Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 Rehabilitaion 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
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Kashani Avenue
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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
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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