

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of designed orthosis based on dynamic plantar pressure distribution in patient with chronic plantar fasciitis: A randomized controlled trail.

Protocol summary

Summary

Plantar fasciitis is one of the most common causes of heel pain. The chief complaint is typically a sharp pain in the inner aspect of the heel with the first few steps in the morning or after long periods of no weight-bearing. The main reason for the occurrence of this disorder is unknown. It is estimated to affect 10% of the general population during their lifetime. The prevalence of this disorder has been reported in middle age compared with other age range. Factors such as biomechanical, structural and environmental factors and systemic disease are suggested to be the main risk factors. Different surgical and non-surgical treatments are suggested in the management of this disorder. The purpose of this study will be to affect a new orthosis based on the plantar pressure distribution with night splint and current medication on pain, functional ability, quality of life, dynamic plantar pressure distribution and plantar fascia thickness in patients with plantar fasciitis in a randomized controlled clinical trial. Forty patients with plantar fasciitis referred to rehabilitation at the age range of 18 to 60 years (men and women) will be recruited. Following agreement, the initial assessment will be performed (plantar fascia thickness using ultrasonography, plantar pressure index using platform Emed, assessment of symptoms and functional limitations of the foot and ankle with foot and ankle outcome score); the patients will be randomly assigned into two groups through block-style randomization scheme: the experimental group (given medication with newly designed orthosis and night splint) and the control group (given medication and night splint). All data will be record again after four weeks of intervention. Descriptive statistics and Kolmogorov-Smirnov test will be used to analyze demographic data and to evaluate normality of data, respectively. Paired t-test and independent t-test will be used to assess within group and between groups

changes. Pearson correlation coefficient will be employed to assess the relationship between different variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051717716N1**

Registration date: **2014-05-29, 1393/03/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-05-29, 1393/03/08

Registrant information

Name

Masoomeh Nakhaee

Name of organization / entity

Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2014-06-05, 1393/03/15

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of designed orthosis based on dynamic plantar pressure distribution in patient with chronic plantar fasciitis: A randomized controlled trail.

Public title
The effect of orthosis in patient with chronic plantar fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: early symptoms of chronic plantar fasciitis; age from 18 to 60 years old; no history of leg surgery; no systemic inflammatory diseases (such as rheumatoid arthritis, ankylosing spondylitis, Reiter 's syndrome and diabetes); no foot fracture; no lower back pain with radicular pain; no deformity heels; no use nonsteroidal anti-inflammatory drugs in the last six months of physiotherapy to treat inflammation of the sheath foot plantar and untreated; no use of nonsteroidal anti-inflammatory drugs during the past six weeks, even for pain and inflammation in other parts of the body.
Exclusion criteria: failure to follow the treatment program during the study; inaccuracy in the implementation of the proposed treatment; use other treatments along with treatment designated in the study; it is diagnosed by the criteria above specialist.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
University of Social Welfare and Rehabilitation Sciences
Street address
kodakyar Ave., daneshjo Blvd.,Evin
City
Tehran
Postal code
1985713834

Approval date
2013-08-03, 1392/05/12

Ethics committee reference number
5052/2

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
Plantar fascia thickness

Timepoint
Before entering the study - one month after intervention

Method of measurement
Ultrasonography application

2

Description
Pain

Timepoint
Before entering the study - one month after intervention

Method of measurement
Foot and Ankle Outcome Score (FAOS)-Pain Subscale

3

Description
Quality of Life

Timepoint
Before entering the study - one month after intervention

Method of measurement
Foot and Ankle Outcome Score (FAOS)- Quality of Life Subscale

4

Description
Function, Daily living

Timepoint

Before entering the study - one month after intervention
Method of measurement
Foot and Ankle Outcome Score (FAOS)-Function, daily living Subscale

5

Description

Maximum plantar pressure

Timepoint

Before entering the study - one month after intervention

Method of measurement

Emed Platform

6

Description

Maximum force

Timepoint

Before entering the study - one month after intervention

Method of measurement

Emed Platform

7

Description

Pressure-time integrals

Timepoint

Before entering the study - one month after intervention

Method of measurement

Emed Platform

8

Description

Force-time integral

Timepoint

Before entering the study - one month after intervention

Method of measurement

Emed Platform

9

Description

Contact area

Timepoint

Before entering the study - one month after intervention

Method of measurement

Emed Platform

10

Description

Arch Index

Timepoint

Before entering the study - one month after intervention

Method of measurement

Emed Platform

Secondary outcomes

1

Description

Height

Timepoint

Before entering the study

Method of measurement

Stadiometer

2

Description

Weight

Timepoint

Before entering the study

Method of measurement

Bathroom scales

3

Description

Body Mass Index

Timepoint

Before entering the study

Method of measurement

BMI Formula

4

Description

Standing Duration

Timepoint

Before entering the study

Method of measurement

Patient Self-report

5

Description

Direction of pain

Timepoint

Before entering the study

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: designed orthosis based on dynamic plantar pressure distribution + Night splint + Diclofenac 25mlgr, 3times per day (75 mlgr)

Category

Treatment - Devices

2

Description

Control group: Night splint + Diclofenac 25mlgr, 3times per days (75 mlgr)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Masoomeh Nakhaee

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research-University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr. Amir Massoud Arab

Street address

University of Social Welfare and Rehabilitation Sciences, kodakyar Ave., daneshjo Blvd.,Evin

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Tehran

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

Yes

Title of funding source

Vice-Chancellor for Research-University of Social Welfare and Rehabilitation Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Masoomeh Nakhaee

Position

PhD Candidate

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty