Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Recruitment status
recruiting

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 Sciencess
Full name of responsible person
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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
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Street address
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
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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

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Person responsible for updating data

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Physiotherapy
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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