

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of trigger points Dry needling and Shockwave therapy on pain, function and quality of life in patients with chronic plantar fasciitis

Protocol summary

Study aim

Comparison of trigger points Dry needling and Shockwave therapy on pain, function and quality of life in patients with chronic plantar fasciitis

Design

This is a randomized clinical trial with subjects in two groups of 42 people. the examiner is blind and Block Randomization and sealed opaque envelopes concealment will perform.

Settings and conduct

84 patients were randomly assigned into two groups of shockwave therapy and dry needles. The shockwave therapy group undergoes three sessions of treatment for three weeks and once a week. Dry needle group also undergoes three sessions of treatment for three weeks and once a week. Assessments will performed before the intervention , after and five weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years Resistance to treatment in the last 6 months Point pain on the inside of the calcaneus and origin of plantar fasciitis Having a minimum score of numerical scale of pain 4 in the first step Having or not having heel spur Having trigger points in the initial assessment of cuff muscles Adoption interrupted of analgesics, anti-inflammatory and non-steroidal drugs and topical or oral analgesics for at least 14 days before the initial assessment and during the study. Ability to walk 50 meters without assistance
Exclusion criteria: Dry needle contraindication Secondary heel pain leads to more serious problems such as fractures, cancer and infection History of coagulation disorders or taking anticoagulants other than acetylsalicylic acid to a dose of 325 mg / day Dermatological Disease Previous experience in using dry needles or acupuncture A history of chronic diseases Systemic or topical neurological disorders Spinal deformities Lower limb bone disorders

Intervention groups

Groups consist two groups of shockwave therapy and dry

needles.

Main outcome variables

pain; function; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190715044217N1**

Registration date: **2019-09-04, 1398/06/13**

Registration timing: **prospective**

Last update: **2019-09-04, 1398/06/13**

Update count: **0**

Registration date

2019-09-04, 1398/06/13

Registrant information

Name

tahere salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 1551

Email address

t_salehi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of trigger points Dry needling and Shockwave therapy on pain, function and quality of life in patients with chronic plantar fasciitis

Public title
Comparison of trigger points dry needling and shockwave therapy on pain, function and quality of life in patients with chronic plantar fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Resistance to treatment in the last 6 months Point pain on the inside of the calcaneus and origin of plantar fasciitis Having a minimum score of numerical scale of pain 4 in the first step Having or not having heel spur Adoption interrupted of analgesics, anti-inflammatory and non-steroidal drugs and topical or oral analgesics for at least 14 days before the initial assessment and during the study Having trigger points in the initial assessment of cuff muscles Ability to walk 50 meters without assistance
Exclusion criteria:
Dry needle contraindications include: Needle phobia, People with a history of needle or injection abnormal reactions, Emergency situations, Anticoagulant drugs, Lymphedema, Vascular Diseases, Diabetes, Pregnancy, Epilepsy, and Metal Sensitivity latex Secondary heel pain leads to more serious problems such as fractures, cancer and infection History of coagulation disorders or taking anticoagulants except acetylsalicylic acid to a dose of 325 mg / day Dermatological Disease in place of dry needle Previous experience in using dry needles or acupuncture connective tissue disease A history of chronic diseases such as RA, PSORIATIC, SCIATIC History of Plantar Fascia Surgery or Injection 3 months ago Systemic or topical neurological disorders Spinal deformities Lower limb bone disorders such as gout and Paget's

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are randomly allocated blocks and hiding in a non-transparent envelope sealed into two groups

Blinding (investigator's opinion)

Single blinded

Blinding description
In this study, the evaluator and analyst are blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Shiraz School of Rehabilitation Sciences
Street address
School of Rehabilitation Sciences - Abiverdi 1 St. - Chamran Blvd. - Shiraz - Iran
City
shiraz
Province
Fars
Postal code
33669-71947
Approval date
2019-07-13, 1398/04/22
Ethics committee reference number
IR.SUMS.REHAB.REC.1398.020

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
Before the intervention, one week and five weeks after the intervention

Method of measurement
Numeric rate scale

2

Description
Function

Timepoint

Before the intervention, one week and five weeks after the intervention

Method of measurement

FAAM questionnaire

3

Description

Quality of life

Timepoint

Before the intervention, one week and five weeks after the intervention

Method of measurement

Short form 12 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 3 sessions of shockwave therapy will apply for three weeks and once a week

Category

Rehabilitation

2

Description

Intervention group: In this group, individuals will receive dry needling for 3 weeks and once a week at painful trigger points of cuff muscles. These muscles include Soleus, Quadratus plantae, Flexor digitorum brevis, Flexor hallucis longus, Gastrocnemius and Abductor hallucis.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals of Shiraz university of medical sciences

Full name of responsible person

Tahere salehi

Street address

School of Rehabilitation Sciences, Abiverdi 1 St., Chamran Blvd., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 71 3627 1551

Email

t_salehi71@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ghasemi Unes

Street address

Floor 7, Center Bilding of Shiraz Univercity of Medical Science, beside Helale Ahmar, Zand street

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Web page address

<http://research.sums.ac.ir/fa/contact-information/index.html>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ebrahimi samaneh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences, Abiverdi 1 St.,
Chamran Blvd., Shiraz, Iran

City

shiraz

Province

Fars

Postal code

1733-71345

Phone

+98 71 3627 1551

Email

EbrahimiS@Sums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Ebrahimi samaneh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, Abiverdi 1 St., Chamran
Blvd., Shiraz, Fars, Iran

City

Shiraz

Province

Fars

Postal code

71345-1733

Phone

+98 71 3627 1551

Email

EbrahimiS@Sums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Tahere salehi

Position

master of physical therapy student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, Abiverdi St. 1, Chamran
Blvd., Shiraz, Fars, Iran

City

Shiraz

Province

Fars

Postal code

71345-1733

Phone

+98 71 3627 1551

Email

t_salehi71@yahoo.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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

The results will be published as an article in the research
international journals

When the data will become available and for how long

In the next one to two years

To whom data/document is available

Only people who ask the information from the main
investigator

Under which criteria data/document could be used

With the permission through a written or an oral request

From where data/document is obtainable

School of Rehabilitation Sciences, Shiraz University of
Medical Sciences, 1st Abiverdi, Chamran Blv., Miss
Tahere salehi, Phone number: 0098 71 36271551

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

With a written request, they can access the library of
Shiraz University of Medical Sciences, School of
Rehabilitation Sciences

Comments