Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the three treatment methods, single miniplate, double miniplates and 3D miniplate for open reduction of mandibular angle fracture

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is to compare of the three treatment methods, single miniplate, double miniplates and 3D miniplate for open reduction of mandibular angle fracture. Total of sample size is 45 patients. The patients with infection before surgery, comminuted fracture and with immune deficiency will be excluded. The patients are randomly divided into three groups. The patients do not know about the protocol of the study and type of categories and evaluation of patients is performed by person who does not know about the protocol of the study. All the patients are under general anesthesia. First group is undergoing osteosynthesis by using single 2 mm miniplate with common champy technique. Second group isundergoing osteosynthesis by using two 2 mm miniplate. Third group is undergoing osteosynthesis by using single 3D miniplate. The amount of hemoglobin and hematocrit levels in patients is recorded before and after surgery in both groups by sampling blood. The amount of blood loss is calculated with subtracting preoperative and postoperative hemoglobin and hematocrit levels in blood. Patients do not use any medications before surgery. The temperature and the amount of body fluids can be controlled precisely by the anesthesiologist. Panoramic X-ray and facial CT scan will be recorded before and after surgery and six months after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052834186N1**
Registration date: **2017-06-15, 1396/03/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-06-15, 1396/03/25

Registrant information

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Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-03-06, 1394/12/16

Expected recruitment end date

2017-03-06, 1395/12/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the three treatment methods, single miniplate, double miniplates and 3D miniplate for open reduction of mandibular angle fracture

Public title

Comparison of three methods of treatment by using plate in the treatment of mandibular fracture

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Patients with unilateral or bilateral fracture of the mandible angle. Exclusion Criteria: infection before surgery; Patients with immunodeficiency; Patients with comminuted fracture; Dissatisfaction.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Ahvaz Jundishapur University Of Medical Sciences

Street address
Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City
Ahvaz

Postal code

Approval date
2016-03-05, 1394/12/15

Ethics committee reference number
IR.AJUMS.REC.1394.711

Health conditions studied

1

Description of health condition studied
Fracture of mandible

ICD-10 code
S02.6

ICD-10 code description
Fracture of mandible

Primary outcomes

1

Description
Bone healing and bone density analysis

Timepoint
Before and after the surgery and six months after surgery

Method of measurement
Panoramic radiography

2

Description
Pairing fracture fragments

Timepoint
Before and after the surgery and six months after surgery

Method of measurement
Facial CT scan

Secondary outcomes

1

Description
Palpability of the implants

Timepoint
Six months after surgery

Method of measurement
Questions from patient and touch the face

2

Description
Infection

Timepoint
Six months after surgery

Method of measurement
Observation and blood tests

Intervention groups

1

Description
Group I (control group): Osteosynthesis surgical of patients by using the single 2 mm miniplate with common champy technique.

Category
Treatment - Surgery

2

Description
Osteosynthesis surgical of patients by using the two 2

mm miniplate.

Category

Treatment - Surgery

3

Description

Group III (intervention group): Osteosynthesis surgical of patients by using the single 3D miniplate.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Shahryar Shabaninia

Street address

Khomeini Hospital, ShahidAhwazian St., Ahwaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

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Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

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 Of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Shahryar Shabaninia

Position

Resident of oral and Maxillofacial Surgery

Other areas of specialty/work

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Sanaz Nazari

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Postal code

Phone

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Fax

Email

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