

# 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

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

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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

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**Province**

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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

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## 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

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## 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

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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**

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**