

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of leg related exercises on foot posture and dynamic force distribution pattern in recreational runner with medial tibial stress syndrome

Protocol summary

Study aim

Investigating of the effects of leg related exercises training on foot posture and dynamic force distribution pattern in recreational runner with medial tibial stress syndrome.

Design

The present study is a phase 3 randomized controlled trial with parallel groups. In this study 50 recreational runner with medial tibial stress syndrome from 18 to 35 years of age will be selected through screening in the university and community of Shahrud city. The participants will randomly be assigned into two groups of control (anti-pronation foot orthoses) and lower leg related exercise (anti-pronation foot orthoses and exercise).

Settings and conduct

The research will be conducted in the Shahrood city and participants will be selected from the Universities of this city and community. Blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Leg pain exertion caused by exercise, which lasts for several hours or days after exercise; Place of pain on the posterior-medial border of the tibia; Exclusion criteria: A history of parenthesis or other symptoms indicating legs pain caused by exercise (such as tibial fractures stress and chronic compartment syndrome); history of traumatic injury and lower limb surgery during the last 6 months; leg length difference.

Intervention groups

Lower extremity related exercise group: In addition to anti-pronation foot orthoses, this group also receives an exercise training intervention. Exercise training intervention is focused in the stretching and strengthening exercises that has been selected based on previous studies that show the effectiveness of these exercises for those with overpronation foot. The strengthening exercises involves of foot intrinsic

muscles, toe flexor muscles, plantar flexors and foot inverters muscles. The stretching exercises of the training intervention is provided to enhance the flexibility of the soleus and gastrocnemius muscles. Participants in the intervention group are trained by a corrective training specialist. The training program conduct for 24 weeks, three sessions per week and for 1 hour in each session. Control group: Participants of this group receives anti-pronation foot orthoses.

Main outcome variables

Dynamic arch index; Dynamic distribution of plantar forces; Foot and ankle muscle strength; Foot and ankle muscle endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170114031942N5**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **prospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Aynollah Naderi

Name of organization / entity

Shahrood University of Technology

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Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2018-04-20, 1397/01/31

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of leg related exercises on foot posture and dynamic force distribution pattern in recreational runner with medial tibial stress syndrome

Public title

Leg related exercises and medial tibial stress syndrome

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Leg pain exertion caused by exercise, which lasts for several hours or days after exercise; Place of pain on the posterior-medial border of the tibia; incidence of pain during the palpation should be at least 5 cm; the nature of the diffuse pain in the palpation of the tibia, which is limited to the posterior- medial border of the bone, the rugged surface of the bone in the area of discomfort or pain in the tibia bone.

Exclusion criteria:

A history of paresthesia or other symptoms indicating legs pain caused by exercise (such as tibial fractures stress and chronic compartment syndrome); history of traumatic injury and lower limb surgery during the last 6 months; leg length difference.

AgeFrom **18 years** old to **35 years** old**Gender**

Male

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants are enrolled by one of the research colleagues. An independent assessor, blinded person who has no further involvement in the study creates a random allocation sequence using a computer Software prior to the initiation of the study that use to randomize participants with 1:1 allocation ratio. A block randomization design (block size of 4) are applied to ensure an equal number of participants in each group. Group allocation are concealed in sequentially

numbered, opaque, sealed envelopes, and corresponding envelopes are opened after enrolled participants complete all baseline assessments.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of shahroud university of medical sciences

Street address

Seventh Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2018-02-06, 1396/11/17

Ethics committee reference number

IR.SHMU.REC.1396.168

Health conditions studied**1****Description of health condition studied**

Medial tibial stress syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Dynamic arch index

Timepoint

Before the intervention and 12 and 24 weeks after the intervention

Method of measurement

By using of Footscan

2**Description**

Dynamic distribution of plantar forces

Timepoint

Before the intervention and 12 and 24 weeks after the intervention

Method of measurement

By using of Footscan

3**Description**

Foot and ankle muscle strength

Timepoint

Before the intervention and 12 and 24 weeks after the intervention

Method of measurement

Dynamometer

4**Description**

Foot and ankle muscle endurance

Timepoint

Before the intervention and 12 and 24 weeks after the intervention

Method of measurement

Dynamometer

Secondary outcomes**1****Description**

Level of physical activity in the previous week

Timepoint

Before the intervention, 12 and 24 weeks after the intervention

Method of measurement

7-day Physical Activity Recall Questionnaire

2**Description**

Level of impairment caused by injury

Timepoint

Before the intervention, 12 and 24 weeks after the intervention

Method of measurement

Using a numerical rating scale

3**Description**

Activity limitations level

Timepoint

Before the intervention, 12 and 24 weeks after the intervention

Method of measurement

Using a numerical rating scale

4**Description**

perceived treatment effect

Timepoint

Before the intervention, 12 and 24 weeks after the intervention

Method of measurement

Using a patient perceived treatment effect questionnaire

Intervention groups**1****Description**

Intervention group: Intervention group: In addition to anti-pronation foot orthoses, this group also receives an exercise training intervention. Exercise training intervention is focused in the stretching and strengthening exercises that has been selected based on previous studies that show the effectiveness of these exercises for those with overpronation foot. The strengthening exercises involves of foot intrinsic muscles, toe flexor muscles, plantar flexors and foot inverters muscles. The stretching exercises of the training intervention is provided to enhance the flexibility of the soleus and gastrocnemius muscles. Participants in the intervention group are trained by a corrective training specialist. The training program conduct for 24 weeks, three sessions per week and for 1 hour in each session.

Category

Prevention

2**Description**

Control group: Participants of this group receives anti-pronation foot orthoses.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahrood city

Full name of responsible person

Aynollah Naderi

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Sponsors / Funding sources

Sponsor**Name of organization / entity**

Shahrood University of Technology

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

Shahrood University of Technology

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**

Shahrood University of Technology

Full name of responsible person

Aynollah Naderi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physical Education and Sports Science

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Shahrood University of Technology

Full name of responsible person

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Position

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

Shahrood University of Technology

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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 more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available