

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigating the Therapeutic Effects of Pulsed Electromagnetic Fields on Bone healing period in patients with fresh tibia fracture

Protocol summary

Summary

This study aims to investigate the therapeutic effects of electromagnetic fields (EMFs) on the healing period of fresh Tibia fracture. Inclusion criteria are male or female patients (15 to 65 years old) with fresh tibia fracture, with no concurrent application of physical exercise or physiotherapy. Exclusion criteria are presence of cardiovascular diseases, pace-maker, osteoporosis induced fracture, use of opioid drugs and addiction treatment medications, abnormal orthopedic and musculoskeletal conditions. Forty patients are randomly divided into three groups (each 15 cases): one control group and two intervention groups. The intervention group 1 receives daily low frequency pulsed EMFs (20 Hz, 4 mT, 20 min) for 5 consecutive days per week and 4 consecutive weeks. Group 2 receives Calcium ion cyclotron resonance exposure (76.6 Hz, 0.1 mT, 20 min) for 5 consecutive days per week and 4 consecutive weeks. The patients receive interventions within 4 days after fixation surgery. The primary outcome is fracture healing period, defined as forming 3 cortices in the radiographic image. The secondary outcome is bone mineral density in the tibial bone which is measured by dual energy X-ray technique.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042324635N3**

Registration date: **2016-11-22, 1395/09/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-22, 1395/09/02

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2016-05-01, 1395/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Therapeutic Effects of Pulsed Electromagnetic Fields on Bone healing period in patients with fresh tibia fracture

Public title

Therapeutic Effects of Pulsed Electromagnetic Fields on Healing Period of Bone Fracture:

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: fresh fracture of tibia; no use of medications; no use of physical exercise and

physiotherapy. Exclusion criteria: cardiovascular diseases, patients with pace-maker, fracture because of osteoporosis, Opioids and addiction treatment medications, abnormal orthopedic; and musculoskeletal conditions.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Physics department, Scholl of Medicine,
Ahvaz Jundishapur University of Medical Physics, Ahv

Street address

Golestan Blv., Research deputy , Ahvaz Jundishapur
University Of Medical Sciences

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Postal code

6135715794

Approval date

2015-10-10, 1394/07/18

Ethics committee reference number

IR.AJUMS.REC.1394.718

Health conditions studied

1

Description of health condition studied

fresh tibia fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes

1

Description

Fracture healing period

Timepoint

30 and 45 days after start of intervention

Method of measurement

Using X-ray radiography- formation of 3 cortices

Secondary outcomes

1

Description

bone mineral density

Timepoint

pre and post intervansion

Method of measurement

dual energy X-ray (Dexa)

Intervention groups

1

Description

In the control group, patients are matched by gender and age with the intervention groups and do not receive stimulation.

Category

Treatment - Devices

2

Description

Group 1 intervention: patients receive low frequency pulsed electromagnetic fields (25 Hz, 4 mT, daily 20 min, 5 consecutive days per week, 4 consecutive weeks).

Category

Treatment - Devices

3

Description

Group 2 intervention: Patients receive Calcium ion cyclotron resonance exposure (76.6 Hz, 0.1 mT, 20 min daily, for 5 consecutive days per week and 4 consecutive weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Bioelectromagnetic Clinic, Ahvaz Imam Khomeini
Hospital

Full name of responsible person

Samaneh Rashidi

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Grant name**Grant code / Reference number**

B-9475

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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**

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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