

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing of the effect of gluteus maximus, gluteus medius, and tensor fascia lata muscle needling versus sham needling on the findings of clinical tests and symptoms in patients with iliotibial band syndrome: A randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of tensor fascia lata, gluteus medius, and gluteus maximus muscle needling with sham needling on symptoms and findings of the clinical tests in patients with iliotibial band syndrome

Design

Clinical trial study with a control group with parallel groups, double-blind (patient and investigator), randomized, phase 2 on 30 patients, randomization by permutation method with Pass software

Settings and conduct

The sampling method is simple, selected from active individuals in Yazd city. The participants are patients with iliotibial band syndrome who are in the subacute or chronic phase of the disease and have positive diagnostic test results for the Noble, Ober, Rene, and modified Thomas tests.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 45 years, pain and tenderness at the site of the band's attachment to the lateral epicondyle of the femur, activity level 5 to 10 according to the Tegner scale. Exclusion criteria: Body mass index greater than 30, any musculoskeletal, orthopedic and neurological disorder, history of knee injury or history of physiotherapy in the previous 12 months in the knee, limited range of motion, fibromyalgia or chronic pain syndrome, systemic inflammatory diseases, corticosteroid injections or use of anti-inflammatory drugs in the past month, severe fear of needles, use of anticoagulant drugs, uncontrolled diabetes

Intervention groups

Patients will be treated in two groups: muscle needling and sham needling. Both groups will receive 10 sessions of conventional treatment, including TENS, ultrasound, hot packs, and stretching exercises. The intervention

group will receive dry needling for 5 sessions over two weeks, and the control group will receive sham needling for 5 sessions over two weeks.

Main outcome variables

Pain, lower limb function, findings of Rene, Noble, Uber, and the modified Thomas clinic tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160221026674N9**

Registration date: **2026-01-24, 1404/11/04**

Registration timing: **prospective**

Last update: **2026-01-24, 1404/11/04**

Update count: **0**

Registration date

2026-01-24, 1404/11/04

Registrant information

Name

Marzieh Mohamadi

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-31, 1404/11/11

Expected recruitment end date

2026-08-02, 1405/05/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of the effect of gluteus maximus, gluteus medius, and tensor fascia lata muscle needling versus sham needling on the findings of clinical tests and symptoms in patients with iliotibial band syndrome: A randomized clinical trial

Public title

Studying the effect of needling muscles attached to the iliotibial band on clinical symptoms of patients with iliotibial band syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with iliotibial band syndrome in the subacute or chronic phase of the disease Aged between 18 and 45 years Presence of pain and tenderness (4 or higher on the numerical pain scale) at the site of attachment of the band to the lateral epicondyle of the femur Activity level 5 to 10 according to the Tegner scale

Exclusion criteria:

Body mass index greater than 30 Any orthopedic or neurological disorder A history of knee injury or history of knee physiotherapy in the previous 12 months Limited range of motion Fibromyalgia or chronic pain syndrome Systemic inflammatory diseases Corticosteroid injections or use of anti-inflammatory drugs in the past month Phobia of needles Use of anticoagulant drugs Uncontrolled diabetes Any musculoskeletal disorder in the lower extremities except iliotibial band syndrome

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study will be the permutation block method, which will be generated using the PASS 2021 software. A desired random list, consisting of 5 blocks of 6, will be generated. The project

manager will carry out this process. The allocation of samples will be done in a 1:1 ratio. In order to conceal the allocation, opaque and sealed envelopes will be used, which will be opened by the therapist after the evaluation process is completed by the evaluator.

Blinding (investigator's opinion)

Double blinded

Blinding description

The assessor and the therapist are two separate individuals, and the assessor is blind to the intervention groups. Patients are unaware of the intervention when receiving the sham needling technique.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Ethics committee, Research and Technology Vice-Chancellor, 7th floor, central building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7198754361

Approval date

2025-12-03, 1404/09/12

Ethics committee reference number

IR.SUMS.REHAB.REC.1404.023

Health conditions studied**1****Description of health condition studied**

Iliotibial band syndrome

ICD-10 code

M76.3

ICD-10 code description

Iliotibial band syndrome

Primary outcomes**1****Description**

Pain intensity

Timepoint

Before, one day after and two weeks after treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Lower Limb Function

Timepoint

Before, one day after and two weeks after treatment

Method of measurement

Lower extremity functional scale

2**Description**

The findings from the Rene, Noble, Uber, and modified Thomas diagnostic tests

Timepoint

Before, one day after and two weeks after treatment

Method of measurement

Positive or negative test result

Intervention groups**1****Description**

Intervention group:10 sessions of Burst TENS with a pulse frequency of 100 Hz and a burst frequency of 10 Hz, a pulse width of 200 microseconds, for 20 minutes10 sessions of continuous ultrasound (duty cycle 100%), with a frequency of 3 MHz, an intensity of 1 W/cm2, and a duration of 5 minutes10 sessions of hot packs for 20 minutes10 sessions of stretching exercises for the tensor fascia lata, gluteus maximus, and gluteus medius muscles in four sets of 30 seconds5 sessions (every other day) of static dry needling in the motor points of the tensor fascia lata, gluteus maximus, and gluteus medius muscles for 20 minutes

Category

Rehabilitation

2**Description**

Control group: 10 sessions of Burst TENS with a pulse frequency of 100 Hz and a burst frequency of 10 Hz, a pulse width of 200 microseconds, for 20 minutes10 sessions of continuous ultrasound (duty cycle 100%), with a frequency of 3 MHz, an intensity of 1 W/cm2, and a duration of 5 minutes10 sessions of hot packs for 20 minutes10 sessions of stretching exercises for the tensor fascia lata, gluteus maximus, and gluteus medius muscles in four sets of 30 seconds5 sessions (every other day) of sham dry needling in the the tensor fascia lata, gluteus maximus, and gluteus medius muscles with guide pressure and without entering the patient's body

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Ali Barzegar

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Pardis of Shahid Sadoughi University of Medical Sciences, Shohadaye gomnam boulevard, Aalam square, Yazd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

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Research and Technology Vice-Chancellor, 7th floor, central building of Shiraz University of Medical Sciences, Zand Street

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Mohamadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences, after Amir-al-Momenin Burn Accident Hospital, Shahid Doran Campus, Sadra Town Road

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

Data collection form including primary and secondary outcomes, informed consent form, and SPSS file

When the data will become available and for how long

After the publication of the study results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Recording information in scientific databases

From where data/document is obtainable

Correspondence with the project manager by email.
mohamadm@sums.ac.ir

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

Maximum one month after sending the request by email

Comments