

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluating the effect of pulsed electromagnetic field on pain and function index in people with plantar fasciitis

Protocol summary

Study aim

Comparing the effect of two common physiotherapy treatment methods with common physiotherapy with electromagnetic field on pain score and function index in patients with plantar fasciitis.

Design

The clinical trial has two intervention and control groups, including a total of 40 people, double-blind, randomized in a randomized block manner and using a table of random numbers.

Settings and conduct

In this study, a comparison of two non-surgical treatment methods for people with plantar fasciitis is performed at Sadat Private Physiotherapy Center. Before the treatment, all participants are evaluated in terms of foot function and foot pain score with FFI index and VAS scale, respectively. Also, immediately after the last session and 4 weeks after the end of the treatment, the level of foot function and the pain score of the participants will be evaluated. Double-blinding will be done in such a way that the patients and the evaluator will not know about the grouping of people.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 and 68 years; heel or sole pain for more than three months; heel or sole pain with a score of 5 or more according to the VAS scale in the morning and at the end of the day; Painful palpation with localized pressure at the origin of the plantar fascia. Exclusion criteria: history of foot surgery; any damage; local steroid injection in the last 3 months; systemic inflammatory disease; metal implant; pregnancy; BMI more than 30; diabetes mellitus.

Intervention groups

The patients who refer to the physiotherapy center during the study are divided into two groups of 20 people; the first group receive 10 common physiotherapy sessions (control) and the second group receive 10 common physiotherapy sessions with magnet therapy (intervention).

Main outcome variables

pain score; foot function index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230712058753N1**

Registration date: **2023-08-01, 1402/05/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-01, 1402/05/10**

Update count: **0**

Registration date

2023-08-01, 1402/05/10

Registrant information

Name

Zeinab sadat Yajaddi Arani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of pulsed electromagnetic field on pain and function index in people with plantar fasciitis

Public title

Evaluating the effect of magnet therapy on foot pain and function in people with plantar inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People aged between 20 up to 68 years Pain in the heel or sole of the foot for more than three months The presence of pain in the heel or the sole of the foot with a score of 5 or more according to the VAS scale in the morning and at the end of the day Painful palpation with local pressure at the origin of the plantar fascia on the medial tubercle of the heel

Exclusion criteria:

The presence of any injury, tear and previous local trauma in the heel and sole of the foot History of foot surgery in the past Local steroid injection in the last 3 months The presence of severe and congenital abnormalities in the knee or ankle (such as severe knee braces, etc.) Having diabetes, tumor, peripheral neuropathy with any cause, systemic inflammatory disease The presence of a pacemaker or metal implant The presence of other musculoskeletal disorders with any cause that causes clinical manifestations in the lower limbs or spine Pregnancy People with a body mass index greater than 30

Age

From **20 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups of 20 people in a random block manner using a table of random numbers by a person other than the therapist and evaluator. In this study, there are ten blocks of four, two people from the intervention group and two people from the control group will be randomly placed in each block of four.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to create double blinding, it will be so that the patients as well as the evaluator and statistical analyst do not know how to group people, and someone other than the therapist evaluates the patients. In other words,

the patients are in progress, and we have two treatment groups in this study, but they are unaware of which group they belong to, because in both groups, a magnet device is used, with the difference that in the control group, the device will not have an output and only the therapist is aware of it; Actually, because the device does not generate heat, the patient does not feel any special symptoms when the device is on and the current is established. Therefore, in this study, the patients and the evaluator (a person other than the therapist) are blinded.

Placebo

Used

Assignment

Parallel

Other design features

In this study, two non-surgical treatment methods are compared for people with plantar fasciitis. After starting the study, the patients referred by the orthopedic doctor, who refer to the physiotherapy center during the study period, are divided into two groups of 20 people by a random block method and using a table of random numbers by someone other than the therapist and the evaluator. It is worth mentioning that in this study we will have ten blocks of four, so that two people from the intervention group and two people from the control group will be randomly placed in each block of four.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Nursing, Rehabilitation and Management schools- Isfahan University of medical Sc

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Approval date

2023-05-24, 1402/03/03

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.031

Health conditions studied

1

Description of health condition studied

Plantar fasciitis

ICD-10 code

M72.2

ICD-10 code description

Plantar fascial fibromatosis

Primary outcomes

1

Description

Pain: It is a dependent variable that is usually measured by a score, and it is a score that a person should give to the level of pain from zero to ten. In fact, a score of zero equals no pain and a score of ten equals severe unbearable pain.

Timepoint

Before starting the intervention; immediately after the last treatment session; Four weeks after completion of treatment.

Method of measurement

Visual Analogue Scale

2

Description

Foot Function Index: It is a questionnaire that is used in patients with foot problems, it has 23 items that are placed in three subgroups, and it examines the intensity of pain, disability and limitations of people. People should give each question a score between 0-10.

Timepoint

Before starting the intervention; immediately after the last treatment session; Four weeks after completion of treatment.

Method of measurement

Foot Function Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: People only receive 10 sessions of common physiotherapy treatment. Each session includes 5 minutes of pulse ultrasound therapy (with 50% duty cycle, 1MHz frequency and 1.2W/cm² intensity) and 20 minutes of TENS analgesic modality along (with 8Hz frequency, 300µs pulse width and motor intensity) with stretching exercises for the cuff muscles and plantar fascia and strengthening exercises for the anterior tibialis muscle.

Category

Rehabilitation

2

Description

Intervention group: In addition to receiving 10 sessions of common physiotherapy, people also receive 10 sessions of the electromagnetic field treatment program

(with square wave shape and 30% duty cycle and 7.5Hz frequency and 100mT intensity) for 10 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

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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

Not applicable

Data Dictionary

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