Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Effectiveness Of Ultrasound-Guided Dextrose injection And Radial Extracorporeal Shock Wave Therapy For The Treatment Of Chronic Plantar Fasciitis

Protocol summary

Study aim

Comparative Effectiveness Of Ultrasound-Guided Dextrose injection And Radial Extracorporeal Shock Wave Therapy For The Treatment Of Chronic Plantar Fasciitis

Design

Clinical trial with control group, with parallel groups, blinding is not done and randomization is done by closed envelopes.

Settings and conduct

This study was performed on patients with chronic plantar fasciitis referred to the PMR Clinics of IUMS . After performing physical examinations and the presence of tenderness in the medial part of the heel to confirm the diagnosis,lateral heel X-ray and diagnostic ultrasound will be performed.Patients are randomly assigned to be divided into two groups of 19 people. The treatment is performed at Firoozgar Hospital by a PMR resident.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: age 18 to 65 years, point tenderness of medial calcaneal tubercle, Heel pain with first step in the morning or after prolonged standing , thickness of plantar fascia greater than 4 mm in ultrasound and resistant to supportive treatments for at least three months Main exclusion criteria:coagulopathy,history of foot and ankle fracture or surgery,recent 6 weeks corticosteroid injection, bilateral plantar fasciitis, pregnancy and receive plantar fasciitis treatment in the last 6 months

Intervention groups

In the first group, 1.5 cc dextrose 20% plus 0.5 cc lidocaine 0.5% will be injected into the maximum thickness plantar fascia under ultrasound-guided in-plane injection technique.The cotrol group receive 3 sessions of low energy weekly.Shockwave Radial-SW type with Shock 2000 number, energy of 0.2 to 0.3 mJ / mm2 and frequency of 4 Hz focused on the Tenderness region.

Main outcome variables

The severity of morning and daily pain by Visual Analog Scale (VAS),Evaluation of foot and ankle function by Foot and Ankle Ability Measure (FAAM),Thickness of plantar fascia by Ultrasonography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200223046590N1**
Registration date: **2020-04-08, 1399/01/20**
Registration timing: **prospective**

Last update: **2020-04-08, 1399/01/20**
Update count: **0**

Registration date

2020-04-08, 1399/01/20

Registrant information

Name

Lobaneh Janbazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2021-05-05, 1400/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness Of Ultrasound-Guided Dextrose injection And Radial Extracorporeal Shock Wave Therapy For The Treatment Of Chronic Plantar Fasciitis

Public title

Effect of Dextrose injection in treatment of Chronic Plantar Fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's age 18 to 65 years Point Tenderness at the Medial Calcaneal Tubercle Heel pain with the first step in the morning or after prolonged standing Thickness of plantar fascia greater than 4 mm in ultrasound Resistant to supportive treatments for at least three months

Exclusion criteria:

Diabetes Mellitus Peripheral Neuropathy History of lower extremity radicular pain in L5 and S1 spinal segments Coagulation Disorders Vasculitis and Other Vascular Diseases Tarsal Tunnel Syndrome Instability of foot and ankle joints Foot and Ankle joints Arthritis Evidence of cancer Acute infection Skin diseases History of foot and ankle surgery History of foot and ankle fractures Corticosteroid injection in the last 6 weeks Bilateral Plantar Fasciitis Systemic Inflammatory Diseases Pregnancy Receive shockwave therapy or injectable plantar fasciitis treatment in the last 6 months

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: Block, Unit of randomization: Individual, Tools used in randomization: Sealed Envelope

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran Universiy of Medical Science

Street address

Medical faculty, Iran University of Medical Sience, Hemmat High way

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-09-17, 1398/06/26

Ethics committee reference number

IR.IUMS.FMD.REC.1398.349

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

The severity of morning and daily pain

Timepoint

قبل از تزریق و شاکوپو تراپی ، 1 ماه و 3 ماه پس از تزریق و شاکوپو تراپی

Method of measurement

Visual Analog Scale (VAS)

2

Description

Evaluation of foot and ankle function

Timepoint

Before injection and shock-wave therapy , 1 month and 3 months after injection and shock-wave therapy

Method of measurement

Foot and Ankle Ability Measure (FAAM)

3

Description

Thickness of plantar fascia

Timepoint

Before injection and shock-wave therapy , 1 month and 3 months after injection and shock-wave therapy

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 20% dextrose injection at maximal thickness location in plantar fascia under ultrasound-guided in-plane injection technique
Category
Treatment - Drugs

2

Description
Control group: 3 sessions of low energy weekly shock-wave therapy focused on the tenderness area
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available