

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 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**

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

##### **City**

Semnan

##### **Province**

Semnan

##### **Postal code**

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/mm<sup>2</sup> (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/mm<sup>2</sup> pulse (2 Bar) 0.10 to 0.40 mj/mm<sup>2</sup> (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

#### **Street address**

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

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Semnan

#### **Postal code**

3514799442

#### **Phone**

+98 23 3344 1022

#### **Email**

dr.nrasekhi@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Semnan University of Medical Sciences

##### **Full name of responsible person**

Dr Atefeh Aminianfar

##### **Street address**

Semnan University of Medical Sciences, Semnan-Damghan Road, 5th km

##### **City**

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##### **Province**

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##### **Postal code**

3513138111

##### **Phone**

+98 23 3365 4180

##### **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**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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