Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 exersice).

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

Country

Iran (Islamic Republic of)

Phone

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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 scienece
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.
Age
From **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
Street address
Shahrood University of Technology, Tehran Road
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3619995161
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Ay.naderi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Technology
Full name of responsible person
Aynollah Naderi
Street address
Tehran avenue, Shahroud, Semnan province
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3619995161
Phone
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Email
ay.naderi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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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Person responsible for updating data

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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