Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Effect of foot orthoses on pain and physical function of recreational runners with medial tibia stress syndrome

Protocol summary

Study aim
The survey the effect of foot orthoses on medial tibia stress syndrome in recreational runners
Design
The present research is a prospective, randomized, controlled, clinical trial with parallel groups.
Settings and conduct
Shahrood sports clubs
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 25 years; Taking running for at last 4 months; Running less than 45 min and/or less than 10 km per session and less than 3 times per week; having the ability to run at a self-selected speed for approximately 30 min and/or 5 km at a time. Exclusion criteria: History of lower limb traumatic injury or surgery within the last 6 months; Hallux valgus; Obvious leg-length discrepancy
Intervention groups
Orthoses group will use arch-support full-length foot-orthoses that made from 4-mm thick polypropylene of medium density (Durometer Shore 50A) with an approximately 15-mm high heel cup and a 25-mm peak height arch support. The control group will have their usual daily living conditions.
Main outcome variables
Pain severity; Functional impairment related to pain ; Physical activity level.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170114031942N8**
Registration date: **2018-05-29, 1397/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-29, 1397/03/08**
Update count: **0**
Registration date
2018-05-29, 1397/03/08

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-10, 1397/02/20
Expected recruitment end date
2018-10-12, 1397/07/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of foot orthoses on pain and physical function of recreational runners with medial tibia stress syndrome

Public title
Foot orthoses and medial tibia stress syndrome
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 25 years Taking up running in the

last 4 months, running less than 3 times per week for <45 min and/or <10 km per session Having the ability to run at a self-selected speed for approximately 30 min and/or 5 km at a time Pain is induced by exercise Pain is located in the distal half of the posteromedial side of tibia Not being overweight (BMI > 30 kg•m-2)

Exclusion criteria:

History of paresthesia Symptoms indicative of other causes of exercise-induced leg pain (such as tibial stress fracture and chronic compartment syndrome) History of used arch-support orthoses Receiving physiotherapy treatment in the previous 6 months Current using anti-inflammatory medications History of lower limb traumatic injury or surgery within the last 6 months Hallux valgus Obvious leg-length discrepancy

Age

From **18 years** old to **25 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each participant's foot can be a sample.

Randomization (investigator's opinion)

Randomized

Randomization description

First, participants are enrolled by one of the research colleague. Then, a random allocation sequence using a computer Software is created. In this sequence, participants with 1:1 allocation ratio are randomly divided into control and orthoses groups. A block randomization design (block size of 2, 4, and 6) is applied in this study. Group allocation is concealed in sequentially numbered, opaque, sealed envelopes. Envelopes will be opened after completion of 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

Hafte Tir Square, Shahroud

City

shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2018-03-11, 1396/12/20

Ethics committee reference number

IR.SHMU.REC.1396.194

Health conditions studied

1

Description of health condition studied

Medial tibial stress syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain severity

Timepoint

Before the intervention and 6, 12 and 18 weeks after the intervention

Method of measurement

Visual analog scale

2

Description

Activity limitations level

Timepoint

Before the intervention and 6, 12 and 18 weeks after the intervention

Method of measurement

Run distance

3

Description

Perceived Treatment Effect

Timepoint

Before the intervention and 6, 12 and 18 weeks after the intervention

Method of measurement

5-point Likert scale of perceived Treatment

4

Description

Dynamic Arch Index

Timepoint

Before the intervention and 6, 12 and 18 weeks after the intervention

Method of measurement

Footprint

5

Description
Lower extremity function
Timepoint
Before the intervention and 6, 12 and 18 weeks after the intervention
Method of measurement
Medial tibial stress syndrome score

Secondary outcomes

1

Description
Plantar pressure
Timepoint
Before the intervention and 6,12 and 18 weeks after the intervention
Method of measurement
Foot pressure plat

2

Description
Quality of life
Timepoint
Before the intervention and 6,12 and 18 weeks after the intervention
Method of measurement
Short Form (36) Health Survey

Intervention groups

1

Description
Intervention group: Arch-support full-length foot-orthoses were made from 4-mm thick polypropylene of medium density (Durometer Shore 50A) with an approximately 15-mm high heel cup and a 25-mm peak height arch support
Category
Prevention

2

Description
Control group: Routine daily activity
Category
Placebo

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

1

Sponsor
Name of organization / entity
Shahroud University of Technology
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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
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

Sport Medicine

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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

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