# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)

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**Email address**

esmaeiltabbakhi1996@gmail.com

**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**

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**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
**Street address**
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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**Phone**
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**Email**
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 scientific inquiries

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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