

# 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1545913487

##### Phone

+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

##### City

Tehran

##### Province

Tehran

##### Postal code

149614535

##### Phone

+98 21 8670 2503

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1545913487

##### Phone

+98 21 2222 0947

##### Email

farahmand.b@iums.ac.ir

## 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

**Street address**

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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 correspond 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

**Street address**

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