Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
Randomizated with Flip the Coin Method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ettichs Committe of Shahid Beheshti University of Medical Sciences

Street address
Ettichs Committe, 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.sbmu.rids.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
Befor 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 Vrnyr

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.
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Dr. Hassan Mohajerani
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Person responsible for updating data

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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