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

+98 21 2218 0010

Email address

mnakhaee@uswr.ac.ir

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

Street address

City
Tehran

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

City
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

Other areas of specialty/work

Street address
Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, kodakyar Ave., daneshjo Blvd.,Evin

City
Tehran

Postal code
1985713834

Phone
+98 21 2218 0010

Fax

Email
mnakhaee@uswr.ac.ir, mnakhaee@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Department of Physiotherapy, University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
Mohammad Ali Mohseni Bandepi

Position
Physiotherapy/ PhD/ Professor

Other areas of specialty/work

Street address
Department of Physiotherapy, University of Social Welfare and Rehabilitation Sciences, Kodakyar Ave., Daneshjo Blvd.,Evin

City
Tehran

Postal code

Phone
+98 21 2218 0039

Fax

Email
mohseni_bandpei@yahoo.com

Web page address

Person responsible for updating data

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

Other areas of specialty/work

Street address
Department of Orthotics and Prosthetics, University of Social Welfare and Rehabilitation Sciences, Kodakyar Ave., Daneshjoo Blvd., Evin.

City
Tehran

Postal code

Phone
+98 21 2218 0010

Fax

Email
mnakhaee@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty