

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigation the effect of extracorporeal shock wave therapy on pain and quality of life in patients with chronic plantar fasciitis.

Protocol summary

Summary

(1) Objectives: The aim of the present study is investigation the effect of low energy shockwave therapy on pain, function and quality of life in patients with chronic plantar fasciitis. (2) Design: This is a single blinded randomized clinical trial. The patients will not aware about grouping. (3) Setting and conduct: a) filling the informed consent and general information forms. The quality of life questionnaires will fill, too. b) Recording the variables of the present study before starting the study. c) Grouping the patients randomly to control and intervention groups, each included 15 patients. d) Execution the physiotherapy protocol for both groups for 8 weeks, each week includes 2 sessions. e) Filling the quality of life at the end of the physiotherapy program. f) Comparing before and after physiotherapy program results. 4) Participants: 25 to 50 years old patients with chronic plantar fasciitis for more than 4 months which did not response to other treatments. 5) Most important inclusion criteria: Pain at the heel area which will be increased by pressure. Morning pain score more than 5 based on visual analog scale (VAS). 6) Most important exclusion criteria: If patient exits or does not complete the treatment sessions. (7) Interventions: Using low energy shockwave therapy with energy lower than 1.8 bar for intervention group. For control group the device will be off. Stretching plantar fascia and calf muscles include in physiotherapy program of both groups. There are 8 sessions included 2 sessions per week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070118754N4**

Registration date: **2016-12-10, 1395/09/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-10, 1395/09/20

Registrant information

Name

Javad Sarrafzadeh

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of extracorporeal shock wave therapy on pain and quality of life in patients with chronic plantar fasciitis.

Public title

Effect of extracorporeal shock wave (ESWT) therapy on

chronic plantar fasciitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with plantar fasciitis who have a history of pain at one heel region for more than 4 months with unsuccessful response to some kinds of conservative treatments such as NSAIDs, physiotherapy, stretching exercises and corticosteroids injections; increasing the heel pain with direct pressure on medial tuberosity of the calcaneus; a pain score equal and more than 5 based on visual analog scale (VAS) during the first steps of walking immediately after waking up in the morning; in the absence of any contraindication for shock wave therapy; in the absence of any observable deformity in lower extremity or spines and lower extremity discrepancy in clinical evaluation; in the absence of diabetes; in the absence of pregnancy.
Exclusion criteria: if the patient does not cooperate with therapist; if the patient starts any other treatment for plantar fasciitis along with present study; if patient does not complete the treatment sessions or does not participate in the regular study treatment program.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Iran University of Medical Sciences

Street address

School of Rehabilitation Sciences, Madadkaran st.,
Shahnazari st, Mirdamad st.,

City

Tehran

Postal code

Approval date

2016-05-28, 1395/03/08

Ethics committee reference number

IR.IUMS.REC 1395.9211452201

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

Plantar fasciitis

Timepoint

Before starting the treatment and after 4 weeks.

Method of measurement

Visual analog scale, functional test, quality of life questionnaire.

Secondary outcomes

1

Description

Pain

Timepoint

At the beginning of therapy, 4 weeks after first session.

Method of measurement

Visual analog scale

2

Description

Quality of life

Timepoint

At the beginning of therapy, 4 weeks after the first session and one month after ending the treatment.

Method of measurement

Foot and ankle outcome score (FAOS)

3

Description

Timed up and go

Timepoint

At the beginning of therapy, 4 weeks after first session.

Method of measurement

Timed up and go functional test

Intervention groups

1

Description

Intervention group: Using of shock waves on pain area of the painful heel and stretching plantar fascia and calf muscles of painful side.

Category

Rehabilitation

2

Description

Control group: stretching plantar fascia and calf muscles of painful side.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy clinic of School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Javad Sarrafzadeh

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Physiotherapy department, School of Rehabilitation Sciences, Madadkaran st., Shahnazari st, Mirdamad st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Seyed Ali Javad Moosavi, Vice chancellor for research

Street address

5th Floor, Iran University of Medical Sciences, Hemmat highway

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences, Vice chancellor for research

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

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Javad Sarrafzadeh

Position

PT, PhD in Physiotherapy, Associated Professor of Iran University of Medical Sciences, Head of physi

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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