

# 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

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Kerman

##### Province

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##### 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

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## Person responsible for updating data

### Contact

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Kerman University of Medical Sciences

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## 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