

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 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

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Ph.D.

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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**

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**

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