Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Effectiveness of the Customized poly-propylene Semi-rigid Insole and Prefabricated Silicone Heel Pad in Pain Reduction and Functional Improvement of Patients with Plantar Fasciitis, A Clinical Trial Study.

Protocol summary

Study aim
Determination of the efficacy of customized Semi-rigid Insole and Prefabricated Silicone Heel Pad in Plantar Fasciitis

Design
The final sample size is 27 patients for each group. Patients will be randomly allocated in to two groups by Block Randomization Assignment and Double blind methods as well as parallel study with phase 2 (totally 54 cases). One group will receive prefabricated silicone heel pad while the other group will receive the customized semirigid polypropylene insole. SPSS25 will be used to analyze the data and the significance level in each of the tests will be 0.05.

Settings and conduct
Patients with clinical diagnosis of plantar fasciitis (history and physical examination) referring to Physical Medicine and Rehabilitation clinics under supervision of Shiraz University of Medical Sciences in Shiraz during 2022-2023 will be included. We will fill two questionnaires including Visual Analog Scale and Foot Function Index for each patient before, 3 and 12weeks after treatment. Both orthoses will be received by patients in our clinic. We will try to make orthoses as similar as possible in terms of materials. Each participant will be advised not to show his/her orthosis to the questioner who will apply the scales.

Participants/Inclusion and exclusion criteria
Inclusion Sharp or localized pain in plantar foot for at least 1 month, >18y/o, Tenderness of the posteromedail aspect of the longitudinal arch or medial calcaneal tubercle, starting pain in the morning with ambulation, Decrease pain after walking, Exclusion Stress fracture, plantar steroid injection within 3 months, corn or ingrown toe nail, Active radiculopathy, No cooperation, Previous foot surgery, Foot Congenital defects, Diabetes

Intervention groups
Group1 will receive prefabricated silicone heel pad while the other group will receive the customized semirigid polypropylene insole.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191129045542N2**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **prospective**

Last update: **2022-07-17, 1401/04/26**
Update count: **0**

Registration date
2022-07-17, 1401/04/26

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-08-04, 1401/05/13

Expected recruitment end date

2023-02-02, 1401/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of the Customized poly-propylene Semi-rigid Insole and Prefabricated Silicone Heel Pad in Pain Reduction and Functional Improvement of Patients with Plantar Fasciitis, A Clinical Trial Study.

Public title

Comparative Effectiveness of the Customized poly-propylene Semi-rigid Insole and Prefabricated SiliconeHeel Pad in Pain Reduction and Functional Improvement of Patients with Plantar Fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- Sharp, shooting or localized pain in the sole of the foot for at least one month- 18 year-old patients or older.- Tenderness along the posteromedail aspect of the longitudinal arch or medial calcaneal tubercle.- Start-up pain in the morning with ambulation.- Decrease pain after walking

Exclusion criteria:

- Any lower extremity injuries including foot and ankle within 6 months.- Stress fracture- Receiving plantar steroid injection within 3 months.- Use of nonsteroidal anti-inflammatory medications within the previous one week.- Use of custom foot orthotics previously.- Other painful foot condition such as bunion, corn, or ingrown toe nail.- Any other lower extremity neuromuscular conditions such as active radiculopathy- Non-ambulatory, non-communicative.-Unable to complete the interview .- Spasticity due to a neurologic disorder.-Previous foot surgery.- Congenital defects of the lower extremity..- Diabetic mellitus

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

This research is a clinical trial study. Using the formula for comparing the mean in community with alpha 0.05 and the ability (power) of 99% (1-beta:99%) as well as using the result of the same article (Baldassin et al), the sample size was calculated as 22 patients for each group. Taking into account the 20% drop, 27 patients for each group were .determined as the final sample size. Patients will be randomly allocated in to two groups by Block Randomization Assignment and Double blind methods. We will describe the mechanism of the disease, various approaches of treatment, prognosis and our study process as well as case selection for each patient.). After the eligibility is determined, all subjects will be evaluated by one of the colleagues who will obtain baseline characteristic data of the participants including age, sex, weight, duration of symptoms, history of analgesic consumption. He/she will train stretching exercise of the plantar fascia and calf muscles as well as ask the items of both questionnaires. He/she will not know the type of orthoses prescribed for each patient. If both heels are painful, only the data from the most symptomatic foot will be analyzed. If the pain severity is similar in both feet, only the right foot will be evaluated. All patients will be advised to test the foot orthoses on their footwear. If a participant complained of discomfort, he/she will be advised to use the orthosis for a minimum of one week. If the orthosis still bothers the participant, he/she will be advised to return to our clinic (center of Orthosis and Prosthesis in Shahid Chamran Hospital) for further evaluation. For improvement of blinding method, both orthoses will be received by patients in our clinic. All insoles will tried to be made as similar as possible in terms of materials. Each participant will be advised not to show his/her orthosis to the questioner who will apply the scales. Each patient in both groups should perform stretching exercises for plantar fascia and calf muscles with 5-10 times repetition in 3 sets per day which will be trained by one of the colleagues in the first visit. .Descriptive Statistics: To describe quantitative variables, mean +_ standard deviation and 95% confidence interval as well as to describe qualitative variables, frequency and frequency percentage will be used. Inferential statistics: Independent sample t-test (nonparametric equivalent: Mann-Whitney test) which will be used to compare the two groups in each time and also repeated measurement test (nonparametric equivalent: Friedman test) will be used to check the comparison of times in each group. Relationship between qualitative demographic variables such as gender and VAS, FFI scores through Independent sample t-test (Mann-Whitney test) and the relationships of quantitative variables such as age, symptom duration and weight with VAS and FFI scores will be determined by the Pearson correlation coefficient (nonparametric equivalent: Spearman). .SPSS25 will be used to analyze the data and the significance level in each of the tests is 0.05.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be randomly allocated in to two groups by Block Randomization Assignment and Double blind

methods. We will describe the mechanism of the disease, various approaches of treatment, prognosis and our study process and case selection for each patient. After the eligibility is determined, all subjects will be evaluated by one of the colleagues who will obtain baseline characteristic data of the participants including age, sex, weight, duration of symptoms and history of analgesic consumption. He/she will train stretching exercise of the plantar fascia and calf muscles as well as ask the items of both questionnaires. He/she will not know the type of orthoses prescribed for each patient. If both heels are painful, only the data from the most symptomatic foot will be analyzed. If the pain severity is similar in both feet, only the right foot will be evaluated. The colleagues who provide the services in all steps of the project as well as analyzers will be blinded. For improvement of blinding method, both orthoses will be received by patients in our clinic. All insoles will tried be made as similar as possible in terms of materials. Each participant will be advised not to show his/her orthosis to the questioner who will apply the scales. Each patient in both groups should perform stretching exercises for plantar fascia and calf muscles with 5-10 times repetition in 3 sets per day which will be trained by one of the colleagues in the first visit.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
ZAND

City
Shiraz

Province
Fars

Postal code
0098

Approval date
2022-05-23, 1401/03/02

Ethics committee reference number
IR.SUMS.MED.REC.1401.103

Health conditions studied

1

Description of health condition studied
plantar fasciitis

ICD-10 code
M72.2

ICD-10 code description
Plantar fascial fibromatosis

Primary outcomes

1

Description
Pain reduction and foot functional improvement

Timepoint
Before, 3 and 12 weeks after treatment

Method of measurement
Visual Analog Scale, Foot Function Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: prefabricated silicone heel pad

Category
Treatment - Devices

2

Description
Intervention group: customized semi rigid polypropylene insole

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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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
Shiraz 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
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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 need
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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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

-

Comments

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