Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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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 Fist 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 fascitiis

ICD-10 code
M72.2

ICD-10 code description
Plantar fascial fibromatosis

Primary outcomes

1

Description
Plantar fascia thickness

Timepoint
Fist 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr Parviz Kokhaei

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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
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

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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