Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 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 physiotherapyکار

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

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Nooshin Rasekhi
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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

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

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

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

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.

Blinding (investigator's opinion)

Double blinded

Blinding description

After completing the informed consent form, the 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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences and Health Services, Basij Boulevard ,Semnan, Iran

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Province

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3514799442

Approval date

2024-01-01, 1402/10/11

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
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Sponsors / Funding sources

1

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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
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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