

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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+98 21 7752 8468

Email address

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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

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Hasan Abad Square; Imam Khomeini Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraiyani

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

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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

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Position

Professor

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Other areas of specialty/work

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

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Position

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Other areas of specialty/work

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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

