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
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
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 Sahraiyan
Street address
Department of research and technology of Tehran University of Medical Sciences; Keshavarz Blvd; Ghods St
City
Tehran
Province
Tehran
Postal code
3439123900
Phone
+98 21 8163 3685
Email
salehis@razi.tums.ac.ir
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
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7752 8468
Email
salehis@razi.tums.ac.ir

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
Street address
School of rehabilitation of Tehran University of Medical Science; Piche Shemiran; Enghelab street
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7752 8468
Email
shadmehr@tums.ac.ir

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
Street address
School of rehabilitation of Tehran University of Medical Science; Piche Shemiran; Enghelab street
City
Tehran
Province
Tehran
Postal code
1148956111
Phone
+98 21 7752 8468
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