Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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 hallusic 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
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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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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
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Person responsible for updating data

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master of physical therapy student

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Bachelor

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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