Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between two close reduction techniques for treatment of mandibular subcondylar fracture: elastic versus intermaxillary wire fixation

Protocol summary

Summary

This study will be done as a randomized prospective trial with a six months follow-up. The Inclusion criterion is Mandibular subcondyle fracture. Patients with infection before surgery, crashed fractures, patients with indication of open reduction and patients with Immunodeficiency will be excluded from the study. In total, 34 patients over 12 years, with sub-mandibular condyle fracture will be enrolled in the study and randomly will be classified to two groups of 17 participants. Patients in group A will be treated with archbar and intermaxillary fixation using wire and group B, will be treated with archbar and elastic method. The duration of treatment is 6 weeks. Intravenous antibiotics (cephazolin injection 1000 mg/stat and dexamethasone 8mg/stat) will be administered 30 min before surgery; and after surgery patients will receive cephazoline 4 times a day, for 3 days. After that, antibiotic (Amoxicillin 250 mg, 3 times a day) Plus Chlorhexidine mouthwash will be used for a week. General anesthesia will be done using intubation or local anesthesia. Then, the archbar for maxillary and mandibular, will be closed. After displacement of mandible and obtaining the proper occlusion, in group A, intermaxillary fixation is by wire; and in group B, Instead of fixing the jaw by wire, we will use elastic. Three-dimensional panoramic radiography and CT scan will be done before the surgery and also 6 months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020732448N1**
Registration date: **2017-04-14, 1396/01/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

Behnam Zinhaghayegh

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences.

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 7543

Email address

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University Of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between two close reduction techniques for treatment of mandibular subcondylar fracture: elastic versus intermaxillary wire fixation

Public title

Comparison between two close reduction techniques for

treatment of mandibular subcondylar fracture: elastic versus intermaxillary wire fixation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: The Inclusion criterion is Mandibular subcondyle fracture. Exclusion criteria: Patients with infection before surgery; crashed fracture; fracture in the other site of mandible; fracture in the maxilla and in the midface region; the patients with indication of open reduction and Immunodeficiency; or the patients who are not willing to be followed up and return.

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Street address

Ahvaz Jundishapur University Of Medical Sciences, Golestan Ave.

City

Ahvaz

Postal code

Approval date

2015-06-23, 1394/04/02

Ethics committee reference number

IR.AJUMS.REC.1394.712

Health conditions studied

1

Description of health condition studied

Mandibular subcondyle fracture

ICD-10 code

S02.8

ICD-10 code description

Fractures of other skull and facial bones

Primary outcomes

1

Description

Mandibular subcondyle fracture

Timepoint

3 months and 6 months after intervention

Method of measurement

categorical

Secondary outcomes

1

Description

Vertical height of Ramos

Timepoint

3 and 6 months after the intervention

Method of measurement

Panoramic CT scan

2

Description

Deviation of the jaw,when opening the mouth

Timepoint

3 and 6 months after the intervention

Method of measurement

Ruler in millimeters

3

Description

Infection

Timepoint

3 and 6 months after the intervention

Method of measurement

Observation

4

Description

Facial symmetry

Timepoint

3 and 6 months after the intervention

Method of measurement

Ruler in millimeters

5

Description

Amount of mouth opening

Timepoint

3 and 6 months after the intervention

Method of measurement

Ruler in millimeters

6

Description

Visual Analogue Scale

Timepoint

3 and 6 months after the intervention

Method of measurement

pain

Intervention groups

1

Description

control group: Patients in the control group will be treated with archbar and intermaxillary fixation using wire . Intravenous antibiotics (cephazolin injection 1000 mg/stat and dexamethasone 8mg/stat) will be administered 30 min before surgery and after surgery patients will be received cephazoline 4 times a day, for 3 days. After that, antibiotic (Amoxicillin 250 mg, 3 times a day) Plus Chlorhexidine mouthwash will be used for a week.General anesthesia will be done using intubation or local anesthesia then, the arch bar for maxillary and mandibular will be closed.

Category

Treatment - Other

2

Description

Intervention group: Patients in the Intervention group, will be treated with archbar and elastic method. Intravenous antibiotics (cephazolin injection 1000 mg/stat and dexamethasone 8mg/stat) will be administered 30 min before surgery and after surgery, patients will be received cephazoline 4 times a day, for 3 days. After that, antibiotic (Amoxicillin 250 mg, 3 times a day) Plus Chlorhexidine mouthwash will be used for a week.General anesthesia will be done using intubation or local anesthesia then, the arch bar for maxillary and mandibular arch bar will be closed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr.Behnam Zinhaghayegh

Street address

Imam Khomeini Hospital, Sharifzadeh st. Azadegan Ave.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Full name of responsible person

Dr. Makhmal Zadeh

Street address

Ahvaz Jundishapur University Of Medical Sciences, Golestan Ave.

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

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, Ahvaz, Iran

Full name of responsible person

Pardis V akili

Position

Nutritionist

Other areas of specialty/work

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Person responsible for updating data

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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