

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effectiveness of shock wave therapy combined with topical corticosteroid in improvement of plantar fasciitis

Protocol summary

Summary

purpose of the study: The effectiveness of shock wave therapy combined with topical corticosteroid in improvement of plantar fasciitis. inclusion criteria :Age>18 y; Disease duration more than 6 months; Not responsive to conservative treatment. Exclusion Criteria:Age less than 18; pregnancy; bone tumor; open wound; Received topical corticosteroid within the last 6 weeks; Active infection; Skin disease; peripheral neuropathy; Past history of surgery in this region; vascular disease. A randomized clinical trail; double blind study. sample size: 40 patients referring to Physical Medicine Clinics of Isfahan University of Medical Sciences intervention: shock wave therapy weekly for 4 weeks for both groups and 30 min before shock wave session, Clobetasol ointment for interventional group and Vaseline oil for control group. Primary outcomes are reduction in pain measured with VAS and modified Roles and Maudsley score. Secondary outcome is plantar fascia thickness assessed by sonography.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081029296N1**

Registration date: **2016-09-16, 1395/06/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-16, 1395/06/26

Registrant information

Name

Arghavan Mokhtarian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3626 1811

Email address

a.mokhtarian@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of shock wave therapy combined with topical corticosteroid in improvement of plantar fasciitis

Public title

A novel way in treatment of chronic plantar fasciitis:
Combination of Extracorporeal shock wave therapy and topical corticosteroid with occlusive dressing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age>18 y; Disease duration more than 6 months; Not responsive to conservative treatment; Exclusion criteria : Age less than 18 ;Open growth plate; pregnancy; bone tumor or other malignancy near treatment site; metabolic disease; open wound; Received systemic corticosteroid within the last month; Received topical corticosteroid in plantar fascia region within the

last 6 weeks; Active infection; Skin disease; peripheral neuropathy; coagulopathy disorder; received heparin or warfarin; Past history of plantar ligament rupture; Past history of surgery in this region; vascular disease; Allergic reaction to sulfonamide, NSAID or Aspirin; Heart failure; tarsal tunnel syndrome

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib Street

City

Isfahan

Postal code

7346181746

Approval date

2016-01-09, 1394/10/19

Ethics committee reference number

IR.MUI.REC.1394.3.764

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

Timepoint

before intervention /1 month and 3 months after intervention

Method of measurement

Visual Analogue Scale

2

Description

Modified Roles and Maudsley score

Timepoint

before intervention /1 month and 3 months after intervention

Method of measurement

Modified Roles and Maudsley Scale

Secondary outcomes

1

Description

Plantar fascia thickness

Timepoint

before and 3 months after intervention

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: 4 session of shock wave weekly and 30 minutes before each session Clobetazol oint with occlusive dressing on plantar region. Focus-SW Shock : 2000 Energy: 0.2-0.3 Frequency :4Hz Radial-SW Shock: 3000 Energy: 1.8-3 Frequency: 15Hz

Category

Treatment - Other

2

Description

Control group: 4 session of shock wave, weekly and 30 minutes before each session Vaseline oil with occlusive dressing on plantar region. Focus-SW Shock : 2000 Energy: 0.2-0.3 Frequency :4Hz Radial-SW Shock: 3000 Energy: 1.8-3 Frequency: 15Hz

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Medicine and Rehabilitation Clinic of Alzahra Hospital

Full name of responsible person

Arghavan Mokhtarian

Street address

Soffeh Avenue

City

Isfahan

2

Recruitment center

Name of recruitment center

Physical Medicine and Rehabilitation Clinic of Kashani Hospital

Full name of responsible person

Arghavan Mokhtarian

Street address

Kashani Avenue

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr.Mansour.Siavash

Street address

Vice Chancellor of Research, Isfahan University of Medical Sciences, Hezar Jerib street

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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 Science

Full name of responsible person

Arghavan Mokhtarian

Position

Resident of Physical Medicine and Rehabilitation

Other areas of specialty/work

Street address

Department of Physical Medicine and Rehabilitation, Alzahra Hospital

City

Isfahan

Postal code

Phone

+98 31 3668 5555

Fax

Email

a.mokhtarian@resident.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Dr.Babak Vahdat Pour

Position

Assistant Professor

Other areas of specialty/work

Street address

Department of Physical Medicine and Rehabilitation, Alzahra Hospital

City

Isfahan

Postal code

Phone

+98 31 3668 5555

Fax

Email

vahdatpour@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Arghavan mokhtarian

Position

Resident of Physical Medicine and Rehabilitation

Other areas of specialty/work

Street address

Department of Physical Medicine and Rehabilitation, Alzahra University Hospital, Soffeh Avenue

City

Isfahan

Postal code

Phone

+98 31 3668 5555

Fax
Email
a.mokhtarian@resident.mui.ac.ir
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