

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of Quadratus Plantae Muscle Dry Needling on Pain and Plantar Fascia Thickness in Patients with Plantar Heel Pain

Protocol summary

Study aim

Investigating the immediate and delayed effect of Quadratus plantae muscle dry needling on pain and plantar fascia thickness in patients with plantar heel pain. Determining the immediate and delayed effect of dry needling on variables and comparing them between the two groups of study.

Design

A randomized clinical trial study with two parallel group including control and intervention groups, single-blind on 40 patients. Randomization will be done simply by selecting a closed envelope by every patient.

Settings and conduct

This study is performed with the voluntary participations with plantar fasciitis at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences. Both groups of study are taught stretch and massage of plantar fascia. The intervention group is also treated by Quadratus plantae dry needling for two weeks, twice a week. In the control group, the intensity of pain and the plantar fascia thickness are measured in the first and last session. In the intervention group, the variables are measured before and after the first and last session. Two weeks after the intervention, the variables will be compared between two groups. Data analyzer is blind.

Participants/Inclusion and exclusion criteria

Patients with plantar fasciitis who are over 18 years of age and plantar fascia thickness should be more than 4 mm. There should be first step pain in the morning and at least one month has passed since the onset of pain. The intensity of pain should be at least 4 based on VAS scale.

Intervention groups

Both group of study will be taught stretch and massage of plantar fascia. The intervention group, in addition, undergoes Quadratus plantae dry needling treatment.

Main outcome variables

Plantar fascia thickness, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160424027562N10**

Registration date: **2020-11-28, 1399/09/08**

Registration timing: **prospective**

Last update: **2020-11-28, 1399/09/08**

Update count: **0**

Registration date

2020-11-28, 1399/09/08

Registrant information

Name

Roghayeh Mohammadi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

mohammadpt@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Quadratus Plantae Muscle Dry Needling on Pain and Plantar Fascia Thickness in Patients with Plantar Heel Pain

Public title

Effect of Dry Needling in plantar fascia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with plantar fasciitis Plantar fascia thickness more than 4 millimeter First step pain At least one month has passed since the onset of pain Intensity of pain should be at least 4 based on the VAS scale

Exclusion criteria:

History of diabetes, rheumatology and cardiovascular diseases Fear of needle Pregnancy Myofascial trigger points and muscle shortness in Hamstring and Gastrocnemius muscles Infection, neuropathy and coagulation problems History of injection in the last 6 months

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be simple and individually. In order to make a random selection, the closed envelope will be selected by the patient himself/herself. If the envelope contains the letter A, the person will be included in the control group's list, and if the letter B is displayed, the person will be placed in the intervention group. This method continues until the number of people in both groups reaches the quorum.

Blinding (investigator's opinion)

Single blinded

Blinding description

In order to blind the data analyzer, the data is encoded to the analyzer. Therefore, the analyzer will not be able to distinguish the data of the participants of the two groups from each other.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences., Basij Blvd., Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2020-11-24, 1399/09/04

Ethics committee reference number

IR.SEMUMS.REC.1399.244

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

Plantar fascia thickness

Timepoint

First and last sessions for control group, before and after first and last sessions for intervention group

Method of measurement

Ultrasound imaging

Secondary outcomes

1

Description

Pain

Timepoint

First and last sessions for control group, before and after first and last sessions for intervention group

Method of measurement

Visual analogue scale

Intervention groups

1

Description

Control group: Plantar fascia thickness and intensity of pain are measured in the first session. Stretch and massage of plantar fascia are taught to the control group to perform for two weeks. After two weeks, the thickness of the plantar fascia and the intensity of pain are measured again.

Category

Rehabilitation

2

Description

Intervention group: Stretch and massage of plantar fascia are taught to this group to perform for two weeks. The group also receives Quadratus plantae dry needling treatment. Dry needling is applied to the trigger points of muscle. The plantar fascia thickness and the intensity of pain are measured before and after the first session. Dry needling will be done twice a week for two weeks. plantar fascia thickness and the intensity of pain are measured before and after the last session again.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center

Full name of responsible person

Zeinab Mahmoudi

Street address

Neuromuscular Rehabilitation Research Center,
Ghods Blvd., Semnan

City

Semnan

Province

Semnan

Postal code

3519698375

Phone

+98 23 3332 8502

Email

z.mahmoudi.pt93@gmail

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Basij Blvd.,
Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

P_kokha@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Roghayeh Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Semnan University of Medical
Sciences, 5 kilometer of Damghan Road., Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3365 4180

Email

mohamadipt@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Roghayeh Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road., Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3365 4180

Email

mohamadipt@gmail.com

3514799442

Phone

+98 23 3365 4180

Email

mohamadipt@gmail.com

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after being unidentified.

When the data will become available and for how long

The beginning of the access period is one month after the results are published.

To whom data/document is available

All those who need research results can receive the study documentation.

Under which criteria data/document could be used

All people who use the information are required to mention the source.

From where data/document is obtainable

To receive the information, they can contact the research author at the Faculty of Rehabilitation, Semnan University of Medical Sciences.

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

After receiving the email from the applicant, the applicant will be sent a document within two weeks.

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

Semnan University of Medical Sciences

Full name of responsible person

Roghayeh Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road., Semnan

City

Semnan

Province

Semnan

Postal code