Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effectiveness of dry needling and extracorporeal shockwave therapy (ESWT) of calf muscles (gastrosoleus) in the treatment of patients with plantar fasciitis

Protocol summary

Study aim

The aim of this study was to compare the effectiveness of two treatment methods, dry needling and extracorporeal shockwave therapy (ESWT), on trigger points of the calf muscle in treating patients with plantar fasciitis.

Design

A two-group, single-blind, randomized, parallel-group clinical trial on 44 patients. Block randomization was used for randomization.

Settings and conduct

The study site is the Department of Physical Medicine and Rehabilitation of Firoozgar Hospital in Tehran. Among the patients complaining of foot pain, 44 patients with a clinical diagnosis of plantar fasciitis and calf muscle trigger points who meet the inclusion criteria will be enrolled in the study after obtaining written consent and randomly divided into two groups. Blinding is single-blind in which the assessor and data analyst are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a clinical diagnosis of plantar fasciitis with trigger points in the cuff muscles, symptoms for at least 6 weeks, and a commitment to not taking anti-inflammatory medications. Exclusion criteria: History of inflammatory diseases, use of anticoagulant medications, contraindications to ESWT and dry needling (pregnancy, bleeding disorders).

Intervention groups

The first group will receive extracorporeal shockwave therapy (ESWT) of the plantar fascia and trigger points of the calf muscles, and the second group will receive ESWT of the plantar fascia and dry needling of the trigger points of the calf muscles. Both groups will be taught a home exercise program and ice massage.

Main outcome variables

Patient pain intensity with Visual Analog Scale, ankle function with Foot Function Index questionnaire, response to treatment with Roles and Maudsley Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190306042945N6**
Registration date: **2025-06-04, 1404/03/14**
Registration timing: **prospective**

Last update: **2025-06-04, 1404/03/14**
Update count: **0**

Registration date

2025-06-04, 1404/03/14

Registrant information

Name

Bijan Forogh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-15, 1404/03/25

Expected recruitment end date

2026-06-15, 1405/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of dry needling and extracorporeal shockwave therapy (ESWT) of calf muscles (gastrosoleus) in the treatment of patients with plantar fasciitis

Public title
Studying the effect of dry needling and shockwave therapy on calf muscles in the treatment of plantar fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pain severity: Baseline pain intensity ≥ 4 on a Visual Analog Scale (VAS) 0-10 Duration of symptoms: Presence of symptoms of plantar fasciitis for at least 6 weeks. Clinical diagnosis: Patients with plantar fasciitis and have tender points in the gastrocnemius-soleus muscles on the same side of the affected area, and this issue is clinically assessed and diagnosed by a physical medicine and rehabilitation specialist. No previous treatment or failure of conservative treatment: The patient must not have previously received any medical treatment for this disease or previous conservative treatments (NSAIDs or other analgesics, exercise programs and shoe inserts) have not been effective. Commitment to not taking anti-inflammatory drugs: Acceptance of not taking anti-inflammatory drugs during the treatment period. General health: No known acute or chronic inflammatory diseases or taking medications that interfere with the effects of treatment, including NSAIDs for other reasons Informed consent to participate in the study. Education level: Having sufficient education to understand the treatment methods and interventions performed and the ability to complete the assessment forms in this study

Exclusion criteria:
Malignancy (cancer) Active infections History of systemic inflammatory diseases or disseminated inflammatory rheumatic diseases Trauma Open wounds or injuries in the legs Neuropathy (nerve disorders) Radiculopathy (pressure on the spinal nerves) Peripheral vascular disorders (circulation problems in the limbs) Coagulation disorders (blood clotting problems) Use of anticoagulant drugs (due to increased risk of bleeding) Arthropathy (joint disease) Congenital or acquired deformities in the lower extremities Sequelae of previous fractures in the lower extremities Presence of metal prostheses or implants (including screws, pacemakers or internal fixators) in the treatment area Inability to understand the treatment or cognitive impairment if the person is unable to understand the treatment or complete the relevant assessment forms Previous treatment history including ESWT, injections in the area (corticosteroids, Platelet-rich plasma (PRP), prolotherapy) Not willing to participate in the study Contraindications to ESWT and dry needling, such as metal allergies, pregnancy, bleeding disorders Severe mental disorder including conditions that may impair the ability to provide informed consent or adhere to treatment protocols

