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 referr to physical medicine clinics and rehabilitation centers in Isfahan will 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 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 ricieve shockwave thepay four times in four weeks. In the second group, patients undergo 8 sessions (tow times a week) of dry needling.

Main outcome variables
The amount of pain based on visual analogue scale (VAS) and lower extrimity functional acale(LEFS) and legnth 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)
Phone
+98 31 3262 0338
Email address
raziehmaghroor@med.mui.ac.ir

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 coagulapathy or recegiving 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

Isfehan

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 lenghth

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 tigh for rour 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 needles0.25 mm in diameter and 25 gage in length). Each point will be treated for15 minutes. Treatment is done tow 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
Street address
Ebnesina Ave
City
Isfahan
Province
Isfehan
Postal code
8514933373
Phone
+98 31 3445 5051
Email
amin@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Razieh Maghoori
Street address
Hezar Jarib St
City
Isfahan
Province
Isfehan
Postal code
۸۱۷۴۶۷۳۴۶۱
Phone
+98 31 3668 0048
Email
Alzahra@mui.ac.ir
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, Phisycal Medicine and Rehabilitation
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 6., Besharat Ave., Fajr Blvd
City
Isfahan
Province
Isfehan
Postal code
8514933373
Phone
+98 31 4251 6116
Email
krs.leila@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Leila Karshenas
Position
Resident, Phisycal Medicine and Rehabilitation
Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine
Street address
No. 6., Besharat Ave., Fajr Blvd
City
Najafabad
Province
Isfehan
Postal code
8514933373
Phone
+98 31 4251 6116
Email
krs.leila@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Leila Karshenas
Position
Resident, Phisycal Medicine and Rehabilitation
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 6., Besharat Ave., Fajr Blvd
City
Najafabad
Province
Isfehan
Postal code
8514933373
Phone
+98 31 4251 6116
Email
krs.leila@gmail.com

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