Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of blood flow changes on post-dry needling soreness of the gastrocnemius muscle in patients with myofascial pain syndrome: a single-blinded randomized controlled trial

Protocol summary

Study aim
Determination and comparison of gastrocnemius muscle soreness after dry needling treatment in combination with other treatments in patients with myofascial pain syndrome

Design
This study will be conducted as a single-blind randomized clinical trial with a control group and parallel intervention groups, involving 45 participants. Random allocation of participants to the study groups will be performed using a computer-generated random number sequence.

Settings and conduct
This study will be conducted in the physiotherapy clinics affiliated with the Faculty of Rehabilitation Sciences, Tabriz University of Medical Sciences. Participants will include patients diagnosed with myofascial pain syndrome presenting with an active myofascial trigger point in the lateral head of the gastrocnemius muscle. The outcome assessor will be blinded to the group allocation

Participants/Inclusion and exclusion criteria
Participants aged 20 to 45 years who present with initial pain in the calf region and have an active myofascial trigger point in the lateral head of the gastrocnemius muscle will be included in the study. Patients with any of the following conditions will be excluded: infection, diabetes mellitus, hypertension, fibromyalgia, or cardiovascular diseases

Intervention groups
Group 1: Control Group (Dry Needling Only) Group 2: Dry Needling + Thermotherapy Group 3: Dry Needling + Ischemic Postconditioning (IPOC)

Main outcome variables
Muscle soreness

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20200215046499N7**
Registration date: **2026-04-25, 1405/02/05**
Registration timing: **prospective**

Last update: **2026-04-25, 1405/02/05**
Update count: **0**

Registration date
2026-04-25, 1405/02/05

Registrant information

Name
Hakimeh Adigozali

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2027-03-03, 1405/12/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effects of blood flow changes on post-dry needling soreness of the gastrocnemius muscle in patients with myofascial pain syndrome: a single-blinded randomized controlled trial

Public title
Effects of blood flow changes on post-dry needling soreness

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 20 to 45 years Presence of primary pain in the calf muscles Initial pain intensity between 3 and 8 on the Numeric Pain Rating Scale (NPRS) during initial assessment Presence of an active trigger point in the lateral head of the gastrocnemius muscle on the affected side Individuals with a BMI between 18 and 27

Exclusion criteria:
History of recent surgery in the lower limb History of trauma in recent years Physiotherapy treatment within the past six months Presence of cardiovascular diseases or thrombosis Diabetes mellitus and hypertension Fibromyalgia syndrome, diagnosed by a specialist physician and confirmed by the therapist through palpation of the related tender points Skin injury, infection, or inflammatory edema at the site of the trigger point at the time of testing Pregnancy at the time of testing Use of sedative or anticoagulant medications before or during the treatment Needle phobia Possibility of any systemic inflammation (due to malignancy, common cold, infection, or any other condition associated with inflammatory factors in the blood)

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to one of three study groups: Control (A), Treatment 1 (B), or Treatment 2 (C). Random allocation will be performed by an independent individual who is not involved in the research implementation, in order to minimize allocation bias. Randomization will be conducted using a computer-generated random number sequence based on a parallel assignment method with a 1:1:1 allocation ratio. To maintain balance between groups and prevent predictability of assignments, random block sizes of 3, 6, and 9 participants will be used. Each block will contain an equal number of participants in each group, and the sequence of assignments within each block will be determined completely at random. To ensure allocation concealment, opaque, sealed, and sequentially numbered envelopes will be used. Each envelope will be opened only at the time of a participant's enrollment by the designated study coordinator. Group labels will be coded as A, B, and C. Since outcome assessments will be conducted by an evaluator who is **blinded to group allocation, the study will be designed as a single-blind trial.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will employ a single-blind design, in which the outcome assessor will be blinded to the group allocation of participants. The random allocation sequence will be generated by an independent researcher and placed in sequentially numbered, opaque, sealed envelopes. After each participant is enrolled in the study, the corresponding envelope will be opened in order to determine group assignment. The outcome assessor, who will remain unaware of the type of intervention received by participants, will perform all evaluations and data recordings

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

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East Azarbaijan

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Approval date
2026-02-09, 1404/11/20

Ethics committee reference number
IR.TBZMED.REC.1404.796

Health conditions studied

1

Description of health condition studied
Myofascial pain syndrome
ICD-10 code
G89.4
ICD-10 code description
Chronic pain syndrome

Primary outcomes

1

Description
Muscle sorness
Timepoint
Immediately after, 48 hours and one week after receiving the intervention
Method of measurement
The Numerical Pain Rating Scale, as well as measurements of blood inflammatory factors, used to determine muscle soreness caused by the needle.

