

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of Extracorporeal Shock Wave Therapy on Pain and Ultrasonographic Findings in Adult Patients with Plantar Fasciitis

Protocol summary

Summary

We aimed to evaluate the effects of extracorporeal shock wave therapy (ESWT) on plantar fasciitis symptoms and ultrasonographic findings. In this randomized placebo-controlled trial, adult patients with plantar fasciitis who referred to our clinic from 2010 to 2011 with symptoms for at least three months and no satisfactory response to common treatments such as NSAIDs were included. Patients were assigned to receive ESWT (4000 shock waves/session of 0.2 mJ/mm²) in 3 sessions at weekly intervals or sham therapy (n = 20 in each group). Outcomes were documented by the ultrasonographic appearance of the aponeurosis and by patients' pain scores, performed at baseline and 12 weeks after completion of the therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072910439N1**

Registration date: **2012-08-17, 1391/05/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-17, 1391/05/27

Registrant information

Name

Babak Vahdatpour

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 5555

Email address

vahdatpour@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2010-06-01, 1389/03/11

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Extracorporeal Shock Wave Therapy on Pain and Ultrasonographic Findings in Adult Patients with Plantar Fasciitis

Public title

Extracorporeal Shock Wave Therapy in Patients with Plantar Fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusions criteria: - Age 18 to 65 years - Having plantar heel pain for at least three months and point tenderness at or near the medial calcaneal insertion of the plantar fascia, - Have no satisfactory response to common treatments such as NSAIDs and physiotherapy - Willing to participate
Exclusion criteria: - Having diabetes, additional foot or ankle pathology (including instability, arthritis, generalized polyarthritis, diffuse heel pad tenderness), local dermatological problems, neurological abnormalities, history of recent trauma or foot surgery, connective tissue or infectious diseases, malignancy, or

vasculitis, - Pregnant patients, - Those who received anticoagulant therapy in the preceding six months

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib Street

City

Isfahan

Postal code

Approval date

2011-01-09, 1389/10/19

Ethics committee reference number

389450

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 Fascia Thickness

Timepoint

Before and 12 weeks after therapy

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Pain

Timepoint

Before and 12 weeks after therapy

Method of measurement

Numerical rating scale

Intervention groups

1

Description

Intervention: ESWT by weekly interval for three consecutive weeks; 2000 focused shock waves and 2000 radial pulses in three sessions (4000 shock waves/session of 0.2 mJ/mm²) at weekly intervals.

Category

Treatment - Other

2

Description

Placebo: Sham treatment was done where standard contact of radial and focus probe with the skin was avoided. The machine makes a noise with every shock wave delivered and, in order to enhance the sham design, minimal energy pulses (0.04mJ/mm²) were generated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra University Hospital

Full name of responsible person

Dr. Sepideh Sajadieh

Street address

Department of Rehabilitation Medicine, Alzahra Hospital, Soffeh Ave.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice CHancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Hezar Jarib Street

City

Isfahan

Grant name**Grant code / Reference number**

389450

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

Yes

Title of funding source

Vice CHancellor for Research, Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Sepideh Sajadieh

Position

MD, Resident of Physical Medicine and Rehabilitation

Other areas of specialty/work**Street address**

Department of Rehabilitation Medicine, Alzahra Hospital, Soffeh Ave.

City

Isfahan

Postal code**Phone**

+98 31 1220 6221

Fax**Email**

sepidehsajadieh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Sepideh Sajadieh

Position

MD, Resident of Physical Medicine and Rehabilitation

Other areas of specialty/work**Street address**

Department of Rehabilitation Medicine, Alzahra Hospital, Soffeh Ave.

City

Isfahan

Postal code**Phone**

+98 31 1220 6221

Fax**Email**

sepidehsajadieh@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Sepideh Sajadieh

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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