

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Name

Aynollah Naderi

Name of organization / entity

Shahrood University of Technology

Country

Iran (Islamic Republic of)

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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

Hafta 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

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

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