

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison between rigid intermaxillary fixation and using guiding elastic therapy of nonsurgical treatment in mandibular subcondylar fractures

Protocol summary

Study aim

Aim was comparison between rigid intermaxillary fixation and using guiding elastic therapy of nonsurgical treatment in mandibular subcondylar fractures.

Design

This evaluation is a clinical trial in phase 3, patients who were diagnosed with mandibular sub condylar fracture and approved by a specialist, were considered as a study group, in this study, 110 patients who met the inclusion criteria were selected. Patients were nonrandomly assigned to two groups, 55 patients in the intervention group and 55 patients in the control group. Based on this, immediately, 1 week, 1 month, 6 months and 1 year after treatment, the patients' condition was evaluated based on their signs and symptoms.

Settings and conduct

This study was performed as a clinical trial of Shahid Bahonar Hospital, also the study was unblinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria included as mandibular sub condylar fracture and satisfaction to participate in the study, and exclusion criteria included as pre-surgical infection.

Intervention groups

In first group fracture was treated with MMF method, which does not require opening or direct manipulation of the fracture site, and in second group patients were treated non-surgically with two methods of hard intermaxillary fixation and guiding elastic therapy.

Main outcome variables

Variables included as malocclusion, decreased mandibular movements, facial asymmetry, mandibular deviation, ankylosis, and pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200904048617N1**

Registration date: **2020-10-16, 1399/07/25**

Registration timing: **retrospective**

Last update: **2020-10-16, 1399/07/25**

Update count: **0**

Registration date

2020-10-16, 1399/07/25

Registrant information

Name

ahmad ahrari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3760 4752

Email address

koshk8@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-10, 1398/08/19

Expected recruitment end date

2020-07-09, 1399/04/19

Actual recruitment start date

2019-11-10, 1398/08/19

Actual recruitment end date

2020-07-09, 1399/04/19

Trial completion date

2020-07-09, 1399/04/19

Scientific title

Comparison between rigid intermaxillary fixation and using guiding elastic therapy of nonsurgical treatment in

mandibular subcondylar fractures

Public title

Comparison of treatment methods in patients with mandibular subcondylar fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mandibular subcondylar fracture Satisfaction to participate in the study

Exclusion criteria:

Pre-surgical infection

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **110**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Kerman University of Medical Sciences

Street address

7613747181, Qaraney St, Kerman, Kerman Province

City

Kerman

Province

Kerman

Postal code

7613747181

Approval date

2020-08-03, 1399/05/13

Ethics committee reference number

IR.KMU.REC.1399.300

Health conditions studied

1

Description of health condition studied

Mandibular subcondylar fracture

ICD-10 code

S02.8

ICD-10 code description

Fractures of other specified skull and facial bones

Primary outcomes

1

Description

Malocclusion

Timepoint

Immediately, 1 week, 1 month, 6 months and 1 year after treatment

Method of measurement

Clinical observation and examination

2

Description

Reduction of mandibular movements

Timepoint

Immediately, 1 week, 1 month, 6 months and 1 year after treatment

Method of measurement

Clinical observation and examination

3

Description

Facial asymmetry

Timepoint

Immediately, 1 week, 1 month, 6 months and 1 year after treatment

Method of measurement

Clinical observation and examination

4

Description

Mandibular deviation

Timepoint

Immediately, 1 week, 1 month, 6 months and 1 year after treatment

Method of measurement

Clinical observation and examination

5

Description

Ankylosis

Timepoint

Immediately, 1 week, 1 month, 6 months and 1 year after treatment

Method of measurement

Clinical observation and examination

6

Description

Pain

Timepoint

Immediately, 1 week, 1 month, 6 months and 1 year after treatment

Method of measurement

Question from the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The fracture was treated with MMF method, which does not require opening or direct manipulation of the fracture site.

Category

Treatment - Surgery

2

Description

Intervention group: Patients were treated non-surgically with two methods of hard intermaxillary fixation and guiding elastic therapy.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital

Full name of responsible person

Saeed Haj Mohammadi

Street address

7613747181, Qaraney St, Kerman, Kerman Province

City

کرمان

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

hajmohamadisaeed@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

7613747181, Qaraney St, Kerman, Kerman Province

City

kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3226 3855

Email

abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Saeed Haj Mohammadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

Street address

7613747181, Qaraney St, Kerman, Kerman Province

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

hajmohamadisaeed@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Saeed Haj Mohammadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

Street address

7613747181, Qaraney St, Kerman, Kerman Province

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

hajmohamadisaeed@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Saeed Haj Mohammadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

Street address

7613747181, Qaraney St, Kerman, Kerman Province

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

hajmohamadisaeed@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available