

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Email address

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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

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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