

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The efficacy of pulsed electromagnetic waves on the healing time of mandibular bone fracture

Protocol summary

Summary

The aim of this study was to assess the effects of pulsed electromagnetic field on healing time after mandibular bone fracture reduction. Totally, 20 patients were recruited according to inclusion and exclusion criteria from patients attending operating room of Imam Khomeini Hospital with mandibular fracture. The random sampling was used. Patients were randomly assigned into intervention group to receive the pulsed electromagnetic field therapy and control group with ratio of 1:1. The patients in intervention group, firstly underwent local anesthesia, then the arch bars of maxilla and mandible are closed, mandible bone fracture was reduced using closed reduction, after establishing primary occlusion the strong elastics (3/16 inch- 6/5 oz) were applied and then IMF (intermaxillary fixation) was performed in an appropriate occlusion. Pulsed electromagnetic field was administered for 10 min/day for 10 days after reduction. The same procedures were performed for control group, except they did not received pulsed electromagnetic therapy after reduction. The effectiveness assessment of pulsed electromagnetic field therapy was performed by the bone density measurement using Hounsfield of the CT (computed tomography) scans of head and face at 10th and 40th day after the reduction for both intervention and control groups. All study patients were checked for tooth abscess and tooth infection. In addition, patients were followed-up 8 weeks after IMF extraction to evaluate tooth occlusion after surgery, MAO (maximum anterior opening), pain, bone union and infection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062428608N1**

Registration date: **2016-07-17, 1395/04/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-17, 1395/04/27

Registrant information

Name

Ershad Hemmati

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3221 6104

Email address

hemmati.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of pulsed electromagnetic waves on the healing time of mandibular bone fracture

Public title

Effect of electromagnetic on reducing healing time in jaw fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: minimum age of 14 for women and 16 for men; Non-displaced and mandibular with closed reduction possibility; malocclusion of teeth due to fracture; and resident of Ahvaz. Exclusion criteria: maxillary and mid-face bones fractures; Fractures with indication of ORIF (Open reduction inter maxillary fixation); Infected teeth in the site of fracture; epilepsy; seizure; and pregnancy.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences
Ahvaz, Golestan Boulevard, Ahvaz

City

Ahvaz

Postal code

Approval date

2016-02-13, 1394/11/24

Ethics committee reference number

IR.AJUMS.REC.1395.189

Health conditions studied

1

Description of health condition studied

Mandibular bone fracture

ICD-10 code

S02.6

ICD-10 code description

Fracture of mandible

Primary outcomes

1

Description

Healing time

Timepoint

At 10 and 40 days after surgery

Method of measurement

Bone density by CT scans of head and face

Secondary outcomes

1

Description

Pain

Timepoint

at 10 and 40 days after closed reduction

Method of measurement

Visual analogue scale (VAS)

Intervention groups

1

Description

Intervention group: The patients in intervention group, firstly underwent local anesthesia, then the arch bars of maxilla and mandible are closed, mandible bone fracture was reduced using closed reduction, after establishing primary occlusion the strong elastics (3/16 inch- 6/5 oz) were applied and then IMF (intermaxillary fixation) was performed in an appropriate occlusion. Pulsed electromagnetic field was administered for 10 min/day for 10 days after reduction.

Category

Treatment - Devices

2

Description

Control group: The patients in control group, firstly underwent local anesthesia, then the arch bars of maxilla and mandible are closed, mandible bone fracture was reduced using closed reduction, after establishing primary occlusion the strong elastics (3/16 inch- 6/5 oz) were applied and then IMF (intermaxillary fixation) was performed in an appropriate occlusion. No pulsed electromagnetic field was administered for the control group after reduction.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Maxillofacial Operating Room of Imam Khomeini Hospital

Full name of responsible person

Ershad Hemmati

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Behzad Sharif Makhmalzadeh

Street address

Golestan Boulevared

City

Ahvaz

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 Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Zeinab Shajirat

Position

Master of Sciences

Other areas of specialty/work

Street address

Fourth floor, Imam Khomeini Hospital, Azadegan Boulevard, Research Deputy of Imam Khomeini Hospital Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 3221 6504

Fax

Email

zeinab.shajirat@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Ershad Hemmati

Position

Resident of oral and maxillofacial surgery

Other areas of specialty/work

Street address

Maxillofacial operating room, Imam Khomeini Hospital, Azadegan Boulevard, Research Deputy of Imam Khomeini Hospital

City

Ahvaz

Postal code

Phone

+98 61 3221 6504

Fax

Email

hemmati1984@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Zeinab Shajirat

Position

Master of Science (MSc)

Other areas of specialty/work

Street address

Fourth floor, Research Deputy, Imam Khomeini Hospital, Azadegan Boulevard Ahvaz Ahvaz

City

Ahvaz

Postal code

6193673166

Phone

+98 61 3221 6504

Fax

Email

zeinab.shajirat@gmail.com

Web page address

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