

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 21 8855 3010

##### Email address

janbazi.l@iums.ac.ir

##### 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 University of Medical Science

##### Street address

Medical faculty, Iran University of Medical Science, 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 شاکویو تراپی ، 1 ماه و 3 ماه پس از تزریق و شاکویو 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

Alireza Kazemian

##### Street address

Department of Physical Medicine and Rehabilitation, Firuzgar Hospital, Valiasr Square

##### City

Tehran

##### Province

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##### Postal code

1593747811

##### Phone

+98 21 8214 1201

##### Email

kazemian11@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Seyed Kazem Malakooti

##### Street address

5th floor, Headquarters, Iran University of Medical Sciences, Hemmat Highway, Tehran

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##### Province

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##### Phone

+98 21 8862 2553

##### Email

PR@iums.ac.ir

#### 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

Iran University of Medical Sciences

##### Full name of responsible person

Alireza Kazemian

##### Position

Resident of Physical Medicine and Rehabilitation

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Physical Medicine

##### Street address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Lobaneh Janbazi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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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

**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Alireza Kazemian

**Position**

Resident of Physical Medicine and Rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**