

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Study the Effect of Extracorporeal Shockwave Therapy on Iliotibial Band Thickness, Pain and lower limb function in Athletes with Iliotibial Band Friction Syndrome

Protocol summary

Study aim

The aim of this study is to investigate the effect of shock wave therapy on the thickness of the iliotibial band, pain and lower limb function in athletes with iliotibial band wear syndrome

Design

A randomized clinical trial with a control group with double-blind parallel groups is conducted on 42 patients, 21 of whom are the intervention group and 21 of whom are the control group

Settings and conduct

The study will be conducted on 42 people with iliotibial band syndrome. The people will be randomly divided into two intervention and control groups. The control group will receive routine physiotherapy three times a week for three weeks, and the control group will receive routine physiotherapy twice a week. They receive shock therapy for three weeks. In this study, the participants and the researcher are blinded

Participants/Inclusion and exclusion criteria

Randomized double blind clinical trial with parallel groups on 42 runners with iliotibial band syndrome twice a week for three weeks shockwave therapy

Intervention groups

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

Main outcome variables

Pain and function of lower limbs and iliotibial band thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231217060447N1**

Registration date: **2024-01-22, 1402/11/02**

Registration timing: **prospective**

Last update: **2024-01-22, 1402/11/02**

Update count: **0**

Registration date

2024-01-22, 1402/11/02

Registrant information

Name

Nooshin Rasekhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3251 6402

Email address

dr.nrasekhi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the Effect of Extracorporeal Shockwave Therapy on Iliotibial Band Thickness, Pain and lower limb function in Athletes with Iliotibial Band Friction Syndrome

Public title

Study the Effect of Extracorporeal Shockwave Therapy on Iliotibial Band Thickness, Pain and lower limb function in Athletes with Iliotibial Band Friction Syndrome	
Purpose	participants enter the research and are placed in two groups. At this stage, the machine operator knows about the people in the treatment groups, and the participants, the researcher, do not know about the people in the studied groups to avoid bias in the study.
Treatment	
Inclusion/Exclusion criteria	Placebo
Inclusion criteria:	Used
Age between 18_50 years Runners with experience of more than one year and regular weekly training and participation in running competitions Having pain at least 4 weeks in the lateral of the knee Pain intensity between 4_7	Assignment
Exclusion criteria:	Parallel
Symptoms of knee injury Previous treatment of Iliotibial band syndrome within the last six months Pain intensity more than 7 Using of NSAIDs during the last two weeks Using of hot pack and ice pack Stretching or weight lifting for the previous two days History of knee surgery Pregnancy Broken Leg bones affected in the last 12 months History of treatment with Shock Wave Tumor Diabetes Rheumatic disease Severe Heart disease Psychiatric disease Unwillingness to accept any intervention in the study	Other design features
Age	Secondary Ids
From 18 years old to 50 years old	empty
Gender	Ethics committees
Both	1
Phase	Ethics committee
N/A	Name of ethics committee
Groups that have been masked	Ethics Committee of Semnan University of Medical Sciences
- Participant - Investigator	Street address
Sample size	Semnan University of Medical Sciences and Health Services, Basij Boulevard ,Semnan, Iran
Target sample size: 42	City
Randomization (investigator's opinion)	Semnan
Randomized	Province
Randomization description	Semnan
The samples are assigned (to two groups) randomly and using the method of random permutation blocks with 6 blocks of 6, assigned to the two groups. In this method, A will represent the intervention group and B will represent the control group. In this way, the order of A and B interventions in the form of blocks from 1 to 6 is determined by the methodological consultant of the project, and is provided to the executive supervisor of the project, and the researcher obtains an assignment from the executive supervisor to assign each qualified person. The supervisor first selects the block using a random number generator (or dice roll) and then the eligible individuals are assigned to one of the two groups A or B in the order specified in the table (top to bottom). And the sequence of each item will be crossed out. It should be noted that if a block is selected based on random numbers that have already filled all 6 sequences, another random number will be selected again for that person.	Postal code
Blinding (investigator's opinion)	3514799442
Double blinded	Approval date
Blinding description	2024-01-01, 1402/10/11
After completing the informed consent form, the	Ethics committee reference number
	IR.SEMUMS.REC.1402.232
	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
	Timepoint
	Before starting the study and immediately after treatment
	Method of measurement
	According to Visual Analogue Scale (VAS)

2

Description

Lower Limbs Function

Timepoint

Before starting the study and immediately after treatment

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS)
Questionnaire

3

Description

Iliotibial Band Thickness

Timepoint

Before starting the study and immediately after treatment

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, shock wave ESM device model EMS SWISS DOLORCLAST will be performed. First, the most painful area of the external femoral condyle of the patient will be evaluated using point touch. Then RSWT with 500 pulses in mJ/mm² (2 Bar) 0.10 with a frequency of 15 Hz will be applied in the selected area. Depending on the level of pain tolerance, it will increase up to 2000 mJ/mm² pulse (2 Bar) 0.10 to 0.40 mJ/mm² (4 Bar). No local anesthesia will be used

Category

Treatment - Devices

2

Description

Control group: 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

Neuromuscular Rehabilitation Research Center ,Next
To Nemat Bastani ,Quds Blvd , Semnan ,Iran

Full name of responsible person

Nooshin Rasekhi

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Semnan University of Medical Sciences and Health
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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

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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

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

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