Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Shockwaves Therapy on Lower Extremity Pain, Function and Torque Ratio of Abductors to Hip Adductors in Runners with Iliotibial Band Syndrome

Protocol summary

Study aim

Investigating the effect of shockwave therapy on pain, function and kinematics of lower limbs in runners with iliotibial band syndrome (ITBS) • Determine the effect of actual (SWT) and sham SWT (sham-SWT) on pain in runners with ITBS • Determining the effect of real SWT and sham-SWT on lower limb performance in runners with ITBS • Determining the effect of actual SWT and sham-SWT on and ratio of abductors to hip adductors torque in runners with ITBS. • Comparison of the effect of real SWT and sham-SWT on pain in runners with ITBS • Comparison of the effect of real SWT and sham-SWT on lower limb performance in runners with ITBS • Comparison of the effect of real SWT and sham-SWT on the torque ratio of abductors to hip adductors in runners with ITBS

Design

A controlled, parallel-group, double-blind, randomized clinical trial on 30 runners with ITBS. The intervention includes 2 times a week for 4 weeks of shockviotherapy

Settings and conduct

The study will be conducted on 30 people with ITBS who are runners of Semnan province athletics committee. People are randomly divided into two groups, and group 1 receives shock therapy twice a week along with routine physiotherapy for 4 weeks, and the sham control group receives shock therapy along with routine physiotherapy. Hip abductor and adductor torques, pain intensity and lower limb function will be evaluated before the intervention and after the last session of the intervention. The participant, the therapist and the evaluator are blind.

Participants/Inclusion and exclusion criteria

• Age between 18 and 50 years • Regular runner • Having pain of at least 4 • Diagnosis of ITBS • Pain intensity Noble's test positive

Intervention groups

Group 1) Shock wave therapy with routine physiotherapy
Group 2) Sham shock therapy (control group) with routine physiotherapy

Main outcome variables

pain; performance; Torque ratio of abductors to hip abductors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230107057073N1**
Registration date: **2023-02-21, 1401/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-21, 1401/12/02**
Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Esmaeil Tabbakhi bonab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Shockwaves Therapy on Lower Extremity Pain, Function and Torque Ratio of Abductors to Hip Adductors in Runners with Iliotibial Band Syndrome

Public title

the effect of shockwave therapy on pain and performance in runners with iliotibial band syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 50 years old A runner with experience of more than one year and regular weekly training and participating in cross-country competitions and running at least 20 km per week Having pain for at least 4 weeks in the lateral area of the knee ITBS diagnosis based on history Clinical examination and modified treadmill test • Pain intensity: grade 1 - pain after running, but does not limit the distance or speed of running. Grade 2 - pain while running but no limitation of running distance or speed. Grade 3 - Pain during running severe enough to limit distance or speed. and grade 4 - the pain is severe enough to prevent running. To continue with the baseline assessment, subjects had to report a pain grade of 3 or 4. Positive Noble's test, if pain was present at 30 to 40 degrees of flexion when a finger was held on the lateral condyle of the knee during flexion/extension. It is experienced.

Exclusion criteria:

Symptoms of knee injury Previous treatment of ITBS in the last 6 months Use of painkillers or NSAIDs in the past two weeks Use of hot pack and icepack Stretching or weight lifting two days before History of knee surgery pregnancy Using a heart battery Taking anticoagulants Fracture of damaged leg bones in the last 12 months History of treatment with shock wave infection tumor diabetes Rheumatic disease Severe heart disease Psychiatric illness Other severe systemic diseases Unwillingness to accept any of the interventions in the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by lottery means that at the beginning of the study and in the first referring patient, the group names are written in 2 pieces of paper and placed in one of two intervention or control groups by the patient operator's removal. By identifying the first patient's treatment group, the next patient will be assigned to the other group and thus the patients will be divided into groups. In this study, the researcher, evaluator, and participants are unaware of the study group allocation and only the operator is aware of the group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants enter the research after completing the informed consent form and are divided into two groups. From this stage, only the operator of the device has been informed from the medical group and the participants, the resarcher and the evaluator to avoid the bias in the study from the subjects of the study groups No information is available.

Placebo

Used

Assignment

Parallel

Other design features

Examples include athletes who are brought to the attention of sports federations, who will begin treatment with the approval of the center.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

No. 10, Payvand 21., Payam Blvd., Paknejad Bvd., Saadatabad

City

Seman

Province

Semnan

Postal code

۱۹۸۱۹۴۴۴۱۵

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.SEMUMS.REC.1401.261

Health conditions studied

1

Description of health condition studied
ITBS
ICD-10 code
M76.3
ICD-10 code description
Iliotibial band syndrome

Primary outcomes

1

Description
pain
Timepoint
Before starting the study, immediately after treatment
Method of measurement
VAS

2

Description
Lower Extremity Function
Timepoint
Before starting the study, immediately after treatment
Method of measurement
modified treadmill

3

Description
Torque Ratio of Abductors to Hip Adductors
Timepoint
Before starting the study, immediately after treatment
Method of measurement
Isokinetic

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: It will be applied with 500 pulses with a frequency of 15 Hz in the selected area. Depending on the level of pain tolerance, it will increase up to 2000 pulses. Finally, 3 trigger points in the outer thigh area with 700 pulses and 15 Hz, twice a week for 4 weeks. Shockwave device: ESM, Swiss Dolorclast model, Swiss along with routine physiotherapy
Category
Treatment - Devices

2

Description
Control group: Sham shock therapy along with routine physical therapy. All people in the control group will receive the shockwave in the same position with the device turned on but in such a way that it does not shock their body. First, a few shocks below the receiving threshold and then the device turns off.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Sports and Youth Department of Semnan Province
Full name of responsible person
Seyyed Mohammad Taghi Alavi
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Semnan, Golestan town, Nagaristan Square, West Nagaristan Blvd., building number 2
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Atefeh Aminianfar
Street address
School of rehabilitation, Semnan University of Medical Sciences, 5 km of Semnan-Damghan road
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aminfar@semums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Dr. Atefeh Aminianfar
Position
School of rehabilitation, Semnan University of Medical Sciences, 5 km of Semnan-Damghan road
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Person responsible for updating data

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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