

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of foot orthosis and short foot exercise on morphological characteristics of the intrinsic muscles of foot and plantar fascia in individuals with flexible flatfoot

#### Protocol summary

##### Study aim

Determining the effect of foot orthosis with short foot exercise on thickness and cross section area of the intrinsic muscles of the foot and plantar fascia angle in adults with flexible flat foot

##### Design

A clinical trial with a control group and an intervention group, with parallel groups, single-blind, randomized, on 30 patients, a simple randomization method with a sealed envelope is used.

##### Settings and conduct

This study is conducted on 30 adults with flexible flat feet in the laboratory of Shahid Beheshti College in Tehran. The researcher is not aware of the placement and grouping and the treatments performed. Patients are divided into two groups by simple randomization with sealed envelopes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults with flexible flat feet, the presence of heel valgus, age of 18 to 40 years, foot posture index score 6 and greater than 6, body mass index in the normal range (24.9-18.5) Exclusion criteria: Rigid flatfoot, posterior tibial tendon disfunction and acquired flatfoot due to trauma, severe degree of hallux valgus, plantar fasciitis, ankle instability, knee brace, history of trauma and orthopedic surgery in the last 6 months, pregnancy, orthopedic and inflammatory diseases, history of using foot orthosis or performing foot exercises in the 6 months before the study

##### Intervention groups

Control group: orthosis group alone and intervention group: orthosis and exercise group together Both groups use the orthosis at least 6 hours a day for 8 weeks. In addition to the foot orthosis, the orthosis and exercise group performs short foot exercise daily, twice a day for 8 weeks.

##### Main outcome variables

Plantar fascia angle, abductor hallucis thickness, abductor hallucis cross-sectional area, flexor hallucis brevis thickness, flexor hallucis brevis cross-sectional area, Foot Posture Index score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241110063658N1**

Registration date: **2025-01-15, 1403/10/26**

Registration timing: **prospective**

Last update: **2025-01-15, 1403/10/26**

Update count: **0**

##### Registration date

2025-01-15, 1403/10/26

##### Registrant information

##### Name

Parand vosoughi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7763 4633

##### Email address

parandvosoughi@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-01-19, 1403/10/30

##### Expected recruitment end date

2025-05-21, 1404/02/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Effect of foot orthosis and short foot exercise on morphological characteristics of the intrinsic muscles of foot and plantar fascia in individuals with flexible flatfoot

**Public title**  
Insoles and exercise therapy for people with flat feet

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Adults with flexible flatfoot The presence of heel valgus  
Ages 18 to 40 Foot posture index score 6 and greater than 6  
Body mass index in the normal range (24.9-18.5)  
**Exclusion criteria:**  
Rigid flatfoot Posterior tibial tendon disfunction and acquired flatfoot due to trauma Severe degree of hallux valgus  
Plantar fasciitis Ankle instability Knee genu varum  
History of trauma and orthopedic surgery in the last 6 months pregnancy  
Orthopedic and inflammatory diseases History of using foot orthosis or performing foot exercises in the 6 months before the study

**Age**  
From **18 years** old to **40 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization is performed using sealed envelopes, in which a box contains 30 envelopes, 15 envelopes labeled A and 15 envelopes labeled B, and patients are asked to choose one envelope. The letter A is placed in the foot orthosis alone group and the letter B is placed in the foot orthosis and leg shortening exercise group.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Ultrasound evaluations are done by a person who does not know about the groupings and a statistician who is also blind to the groupings.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

Tehran, Valenjak, Daneshjoo Blvd., Arabi St., Shahid Beheshti University of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2024-10-16, 1403/07/25

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1403.348

## Health conditions studied

### 1

#### Description of health condition studied

Flat foot

#### ICD-10 code

M21.4

#### ICD-10 code description

Flat foot [pes planus] (acquired)

## Primary outcomes

### 1

#### Description

"Plantar fascia angle with the horizontal axis"

#### Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

#### Method of measurement

Ultrasonography

### 2

#### Description

"Abductor hallucis muscle thickness"

#### Timepoint

The beginning of the study before the intervention and 8 weeks after using the intervention

#### Method of measurement

Ultrasonography

### 3

#### Description

"Abductor hallucis muscle cross section area"

**Timepoint**

The beginning of the study before the intervention and 8 weeks after using the intervention

**Method of measurement**

Ultrasonography

**4**

**Description**

"Flexor hallucis brevis muscle thickness"

**Timepoint**

The beginning of the study before the intervention and 8 weeks after using the intervention

**Method of measurement**

Ultrasonography

**5**

**Description**

"Flexor hallucis brevis muscle cross section area"

**Timepoint**

The beginning of the study before the intervention and 8 weeks after using the intervention

**Method of measurement**

Ultrasonography

**Secondary outcomes**

**1**

**Description**

"foot posture index score"

**Timepoint**

The beginning of the study before the intervention and 8 weeks after using the intervention

**Method of measurement**

Observation

**Intervention groups**

**1**

**Description**

Control group: orthosis group alone. The CNC orthosis is scanned and made in static mode through the initial scan of the foot by the Danesh Salar scanner. The full-length orthosis has an internal longitudinal arch and metatarsal pad and is made of semi-hard EVA foam. Participants in both control and intervention groups will receive the orthosis and wear it outdoors for at least 6 hours a day for 8 weeks in walking and sports shoes. The control group does not participate in any ankle and foot exercises.

**Category**

Rehabilitation

**2**

**Description**

Intervention group: Intervention group: group of orthosis and exercise together. The participants in the

intervention group also receive the orthosis and use it for at least 6 hours a day for 8 weeks in walking and sports shoes, and in addition to the foot orthosis, they do short foot exercise without shoes, insoles and with bare feet in a standing position. It is performed on one leg next to the wall in a position where the index finger is connected to the wall to keep the balance of the body and the knee of the other leg is in flexion. in such a way that they raise the internal longitudinal arch and shorten the length of the leg in the anterior-posterior direction and move the head of the first metatarsal to the heel; Without flexing the fingers. Exercises are repeated daily, twice a day in 3 sets of 5. In each repetition, the arch is held for 5 seconds and there is a 2 minute rest between each set. After one to two weeks of training, if the participants were able to hold the contraction without falling down the navicular tuberosity, the duration of holding will increase from 5 to 10 and the number of sets will increase from 3 to 5 sets.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Biomechanics Laboratory, Faculty of Rehabilitation, Shahid Beheshti University, Tehran

**Full name of responsible person**

Parand Vosoughi

**Street address**

Tehran, Imam Hossein Square, Damavand Street, in front of Bo Ali Hospital, Shahid Beheshti Faculty of Rehabilitation Sciences, Faculty Biomechanics Laboratory

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1616913111

**Phone**

+98 21 7754 2057

**Fax**

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**Email**

info@sbmu.ac.ir

**Web page address**

https://rehab.sbmu.ac.ir/

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Tehran, Valenjak, Daneshjoo Blvd., Arabi St., Shahid Beheshti University of Medical Sciences

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**Web page address**

[https://isid.research.ac.ir/Afshin\\_Zarghi](https://isid.research.ac.ir/Afshin_Zarghi)

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Parand Vosoughi

**Position**

Physiotherapy Master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Parand Vosoughi

**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Parand Vosoughi

**Position**

Physiotherapy Master's student

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Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

## **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