

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effectiveness of dry needling and exercise therapy vs. exercise therapy alone on pain, foot function, quality of life, thickness and echogenicity of the plantar fascia in patients with plantar fasciitis

#### Protocol summary

##### Study aim

The effectiveness of dry needling and exercise therapy vs. exercise therapy alone on pain, foot function, quality of life, thickness and echogenicity of the plantar fascia in patients with plantar fasciitis

##### Design

The present study is a randomized control trial, with parallel group and double blind. Participants in the study are divided into two intervention and control groups based on randomized block design. The control group will receive exercise therapy for four weeks. The intervention group will receive exercise therapy and dry needling for four weeks. The sample size is 60.

##### Settings and conduct

Place of study: Musculoskeletal sonography laboratory of physiotherapy of Faculty of Rehabilitation of Tehran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: individuals with plantar fasciitis (PF), age between 20-45 years exclusion criteria: History of direct trauma to the heel; the presence of systemic inflammatory disorders; low back pain caused by disc herniation; the presence of Tarsal tunnel syndrome (TTS); history of fracture in foot and ankle; use aid of support for walking; the presence of contraindication for dryneedling, women who are pregnant; treatment for plantar heel pain in the previous 4 weeks; unwillingness to participate in the study

##### Intervention groups

The intervention group: will receive exercise therapy and dry needling for four weeks. The control group: will receive exercise therapy for four weeks.

##### Main outcome variables

Pain; quality of life; foot function; thickness of the plantar fascia; echogenicity of the plantar fascia

#### General information

##### Reason for update

to determine actual recruitment start date and actual recruitment end date

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180107038257N1**

Registration date: **2018-09-14, 1397/06/23**

Registration timing: **prospective**

Last update: **2021-04-22, 1400/02/02**

Update count: **1**

##### Registration date

2018-09-14, 1397/06/23

##### Registrant information

##### Name

Saman Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7752 8468

##### Email address

salehis@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-07, 1397/06/16

##### Expected recruitment end date

2019-01-19, 1397/10/29

##### Actual recruitment start date

2018-10-01, 1397/07/09

##### Actual recruitment end date

2020-03-01, 1398/12/11

**Trial completion date**

2020-03-01, 1398/12/11

**Scientific title**

The effectiveness of dry needling and exercise therapy vs. exercise therapy alone on pain, foot function, quality of life, thickness and echogenicity of the plantar fascia in patients with plantar fasciitis

**Public title**

The effectiveness of dry needling and exercise therapy vs. exercise therapy alone on foot function in patients with heel pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

individuals with plantar fasciitis age between 20-45 years

**Exclusion criteria:**

History of direct trauma to the heel The presence of systemic inflammatory disorders Low back pain caused by disc herniation The presence of Tarsal tunnel syndrome(TTS) History of fracture in foot and ankle Use aid of support for walking The presence of contraindication for dryneedling Women who are pregnant Treatment for plantar heel pain in the previous 4 weeks Unwillingness to participate in the study

**Age**

From **20 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **37**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: randomized block design, block size:4, ratio 1:1 Randomization tool: software

**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 Tehran University of Medical Science

**Street address**

Department of research and technology of Tehran University of Medical Sciences; Keshavarz Blvd; Ghods St

**City**

Tehran

**Province**

Tehran

**Postal code**

3439123900

**Approval date**

2018-05-25, 1397/03/04

**Ethics committee reference number**

IR.TUMS.VCR.REC.1397.231

**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**

At the baseline, after three weeks of intervention, after six weeks of intervention, and after a two-week follow-up

**Method of measurement**

Visual analog scale

**2****Description**

Quality of life

**Timepoint**

At the baseline, after three weeks of intervention, after six weeks of intervention, and after a two-week follow-up

**Method of measurement**

Short-form36(SF-36) questionnaire

**3****Description**

Foot function

**Timepoint**

At the baseline, after three weeks of intervention, after six weeks of intervention, and after a two-week follow-up

**Method of measurement**

Foot and Ankle Ability Measure questionnaire (FAAM) and Foot and ankle outcome score (FAOS)

## 4

### **Description**

Thickness of the plantar fascia

### **Timepoint**

At the baseline, after six weeks of intervention

### **Method of measurement**

Ultrasonography

## 5

### **Description**

Echogenicity of the plantar fascia

### **Timepoint**

At the baseline, after six weeks of intervention

### **Method of measurement**

Ultrasonography

## **Secondary outcomes**

## 1

### **Description**

Foot range of motion

### **Timepoint**

At the baseline, after three weeks of intervention, after six weeks of intervention and after a two-week follow up period

### **Method of measurement**

Goniometer

## **Intervention groups**

## 1

### **Description**

Intervention group: The intervention group will receive the exercise therapy and the dry needling for six weeks. The exercise therapy consist of the stretching exercise of the plantar fascia; the soleus muscle; the gastrocnemius muscle and the big-toe flexor and stretching on the static wooden wedge. The patients do the stretching exercise two times per day; any time fifteen repetitions; each taking 30 seconds; during six weeks. Dry needling is done according to the modified-delphi protocol. According to the protocol, the muscles that are primarily responsible for the pain including: the soleus; the quadratus plantae; the flexor digitorum brevis and the abductor hallucis. The intervention group will receive the dry needling once a week; during six weeks.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: The control group will receive the exercise therapy for six weeks. The exercise therapy consist of the stretching exercise of the plantar fascia; the soleus muscle; the gastrocnemius muscle and the big-toe flexor and stretching on the static wooden wedge . The patients do the stretching exercise two times per day; any time fifteen repetitions; each taking 30 seconds; during six

weeks.

### **Category**

Rehabilitation

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Sina Hospital

#### **Full name of responsible person**

Saman Salehi

#### **Street address**

Hasan Abad Square; Imam Khomeini Ave

#### **City**

Tehran

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#### **Postal code**

1136746911

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#### **Email**

salehis@razi.tums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Mohammad Ali Sahraiyani

#### **Street address**

Department of research and technology of Tehran University of Medical Sciences; Keshavarz Blvd; Ghods St

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#### **Email**

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Saman Salehi

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

School of rehabilitation of Tehran University of  
Medical Science; Piche Shemiran; Enghelab street

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Azade Shadmehr

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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

Tehran University of Medical Sciences

**Full name of responsible person**

Saman Salehi

**Position**

PhD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Technology Assessment

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**Phone**

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**Email**

salehis@razi.tums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The original data is shared in thesis format.

**When the data will become available and for how long**

After defense of thesis, the original data is shared in  
thesis format.

**To whom data/document is available**

Academic researchers, physiotherapists

**Under which criteria data/document could be used**

In order to use clinical results, the original data is shared  
in thesis format.

**From where data/document is obtainable**

Library of the faculty of rehabilitation of Tehran  
University of Medical Sciences

**What processes are involved for a request to access data/document**

Referral to library of the faculty of rehabilitation of  
Tehran University of Medical Sciences

**Comments**

