Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of routine physical therapy with and without core stability in improving pain, functional mobility and quality of life in patients with iliotibial band syndrome

Protocol summary

Study aim
Primary aim of this study is to evaluate effectiveness of core stability exercises with and without routine physical therapy (RPT) on pain and functional mobility in patients with iliotibial band (ITB) syndrome. Secondary aim, evaluate effectiveness of core stability exercises on quality of life in iliotibial band syndrome (ITBS)

Design
Single center, parallel group, concealed, double blind, randomized controlled trial of 40 participants

Settings and conduct
University Physical Therapy and Rehabilitation Clinic, University of Lahore. Participants and outcome assessor blinded.

Participants/Inclusion and exclusion criteria
Participants were included if age between 18-50 years in both the gender, presence of local tenderness over the lateral epicondyle, positive noble compression test and modified ober's test. Participants with systemic illness, peripheral nerve involvement and any type of Arthritis in lower limb, Tumor and history of previous knee trauma and surgery were excluded.

Intervention groups
In control group participants follows RPT that includes 1- Specific stretching exercises of ITB, tensor fascia latae, and gluteus medius 2- Soft tissue and medial patella mobilizations 3- Active release soft-tissue mobilization and myofascial release 5- Strengthening exercises for ITBS 6- Cryotherapy, Phonophoresis, While interventional group participants follow RPT and core stability exercise , which includes: Transversus abdominus (30 reps with 8s hold) Bracing with heel slides, Abdominal bracing, bridging, standing, standing row, walking, leg lifts. Paraspinals/multifidi (30 reps with 8s hold). Quadruped legs lifts and arm lifts with bracing, Quadruped alternate legs and arms lifts with bracing. Quadratus lumborum and obliques (30 reps with 8s hold). Side plank with knees flexed and extended Trunk curl

Main outcome variables
Numeric Pain Rating Scale and Lower Extremity Functional Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200211046456N1**
Registration date: **2020-08-16, 1399/05/26**
Registration timing: **retrospective**

Last update: **2020-08-16, 1399/05/26**
Update count: **0**

Registration date
2020-08-16, 1399/05/26

Registrant information

Name
Rabia Saeed

Name of organization / entity
The University of Lahore

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-05, 1397/04/14

Expected recruitment end date
2019-07-30, 1398/05/08

Actual recruitment start date
2018-08-10, 1397/05/19
Actual recruitment end date
2019-06-18, 1398/03/28
Trial completion date
2019-08-02, 1398/05/11

Scientific title
Effects of routine physical therapy with and without core stability in improving pain, functional mobility and quality of life in patients with iliotibial band syndrome

Public title
Effect of core stability exercise in treatment of iliotibial band syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age between 18-50 years in both the gender Presence of local tenderness over the lateral epicondyle Subjects with Positive Noble compression test Subjects with Positive modified ober's test
Exclusion criteria:
Systemic illness Peripheral nerve involvement in lower extremity Any type of Arthritis of lower limb Tumor History of previous knee trauma and surgery
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
This study was designed to be a parallel group randomized controlled trial. Random numbers were generated, without stratification, from 1-40 using an online random numbers generator in two sets by an independent statistician. Set 1 was assigned routine physical therapy and set 2 was assigned core stability exercises and routine physical therapy. Opaque, sealed envelope method was used to randomly assign patients (in a 1:1 ration) into both groups and unsealed by a researcher after baseline testing. Outcome assessors were unaware of group assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
After randomisation, patients were told about their treatment regime by their therapist, keeping blind about the other group treatment. Patients were only informed about treatment programme similarities in both groups (soft tissue, cryotherapy, stretching and strengthening exercises). Both treatment programmes were tailored to the patient's abilities to make sure all eligible patients could complete the trial. Outcome assessors and data analyzers were masked to group allocation. Patients were told not to talk about the treatment protocol they were given during the trial with the outcome assessors and could contact their therapist in case of any problems during trial participation. Besides, if two or more study participants were in the clinic at the same time, they were assigned to different treatment areas without any opportunity to observe each other or their treatment times were rearranged to prevent unintended crossover.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Review Board of University of Lahore
Street address
1-KM Defence Road, Off Bhobatian Chowk, Lahore
City
Lahore
Postal code
54000
Approval date
2018-05-31, 1397/03/10
Ethics committee reference number
IRB-UOL-FAHS/347/2018

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
At baseline (before intervention), 3 weeks of treatment and at end of treatment (6 weeks)
Method of measurement
Numeric Pain Rating Scale

2

Description
Functional Mobility
Timepoint
At baseline (before intervention), 3 weeks of treatment and at end of treatment (6 weeks)
Method of measurement
Lower Extremity Functional Scale

Secondary outcomes

1

Description
Quality of Life
Timepoint
At baseline (before intervention) and at end of treatment (6 weeks)
Method of measurement
Short Form (36) Health Survey

Intervention groups

1

Description
Intervention group: This group include combination of routine physical therapy and core stability exercises as part of treatment. Core stability exercise includes: 1- Transversus abdominus (perform 30 reps with 8s hold) Bracing with heel slides, Abdominal bracing, bridging, standing, standing row, walking, leg lifts. 2- Paraspinals/multifidi (perform 30 reps with 8s hold). Quadruped legs lifts and arm lifts with bracing, Quadruped alternate legs and arms lifts with bracing. 3- Quadratus lumborum and obliques ((perform 30 reps with 8s hold). Side plank with knees flexed and extended. 4- Trunk curl. (Conventional) Routine physical therapy protocol include 1- specific stretching exercises focused on the ITB, tensor fascia latae, and gluteus medius. 2- soft tissue and medial patella mobilizations. 3- active release soft-tissue mobilization techniques. 4- foam roller as a myofascial release tool. 5- strengthening exercises for ITBS. 6- cryotherapy. 7- phonophoresis. 8- immobilization. Total treatment duration was 40 mins per session, 3 days a week (on alternate basis) for 6 weeks.
Category
Rehabilitation

2

Description
Control group: In this group participant only received (Conventional) Routine physical therapy protocol include 1- specific stretching exercises focused on the ITB, tensor fascia latae, and gluteus medius. 2- soft tissue and medial patella mobilizations. 3- active release soft-tissue mobilization techniques. 4- foam roller as a myofascial release tool. 5- strengthening exercises for ITBS. 6- cryotherapy. 7- phonophoresis. 8- immobilization. Total treatment duration was 40 mins per session, 3 days a week (on alternate basis) for 6 weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
University Physical Therapy and Rehabilitation Clinic, University of Lahore
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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
The University of Lahore
Proportion provided by this source
100
Public or private sector
Private
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
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Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
Yes - There is a plan to make this available
Clinical Study Report
No - There is not 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
No - There is not a plan to make this available
Title and more details about the data/document
Study protocol, statistical analysis plan, informed consent form will be shared for primary and secondary outcome measure with interested research after considering the ethics and confidentiality.
When the data will become available and for how long
Data will be available after 9 months of publication for 2 consecutive years.
To whom data/document is available
Data will only be shared with individual researcher and academic researchers working with sports/orthopedic injuries. Data will not be shared for any commercial purposes/businesses for any reasons.
Under which criteria data/document could be used
Data can be used under confidentiality and medical ethics
From where data/document is obtainable
Data can be obtained by emailing at rabiasaeed534@gmail.com.

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

Simple email can do this. But this can take up to 6 weeks depends on busy schedule of researcher.

Comments