

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Clinical Trial to Comparison of Fracture Healing between Closed Reduction Surgery Alone and in Combination with Pulsed Magnetic Filed in Patients with Mandibular Fracture

#### Protocol summary

##### Summary

**Objectives:** Considering the role of pulsed electromagnetic field on repair of Non-Union bones, the plan is designed to investigate the effect of pulsed electromagnetic field on mandibular fracture healing.

**Design:** The project will be implemented by way of clinical trial. Cases will be selected among the patients referred to Taleghani Hospital for treatment of mandibular fracture with close reduction method.

**Design:** In this randomized clinical trial study, of those who did undergo closed reduction in Taleghani hospital, 32 patients were selected sequentially and were divided in 2 different groups (control=16, treatment=16) randomly with flip the coin method.

**Setting & Conduct:** After Operation The fracture sites of group T expose to pulsed electromagnetic fields (PEMF) for 6 hours immediately. Then repeat this procedure on the 7th day for 3 hours and on the 14th day for 1.5 hours. In Treatment group, the MMF will be removed at fourth weeks after surgery and in control group at sixth weeks. The effectiveness of the treatment modalities evaluate clinically and radiographically using computerized densitometry by direct digital panoramic machine.

**Inclusion/exclusion criteria:** Inclusion criteria included the mandible fracture in dental region; existence of enough dental contacts in both sides of fracture line; absence of signs of infection in fracture region; lack of systemic diseases affecting favorable stages of bone regeneration.

**Intervention:** Exposer to pulsed electromagnetic fields (PEMF) Main outcomes measures: Changes in bone mineral density, The post-operative pain, The maximum amount of open mouth, Sensory changes.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2016022526769N1**

Registration date: **2016-12-17, 1395/09/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-17, 1395/09/27

##### Registrant information

###### Name

Hassan Mohajerani

###### Name of organization / entity

Dental school, Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2225 9203

###### Email address

mohajerani@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2012-03-20, 1391/01/01

##### Expected recruitment end date

2013-03-21, 1392/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Clinical Trial to Comparison of Fracture Healing between Closed Reduction Surgery Alone and in Combination with Pulsed Magnetic Filed in Patients with Mandibular Fracture

## Public title

Clinical Trial to Comparison of Fracture Healing between Closed Reduction Surgery Alone and in Combination with Pulsed Magnetic Filed in Patients with Mandibular Fracture

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria included the consent of participating in study, mandible fracture in dental region, existence of enough dental contacts in both sides of fracture line that possibility of application of arch bar and maxillary mandibular fixation (MMF) establishment exists, absence of signs of infection in fracture region, lack of systemic diseases affecting favorable stages of bone regeneration, treatment indications of closed reduction. Exclusion criteria included lack of consent of participating in study and contraindications of closed reduction treatment

## Age

No age limit

## Gender

Both

## Phase

1-2

## Groups that have been masked

No information

## Sample size

Target sample size: 32

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

Randomized with Flip the Coin Method.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Ethics Committee, Shahid Beheshti University of Medical Sciences, Daneshjoo Sq., Evin st., Tehran-

Iran.

#### City

Tehran

#### Postal code

۱۹۸۳۹۶۳۱۱۳

#### Approval date

2016-07-02, 1395/04/12

#### Ethics committee reference number

ir.sbmurids.rec.1395.212

## Health conditions studied

### 1

#### Description of health condition studied

Mandible fx

#### ICD-10 code

S02.6

#### ICD-10 code description

Lower jaw (bone)

## Primary outcomes

### 1

#### Description

Changes in bone mineral density

#### Timepoint

Before Operation, 2 weeks & 4 weeks later

#### Method of measurement

Radio densitometry

### 2

#### Description

The post-operative pain

#### Timepoint

Operation Day, One day later & one week & two weeks later

#### Method of measurement

Visual Analog Scale (VAS)

### 3

#### Description

The maximum amount of open mouth

#### Timepoint

End of treatment

#### Method of measurement

Caliper Vernier

### 4

#### Description

Sensory changes

#### Timepoint

Prior to operation, a month later, two months later

#### Method of measurement

Patient verbal affirmation of abnormal lip sensation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, fracture sites expose to pulsed electromagnetic fields (PEMF) for 6 hours immediately after surgery. Then, this procedure will repeat on the 7th day for 3 hours and on the 14th day for 1.5 hours. The MMF (mandibular fixation) will be removed at fourth weeks after surgery.

#### Category

Other

### 2

#### Description

Control group: Only treatment of Mandibular fracture with closed reduction method. The MMF will be removed at sixth weeks.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital, Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Hassan Mohajerani

##### Street address

Taleghani Hospital, Arabi Ave, Yaman St., Chamran Highway, Tehran-Iran.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research of Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Hassan Mohajerani

##### Street address

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences, Daneshjoo Sq., Evin st., Tehran-Iran.

##### City

Tehran

#### 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 Shahid Beheshti 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

Dental School, Shahid Beheshti University of Medical Sciences.

##### Full name of responsible person

Dr. Hassan Mohajerani

##### Position

Associate prof.

##### Other areas of specialty/work

##### Street address

Dental School, Shahid Beheshti University of Medical Sciences, Daneshjoo Sq., Evin st., Tehran-Iran.

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##### Phone

+98 21 2222 8511

##### Fax

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Mohajeranih@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Dental School, Shahid Beheshti University of Medical Sciences

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Dr. Hassan Mohajerani

**Position**

Associate Prof.

**Other areas of specialty/work**

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**City**

Tehran

**Postal code**

## 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*