

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Effect of magnetic field therapy on pain and function in individuals with grade II lateral ankle sprain, a randomized clinical trial

Protocol summary

Study aim

Evaluating the effect of magnetic field therapy on pain and function in individuals with grade II ankle sprain

Design

A randomized, double-blinded, sham controlled clinical trial on 50 patients. Randomization will be performed using an online block randomization tool (www.sealedenvelope.com).

Settings and conduct

The study population includes patients with grade 2 ankle sprains who refer to Shohadaye Tajrish Hospital, Tehran. Patients are then randomly divided into two groups, sham and intervention. Both groups receive standard treatment including RICE (Rest, Ice, Compression and Elevation) for 10 days, followed by standard physiotherapy program. Standard physiotherapy program includes Diathermy with Ultrasound (US) and Transcutaneous Electrical Nerve Stimulation (TENS), for 10 sessions, performed every other day. Diathermy was performed with a therapeutic US device for 10 min to the relevant ankle at a dose of 1 W/cm². The TENS device with two electrodes surrounding tendon was performed for 30 min at a frequency of 100 Hz for current application. Intervention group concurrently receives magnet therapy for 10 sessions, performed every other day. Magnetic field is applied to relevant ankle with the PEMF device for 25 min at 25 G intensity at a frequency of 50 Hz. The device is set to 0 when applying to patients in sham group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with lateral ankle sprain grade II
Exclusion criteria: No history of ankle surgery, ankle osteoarthritis, and ankle deformities

Intervention groups

Sham group receives standard treatment including RICE (Rest, Ice, Compression and Elevation) for 10 days, followed by standard physiotherapy protocol. Intervention group receives standard treatment along with magnet therapy.

Main outcome variables

Ankle pain by visual analogue scale
Ankle function by American Orthopedic Foot and Ankle Society Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200307046714N2**

Registration date: **2023-12-30, 1402/10/09**

Registration timing: **prospective**

Last update: **2023-12-30, 1402/10/09**

Update count: **0**

Registration date

2023-12-30, 1402/10/09

Registrant information

Name

Hooshmand Zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4409 8132

Email address

hooshmand.z1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-06, 1402/10/16

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of magnetic field therapy on pain and function in individuals with grade II lateral ankle sprain, a randomized clinical trial

Public title
Effect of magnet therapy in ankle sprain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years and under 65 years Grade 2 (moderate) ligament injury based on clinical and imaging criteria absence of ankle fracture presented within the first 72 hours after the injury
Exclusion criteria:
Pregnancy Breastfeeding Those who intend to become pregnant Radiologic evidence of fracture or damage to syndesmosis at presentation history of previous sprain or fracture in each of ankles History of surgery and active infection at the site of injury History of peripheral vascular diseases Foot deformities Knee or ankle osteoarthritis Rheumatoid Arthritis Ankylosing spondylitis Diabetes Mellitus Neurological disorders Psychiatric disorders

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed using an online block randomization tool (www.sealedenvelope.com), with a variable block size of 2 or 4, and stratified based on age (≥ 40 or < 40 years).

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are informed about study, but will be blinded to randomization. All patients will receive standard therapy. Evaluation of the outcomes will be performed by an orthopedic surgeon who is unaware of patients' randomization.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2023-12-10, 1402/09/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.549

Health conditions studied

1

Description of health condition studied

lateral ankle sprain

ICD-10 code

S93.40

ICD-10 code description

Sprain of unspecified ligament of ankle

Primary outcomes

1

Description

Determination of ankle pain with VAS

Timepoint

At first visit, one month after injury, three months after injury

Method of measurement

Questionnaire (Visual Analogue Scale)

2

Description

Determination of ankle function with AOFAS

Timepoint

At first visit, one month after injury, three months after injury

Method of measurement

Questionnaire (American Orthopedic Foot and Ankle Score)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in this group receive standard treatment including RICE (Rest, Ice, Compression and Elevation) for 10 days, followed by standard physiotherapy program. Standard physiotherapy program includes Diathermy with Ultrasound (US) and Transcutaneous Electrical Nerve Stimulation (TENS), for 10 sessions, performed every other day. Patients concurrently receives magnet therapy for 10 sessions, performed every other day. The device is set to 0 when applying to patients in control group.

Category

Treatment - Other

2

Description

Intervention group: Patients in this group receive standard treatment similar to control group. This group concurrently receives magnet therapy for 10 sessions, performed every other day. Magnetic field is applied to relevant ankle with the PEMF device for 25 min at 25 G intensity at a frequency of 50 Hz.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Hooshmand Zarei, MD

Street address

Shohadaye Tajrish Hospital, Shahr-dari St., Tajrish Sq.

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Fax

Email

hooshmand.z1994@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi, Ph.D

Street address

Vice-Chancellor in Research Affairs, 5th Floor, Bldg No.2 Shahid Beheshti University of medical sciences Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Fax

+98 21 2243 9981

Email

Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hooshmand Zarei, MD

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Unit 6, No. 19, 3th St., North Shaghayegh Blvd., Ayatollah Kashani St., North Sazman Barnameh

City

Tehran

Province

Tehran

Postal code

1483877468

Phone

+98 21 4409 8132

Email

hooshmand.z1994@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Sabbaghzadeh Irani, MD

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Shohadaye Tajrish Hospital, Tajrish Sq

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

dramirsabbaghzadeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hooshmand Zarei, MD

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Unit 6, No. 19, 3th St., North Shaghayegh Blvd.,
Ayatollah Kashani St., North Sazman Barnameh

City

Tehran

Province

Tehran

Postal code

1483877468

Phone

+98 21 4409 8132

Email

hooshmand.z1994@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available