

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of radial extracorporeal shockwave therapy with dryneedling in patients with iliotibial band syndrome

Protocol summary

Study aim

The purpose of this study is to compare the effect of shock wave therapy with dry needling on the treatment of symptoms of patients with iliotibial band syndrome

Design

A single-blind randomized controlled clinical trial with a parallel group design of 40 patients.

Settings and conduct

The 40 patients who refer to physical medicine clinics and rehabilitation centers in Isfahan will be enrolled in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include ages over 18 years, positive Ober test, at least one trigger point on the iliotibial band and normal neurologic exam. Exclusion criteria include previous surgery on the affected knee in the last 12 months, previous treatment for ITBS in the last 2 months, symptoms of radiculopathy, past history of trauma or bone fracture of the affected leg, knee or femur in the last 12 months, coagulopathy or receiving anticoagulants, use of non-steroidal anti-inflammatory drugs later than two weeks before baseline.

Intervention groups

In this study, 20 participants will be assigned to shockwave therapy group and 20 in the dry needling therapy group. In the first group, patients will receive shockwave therapy four times in four weeks. In the second group, patients undergo 8 sessions (two times a week) of dry needling.

Main outcome variables

The amount of pain based on visual analogue scale (VAS) and lower extremity functional scale (LEFS) and length of iliotibial band.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190824044598N1**

Registration date: **2019-10-16, 1398/07/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-16, 1398/07/24**

Update count: **0**

Registration date

2019-10-16, 1398/07/24

Registrant information

Name

Razieh Maghroori

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3262 0338

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of radial extracorporeal shockwave therapy with dryneedling in patients with iliotibial band syndrome

Public title

Comparison of radial extracorporeal shockwave therapy

with dryneedling in iliotibial band syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

positive ober test at least one trigger point on the iliotibial band normal neurologic exam

Exclusion criteria:

previous surgery on the affected knee in the last 12 months previous treatment for ITBS in the last 2 months symptoms of radiculopathy past history of trauma or fracture of leg or knee or femur in the last 12 months coagulopathy or receiving anticoagulants use of non steroidal anti inflammatory drugs later than two weeks before baseline

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random allocation: In this study, a specific code will be given to each of the individuals who are eligible for inclusion and exclusion criteria. Then 20 people will be allocated in the group of dry needling therapy and 20 people in the group of shock wave therapy via sortition.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the main executor is considered as a physician who knows the goals of the study and the types of treatments. The patients know their treatment, but they will not be aware of how the treatments will be compared. The statistical consultant does not know the two methods of treatment and the name of the patients so he randomized and assigned patients code and analyze the results. Therefore, this study is a single blind clinical trial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St

City

Isfahan

Province

Isfahan

Postal code

8514933373

Approval date

2019-06-22, 1398/04/01

Ethics committee reference number

IR.MUI.MED.REC.1398.161

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

The amount of pain

Timepoint

Before starting the study, immediately after treatment and one month after the end of treatment

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Lower Extrimity Function

Timepoint

Before starting the study, immediately after treatment and one month after the end of treatment

Method of measurement

Questionnaire of Lower Extrimity Functional Scale

3

Description

Iliotibial band length

Timepoint

Before starting the study, immediately after treatment and one month after the end of treatment

Method of measurement

Meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 the patients will receive ECSWT with radial probe delivering 2,000 shock waves of 2-4 Bar per session with 15 Hz frequency directed to maximum tender points on lateral aspect of thigh for four sessions by 1 week intervals.

Category

Treatment - Devices

2

Description

Intervention group: 20 patients will be treated with dry needles according to the protocol (sterile epoxy needles 0.25 mm in diameter and 25 gage in length). Each point will be treated for 15 minutes. Treatment is done two sessions in week for four weeks.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Leila Karshenas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Leila Karshenas

Position

Resident, Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, information on the main outcomes and results of the study will be published. Currently, there is no plan for publishing other patient information, even in an unidentified manner.

When the data will become available and for how long

Since 1399

To whom data/document is available

Unlimited

Under which criteria data/document could be used

Using documentation with citation

From where data/document is obtainable

Download the article from the journal website or contact the corresponding author of the article

What processes are involved for a request to access data/document

Download the article from the journal website or contact the corresponding author of the article

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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