimeters above the inferior miniplate.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry faculty of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Yousef Kananizadeh

Street address

Daneshgah street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Central campus of Tabriz University of Medical Sciences, Golgasht street, Azadi avenue. Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dentistry faculty of Tabriz university of medical sciences

Full name of responsible person

Dr. Yousef Kananizadeh

Position

Resident maxilofacial surgery

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

Dentistry faculty of Tabriz university of medical sciences

Full name of responsible person

Dr. Yousef Kananizadeh

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty