Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Fascia bar-Incorporated insole on Pain, Foot Function, and Quality of Life in subjects with flexible flat foot and plantar fasciitis

Protocol summary

Study aim
The Effect of Fascia bar-Incorporated insole on Pain, Foot Function, and Quality of Life in subject with flexible flat foot and plantar fasciitis

Design
This study will be conducted as a single-blind, randomized clinical trial with two parallel intervention and control groups. The study will employ randomized allocation using the block randomization method.

Settings and conduct
This study will be conducted in orthotic clinics and physical medicine practices in Isfahan. Patients diagnosed with flexible flatfoot and plantar fasciitis will be enrolled upon obtaining informed consent. Participants will be randomly assigned to either an intervention group or a control group using a block randomization method. Evaluations will be performed at three stages. To ensure blinding, the study will be implemented as a single-blind trial, where patients remain unaware of the specific type of insole they have received

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 60 years; experiencing symptoms of plantar fasciitis for less than 6 months (acute phase); pain localized to the medial central aspect of the heel with greater intensity during the first steps in the morning; and the ability to use foot orthoses for at least 6 hours per day. Exclusion criteria: History of using foot orthoses, physiotherapy, or injections in the foot/ankle within the past 3 months; history of lower limb surgery or planned surgery within the next 12 months; pregnancy; and a body mass index greater than 30 kg/m²

Intervention groups
Intervention: Custom-fit full-length insoles, two-part medial longitudinal arch support. Heel: Cushioning foam (30-35 hardness). Midfoot/forefoot: Semi-rigid foam (40 hardness) with fascia bar. Control: Similar insoles, no fascia bar. Duration: 4 weeks, min. 6 hours daily. Manufacturer: Senrest, Isfahan

Main outcome variables
Pain, Foot Function, and Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250315065086N2**
Registration date: **2026-05-03, 1405/02/13**
Registration timing: **prospective**

Last update: **2026-05-03, 1405/02/13**
Update count: **0**

Registration date
2026-05-03, 1405/02/13

Registrant information

Name
Fateme Pol

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3233 6289

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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2026-12-22, 1405/10/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Fascia bar-Incorporated insole on Pain, Foot Function, and Quality of Life in subjects with flexible flat foot and plantar fasciitis

Public title

The impact of a specific type of insole on individuals with flat feet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 60 years History of symptoms consistent with plantar fasciitis for less than 6 months (acute phase) Presence of pain in the medial aspect of the heel Greater pain intensity upon first steps in the morning (first-step pain) A minimum pain intensity of 30 mm on a 100-mm Visual Analog Scale (VAS) during the past week Ability to use foot orthoses for at least 6 hours per day Positive Jack’s test: the appearance of the medial longitudinal arch during hallux dorsiflexion in a standing position, indicating arch flexibility Foot Posture Index (FPI) ≥ +6: the sum of scores from six criteria assessing foot posture in a standing position; a score ≥ +6 indicates a pronated or flexible foot Navicular Drop Test (NDT) ≥ 10 mm: the difference in navicular height between sitting and standing positions; a value greater than 10 mm indicates medial longitudinal arch collapse

Exclusion criteria:

Use of foot orthoses, physiotherapy, or injections in the foot or ankle within the past 3 months History of lower limb surgery or planned surgery within the next 12 months Allergy to orthotic materials Cognitive impairment Medical history of diabetes mellitus (type I or II), inflammatory joint diseases, or neuromuscular disorders Pregnancy at the time of the study Presence of foot deformities History of foot or ankle fractures Body Mass Index (BMI) greater than 30 kg/m²

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be conducted using random allocation with a block randomization method. A total sample of 48 participants will be organized into 12 blocks of four, with each block assigning two participants to the intervention group (P1) and two to the control group (P2), resulting in two equal groups of 24 participants each. The allocation sequence will be generated by an independent statistician and maintained in sequentially numbered, opaque, sealed envelopes. Following screening and informed consent, the corresponding envelope will be opened and the participant will be assigned to the respective group. Outcome assessors will be blinded to group allocation. Participants in group P1 will receive full-length foot orthoses with medial arch support and a fascia bar, while participants in group P2 will receive similar orthoses without a fascia bar. The blocks are written on paper, placed inside a container, and samples are selected via a draw.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in this study will be blinded, as they will be unable to distinguish between orthoses with a fascia bar and those without, due to their highly similar appearance.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Research and Technology Deputy, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.

City

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Province

Isfehan

Postal code

81746-73461

Approval date

2026-03-03, 1404/12/12

Ethics committee reference number

IR.MUI.REC.1404.052

Health conditions studied

1

Description of health condition studied

Flatfoot

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

Primary outcomes

1

Description
Pain Intensity Score
Timepoint
Before receiving the insoles, immediately after receiving the insoles, and four weeks after receiving the insoles
Method of measurement
Visual Analogue Scale

2

Description
Foot Function Score
Timepoint
Before receiving the insoles and four weeks after receiving the insoles
Method of measurement
Foot Function Index questionnaire

3

Description
Quality of Life Score
Timepoint
Before receiving the insoles and four weeks after receiving the insoles
Method of measurement
Orthotics and Prosthetics Users' Survey – Satisfaction Module questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group employs a full-length insole with an medial longitudinal arch support and a fascia bar. These insoles are custom-made and consist of two components: the heel section is constructed from foam with a hardness of 30 to 35, designed to absorb shock and reduce localized pressure, while the midfoot and forefoot sections are made from semi-rigid foam with a hardness of 40 to control pronation and provide support for the arch of the foot. The medial longitudinal arch support is anatomically designed to conform to the natural arch of the foot, preventing arch collapse and ensuring even pressure distribution. The insoles are made to be custom-fitted, meaning they are produced based on a prepared file that incorporates the fascia bar and adjusted solely according to the length of each participant's foot. Furthermore, the thickness of the fascia bar is tailored to match each individual's foot length.The fascia bar is positioned as a semi-cylindrical raise at the anterior heel and beneath the area where the calcaneus connects to the midtarsal region, measuring between 1.6 mm and 9.5 mm in thickness (with a maximum of 5 mm) and 13 mm to 64 mm in length. This structure is made from the same material as the body of the insole (foam) with a hardness of 35 to 40 (within the permissible range of 20 to 80) and continuously applies localized pressure at the heel-midfoot junction to reduce plantar fascia strain, consequently alleviating pain and enhancing foot function. The duration for using the insoles is four weeks, with a minimum recommended usage of six hours per day, and participants are instructed to refrain from other concurrent treatments or orthotic interventions during the study period.In the first session, after obtaining informed consent and completing a personal information questionnaire, participants receive a comprehensive explanation regarding the research introduction, benefits, and potential risks. In the second session, the insoles are provided free of charge, with instructions on proper use and necessary conditions for adherence to the wearing protocol. It is also noted that the manufacturer of the insoles is the Senrest Company in Isfahan. Participants are emphasized to ensure a minimum usage duration of six hours per day. Pain variable measurements are conducted at three intervals (prior to receiving the insoles, immediately after receipt, and four weeks post-receipt), while foot function and quality of life variables are assessed at two intervals (before receiving the insoles and four weeks after receipt). The researcher maintains weekly contact with participants via phone to check on their usage patterns and hours of insole application.
Category
Treatment - Devices

2

Description
Control group:A full-length insole with medial longitudinal arch support, without a fascia bar. It is manufactured from the exact same material and design as the insole used in the Intervention Group, with the exception that it lacks the fascia bar prominence.These insoles are custom-made and consist of two components: the heel section is constructed from foam with a hardness of 30 to 35, designed to absorb shock and reduce localized pressure, while the midfoot and forefoot sections are made from semi-rigid foam with a hardness of 40 to control pronation and provide support for the arch of the foot. The medial longitudinal arch support is anatomically designed to conform to the natural arch of the foot, preventing arch collapse and ensuring even pressure distribution. The insoles are made to be custom-fitted.The duration for using the insoles is four weeks, with a minimum recommended usage of six hours per day, and participants are instructed to refrain from other concurrent treatments or orthotic interventions during the study period.In the first session, after obtaining informed consent and completing a personal information questionnaire, participants receive a comprehensive explanation regarding the research introduction, benefits, and potential risks. In the second session, the insoles are provided free of charge, with instructions on proper use and necessary conditions for adherence to the wearing protocol. It is also noted that the

manufacturer of the insoles is the Senrest Company in Isfahan. Participants are emphasized to ensure a minimum usage duration of six hours per day. Pain variable measurements are conducted at three intervals (prior to receiving the insoles, immediately after receipt, and four weeks post-receipt), while foot function and quality of life variables are assessed at two intervals

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Dr. Reza Kazemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Gholamreza Askari

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
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Position
student

Latest degree
Bachelor

Other areas of specialty/work
Orthopedics

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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
There is no further information
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
There is no further information
When the data will become available and for how long
There is no further information
To whom data/document is available
There is no further information
Under which criteria data/document could be used
There is no further information
From where data/document is obtainable
There is no further information
What processes are involved for a request to access data/document
There is no further information
Comments
There is no further information