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
This study uses a block randomization method, as follows: To ensure a balanced number of subjects in each group, blocks of equal size will be used. Given the sample size of 44 subjects, 11 blocks of 4 subjects will be designed, with each block containing two subjects in the ESWT group and two subjects in the dry-needling group. The order of assignment of subjects in each block is determined randomly using random number generation software. These combinations are written on identical pieces of paper, and each piece of paper is placed in an opaque envelope. The envelopes are organized in blocks and the patient is asked to select one envelope at random when he or she visits. The number inside the envelope determines the patient's treatment group, and this information is recorded on special forms. 1- Preparation of the randomization list: A random list containing different combinations of groups in each block (such as 1-2-1-2) is generated using the random number generation section of SPSS software. This list is given to the principal investigator and is used to assign patients to groups. 2- Preparation of envelopes: Same-sized pieces of paper are prepared and the numbers *1* for ESWT and *2* for dry needling are written on them. Each block will contain a combination of numbers according to the randomly generated list. The papers are placed separately inside opaque envelopes of the same size and shape. The papers are numbered sequentially and placed neatly in the blocks. 3- Allocation of patients to groups: The participant, upon visiting the clinic, randomly selects an envelope from the relevant block. After selecting the envelope, the number inside it indicates the treatment group to which the patient is assigned (1 or 2). The researcher records the allocation code and the remaining envelopes in the block are stored until the block is used up. In order to conceal allocation, the treatment group should not be known to the patient or the researcher until the moment each patient enters the study. This prevents bias.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the nature of the interventions, patients and therapists are aware of the type of treatment or intervention given to the patient, but the evaluator, who is responsible for collecting and analyzing the data, remains unaware of this information. • This is

done as follows: 1- Use of coding: Treatment groups are identified without mentioning the intervention by labeling them as neutral codes (i.e., Group 1 and Group 2), and the evaluation team works only with these codes. The researcher will unassign the groups after conducting statistical analyses. 2- Separation of duties: Assessment and treatment are carried out by different individuals so that the evaluator has no direct interaction with the therapist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Vice-Chancellor of Research and Technology , Central Headquarters Building, Iran University of Medical Sciences, next to Milad tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2025-03-12, 1403/12/22

Ethics committee reference number

IR.IUMS.FMD.REC.1403.684

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

Patient's pain intensity with Visual Analogue Scale

Timepoint

In 3 sessions, before the start of the intervention, one month and three months after completing the three intervention sessions

Method of measurement

Completion of the Visual Analogue Scale by the patient

Secondary outcomes

1

Description

Ankle function assessment based on Foot function index (FFI)

Timepoint

In 3 sessions, before the start of the intervention, one month and three months after completing the three intervention sessions

Method of measurement

Completion of the Foot Function Index (FFI) questionnaire by the patient

2

Description

Response to treatment and satisfaction with patient treatment based on the Roles and Maudsley Scale (RMS)

Timepoint

In 3 sessions, before the start of the intervention, one month and three months after completing the three intervention sessions

Method of measurement

The patient describes their condition after treatment, and the doctor, based on these descriptions and clinical assessment, selects one of the four levels of the Roles and Maudsley Scale (RMS) and assigns the patient a score.

Intervention groups

1

Description

Intervention group 1: Patients will be treated with ESWT of the plantar fascia and the trigger points of the cuff muscles. ESWT treatment will be performed using a STORZ Medical MASTERPULS MP100 device with a protocol of 3000 shock waves per session / Energy Flux Density 0.2 mJ/mm² (average energy flux density: 0.10–0.20 mJ/mm²) / Frequency 8-10 Hz / Intensity 1.3 times based on patient tolerance (adjustable between 1.5 and 2.5 times) for the heel region and for the trigger points of the cuff muscles, 300 shock waves per session for each trigger point / Energy Flux Density 0.2 mJ/mm² / Frequency 8-10 Hz / Intensity up to 2.5 times based on patient tolerance. The treatment sessions of the patients will be arranged and performed in 3 sessions at one-week intervals. In addition, a shared treatment program is taught, including home exercises for stretching the plantar fascia and calf muscles, and the use of cold in the form of ice massage.

Category

Treatment - Devices

2

Description
Intervention group 2: Patients undergoing ESWT of the plantar fascia and dry needling of the calf muscles will receive trigger points. Treatment will be performed using dry needling (DN) with acupuncture needles measuring 50 x 0.6 mm on the trigger points in the gastrosoleus muscles. The physical therapist will manually examine the muscles for the presence of active or latent trigger points. Referred pain after squeezing taut bands/trigger points is considered active trigger points. Local pain after palpation of the trigger points is assessed as latent trigger points. Dry needling is applied based on the location of myofascial trigger points in the gastrosoleus muscles, as defined by Simons et al. The patient will be in the prone position during treatment. The needle will be adjusted with processing or withdrawal movements until a local twitch response is obtained. If the patient feels severe discomfort, the treatment will be performed intermittently. ESWT treatment of the heel region is performed by the STORZ Medical MASTERPULS MP100 device with a protocol of 3000 shock waves per session / Energy Flux Density 0.2 mJ/mm² (average energy flux density: 0.10–0.20 mJ/mm²) / Frequency 8-10 Hz / Intensity 1.3 times based on patient tolerance (adjustable between 1.5 and 2.5 times). Patients' treatment sessions are arranged and performed in 3 sessions at one-week intervals. In addition, a joint treatment program is taught, including home exercises for stretching the plantar fascia and calf cuff muscles and the use of cold in the form of ice massage.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Iran 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
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Full name of responsible person
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Position
Resident

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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
Not applicable
Title and more details about the data/document
All data is potentially shareable after de-identifying individual ID data
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
If needed, for use in future researches, please send a written request via email
From where data/document is obtainable
Main researcher: Dr. Bijan Forough Email: forogh.b@iums.ac.ir
What processes are involved for a request to access data/document
After sending the request to the e-mail, the information will be accessible within a period of about one week
Comments