Secondary outcomes

1

Description
Pain pressure treshold
Timepoint
Before, immediately after, 48 hours and one week after receiving the intervention
Method of measurement
In this study, an algometer was used to press on a trigger point located on the lateral head of the gastrocnemius muscle, and the pressure at which the patient first reports a pain sensation was considered the pressure pain threshold.

2

Description
Functional disability
Timepoint
Before and one week after receiving the intervention
Method of measurement
In this study, the Persian equivalent version of the Lower Extremity Functional Scale (LEFS) questionnaire was used to assess the level of lower extremity functional disability in the treatment groups.

3

Description
Muscle blood flow
Timepoint
Before, immediately after, and 48 hours after receiving the intervention
Method of measurement
In this study, blood flow around the trigger point in the lateral head of the gastrocnemius muscle was calculated using a linear probe by measuring the maximum systolic velocity, minimum diastolic velocity, and vascular resistance index in the posterior tibial artery using a Doppler ultrasound device.

4

Description
Muscle thickness
Timepoint
Before the intervention, immediately after and 48 hours later
Method of measurement
In this study, a B-Mode image is taken of the muscle at rest and contraction states using an ultrasound device and a linear probe. The probe is placed on the lateral gastrocnemius muscle and parallel to the muscle fibers. The maximum horizontal distance between the two hyperechoic fasciae on both sides of the muscle is recorded as the muscle thickness.

5

Description
Blood inflammatory factors
Timepoint
The first sample is collected before the intervention and the second sample is collected 48 hours after the intervention.
Method of measurement
To assess gastrocnemius muscle tissue irritation after dry needling, serum C-reactive protein and creatine kinase levels are measured through a blood test.

6

Description
Dorsiflexion range of motion
Timepoint
Before, immediately after, 48 hours and one week after receiving the intervention
Method of measurement
Ankle dorsiflexion range of motion is measured by bringing the ankle close to the shin and using a goniometer. The fixed probe of the goniometer is placed on the shin and the movable probe is placed on the dorsum of the foot.

7

Description
Pain
Timepoint
Before, 48 hours after, and one week after receiving the intervention
Method of measurement
The NPRS scale is used to determine the patient's initial pain intensity (not the pain from dry needling) before, immediately after, 48 hours after, and one week after the intervention.

Intervention groups

1

Description

Intervention group:In this group, the dry needling technique is performed as in the control group. Then, immediately after the dry needling is completed, a moist hot pack with a temperature of about 40-45 degrees is placed directly on the gastrocnemius muscle for 20 minutes. The aim of this action is to increase blood circulation, improve muscle flexibility, and reduce pain in the area. The patient is placed in a comfortable prone position and the compress is covered with a thin towel to prevent direct contact with the skin. The time of 20 minutes for heat therapy has been selected based on previous studies and clinical standards to achieve optimal therapeutic effects such as increased blood circulation.

Category

Rehabilitation

2

Description

Intervention group: In this group, dry needling is performed on the gastrocnemius muscle, as in the control group. Immediately after that, the IPOC protocol is performed. For this purpose, a non-digital blood pressure cuff is used on the proximal part of the lower limb to apply arterial occlusion pressure (peak systolic pressure + 50 mmHg) for 5 minutes, then the cuff is completely deflated and the perfusion phase begins, which also lasts 5 minutes. This ischemia-perfusion cycle is repeated 3 consecutive times. A blood pressure cuff with a width of about 15-20 cm will be used to distribute the pressure evenly around the limb and reduce the risk of tissue damage. The peak systolic pressure + 50 mmHg and 3 5-minute cycles have been selected according to studies and clinical standards to prevent damage and achieve optimal therapeutic effects.

Category

Rehabilitation

3

Description

Control group:This group receives only dry needling treatment and serves as the control group. To start the treatment, the patient should lie down in a relaxed position. The trigger point location is found using manual touch. To apply the needle, we disinfect the area with cotton soaked in alcohol. Acupuncture needles (Dong bang Acuprime Ltd, with dimensions: 2.5mm*50mm, Korea) are applied to the trigger point using the dry needling technique. The needle, which is held with the dominant hand, is quickly inserted into the trigger point according to the Hong method and a local twitch response is observed. Then the needle is pulled out but not removed from the skin and re-entered into the trigger point. This is repeated until no local twitch response is observed after 10 needle movements. When examining and determining the exact location of the trigger points, if there is more than one painful point, the point that causes the most pain is evaluated and treated. This point is marked to remain constant throughout the process.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

in physiotherapy clinics affiliated with the Faculty of Rehabilitation Sciences, Tabriz University o

Full name of responsible person

Hakimeh adigozalih

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hakimeh adigozali

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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