

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Compare the effect of prefabricated soft medical insole and custom-molded thermoplastic insole on plantar pressure distribution in athletes with Flexible flat Foot

Protocol summary

Study aim

Compare the effect of prefabricated soft medical insole and custom-molded thermoplastic insole on plantar pressure distribution in athletes with Flexible flat Foot

Design

Interventional study, without control and blinding, randomized, 18 subjects

Settings and conduct

This research is conducted at the Institute of sport sciences and Iran rehabilitation school. After making custom-molded thermoplastic insole in Iran rehabilitation school, order shoes and prefabricated soft medical insole, the tests are performed at the institute of sport on Pedar device. Tests include walking without insoles, walking with prefabricated soft medical insole and walking with custom-molded thermoplastic insole. Each of these tests is performed three times on a 9-meter path at a normal speed of 50 Hz.

Participants/Inclusion and exclusion criteria

Flexible flat foot with specialist doctor diagnosis or foot posture index: The age range 18 to 25: Be an amateur athlete: Absence of length difference in the lower extremities: Lack of severe injury to the lower extremities recently: Absence of skeletal malformation: No history of spine or bone surgery in the lower extremities: No neurological or rheumatic problems that affect walking.

Intervention groups

intervention group 1: walking with prefabricated soft medical insole and study with Pedar device. intervention group 2: walking with custom-molded thermoplastic insole and study with Pedar device. intervention group 3: walking without insole and study with Pedar device.

Main outcome variables

peak pressure, mean pressure, force and cross area in eight parts of foot.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140219016643N7**

Registration date: **2020-02-28, 1398/12/09**

Registration timing: **retrospective**

Last update: **2020-02-28, 1398/12/09**

Update count: **0**

Registration date

2020-02-28, 1398/12/09

Registrant information

Name

Behshid Farahmand

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

farahmand.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-18, 1398/10/28

Expected recruitment end date

2020-02-04, 1398/11/15

Actual recruitment start date

2020-01-18, 1398/10/28

Actual recruitment end date

2020-02-01, 1398/11/12

Trial completion date

2020-02-01, 1398/11/12

Scientific title

Compare the effect of prefabricated soft medical insole and custom-molded thermoplastic insole on plantar pressure distribution in athletes with Flexible flat Foot

Public title

Compare the effect of prefabricated soft medical insole and custom-molded thermoplastic insole on plantar pressure distribution in athletes with Flexible flat Foot

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Flexible flat foot with specialist doctor diagnosis or foot posture index. The age rang 18 to 25. Amateur athlete. Absence of length difference in the lower extremities. Lack of severe injury to the lower extremities recently. Absence of skeletal malformation. No history of spine or bone surgery in the lower extremities. No neurological or rheumatic problems that affect walking.

Exclusion criteria:

Individual's dissatisfaction to enter the study. Wound or injury during the study.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Actual sample size reached: **18**

Randomization (investigator's opinion)

N/A

Randomization description

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 Iran university of Medical Sciences

Street address

Hemat Highway next to Milad Tower,Iran University of

Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.IUMS.REC.1398.1035

Health conditions studied

1

Description of health condition studied

Flexible flat foot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description

Peak pressure

Timepoint

Instantly during tests, measurements are made.

Method of measurement

Pedar X (version10.3) / Made by German novel company

2

Description

Mean pressure

Timepoint

Instantly during tests, measurements are made.

Method of measurement

Pedar X (version10.3) / Made by German novel company

3

Description

Force

Timepoint

Instantly during tests, measurements are made.

Method of measurement

Pedar X (version10.3) / Made by German novel company

4

Description

Contact area

Timepoint

Instantly during tests, measurements are made.

Method of measurement

Pedar X (version10.3) / Made by German novel company

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: walking with prefabricated soft medical insole and study with Pedar device.

Category

Other

2

Description

Intervention group 2: Walking with costum-molded thermoplastic insole and study with Pedar device.

Category

Treatment - Devices

3

Description

Intervention group 3: Walking without medical insole and study with Pedar device.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation Sciences of Iran University

Full name of responsible person

Seyede Gelare Razavi Khorasani

Street address

Mother Square, Shahnazari Street, Madadkaran Srteet, Faculty of Rehabilitation Sciences of iran university

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1545913487

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+98 21 2222 8051

Email

gelarerazavii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr kazem Malakoti

Street address

Hemat Highway,next to Milad Tower,Iran University of Medical Science

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149614535

Phone

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Email

research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Behshid Farahmand

Position

Assistance Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

Mother Squre,Shahnazari Street,Madadkaran street,Faculty of Rehabilitation, Iran University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Behshid Farahmand

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared after unidentifiable people.

When the data will become available and for how long

Starting one year after article publication.

To whom data/document is available

Information is available to all researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and organizational affiliation of the correspondent and co-author of the project and the published article.

From where data/document is obtainable

Connect to Dr Behshid Farahmand by email: Farahmandb1@yahoo.com

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

If information is used in scientific and therapeutic activities, information is provided as soon as possible.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Behshid Farahmand

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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