Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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Iran (Islamic Republic of)

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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 dose not cooperation 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 fascitis

ICD-10 code
M72.2

ICD-10 code description
Plantar fascial fibromatosis

Primary outcomes

1

Description
Plantar fascitiis

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
City
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
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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