

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of night splint Strassburg Sock on heel pain and quality of life in patients with plantar fasciitis

Protocol summary

Study aim

The Effect of a type of splint Leg , Ankle and foot orthosis on Heel- pain and Quality of Life in Patient with Plantar Fasciitis Lesion

Design

Clinical trial with control group , two arm parallel group randomized trial ,single blind

Settings and conduct

Al Zahra is the main hospital in Esfahan city and refer all of the people .Study is performed in hospital technical Orthopedic section . Get splint ,education and duration of use at night and periodic review patients in several groups , fill the questionnaires . In the study assessor and analyzer are blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria: pain in the heel . Exclusion criteria :The causes of pain are factors other than plantar fasciitis

Intervention groups

Intervention group 14 people take conventional treatments (Physiotherapy and drugs) and receive splint and control group that only take conventional treatments

Main outcome variables

Reduce pain according to the visual analogue scale .
Quality of life in patients .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041636N1**
Registration date: **2019-05-19, 1398/02/29**
Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**

Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

tahmoures tahmsebi notoraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5015

Email address

t_tahmasbi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

2018-04-04, 1397/01/15

Actual recruitment end date

2018-09-21, 1397/06/30

Trial completion date

2018-11-21, 1397/08/30

Scientific title

Effect of night splint Strassburg Sock on heel pain and quality of life in patients with plantar fasciitis

Public title

Effect of night splint Strassburg Sock in plantar fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with heel pain and touch sensitivity

Exclusion criteria:

Foot surgery fractures or dislocation in the last three months Heel spore Tarsal tunnel syndrome

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **28**Actual sample size reached: **28****Randomization (investigator's opinion)**

Randomized

Randomization description

The numbers from 1 to 28 are written on small paper and folded into an envelope. Referring patients are encouraged to take a number, randomly from the envelope . Those who take odd numbers are placed on control group and others taking even ones placed on intervention group .

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessor and analyzer are blinded when assess and analyses

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

Street address

Hezarjerib St ., Azadi Sq ., Esfahan University of Medical Sciences

City

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Province

Isfahan

Postal code

8174673461

Approval date

2016-06-09, 1395/03/20

Ethics committee reference number

lr.mui.rec.1395.3.375

Health conditions studied**1****Description of health condition studied**

Plantar fasciitis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain scores in Visual Analogue Scale

Timepoint

4 to 6 Weeks after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Quality Of Life In Patients

Timepoint

4 to 6 Weeks after intervention

Method of measurement

Foot Ankle Outcome Score Questionnaire

2**Description**

Reduction Pain

Timepoint

4 to 6 Weeks After Intervention

Method of measurement

Visual Analogue Scale Table Questionnaire

Intervention groups**1****Description**

Intervention group: For this group prescribed ankle splint, leg and foot with conventional treatments includes physiotherapy and anti-inflammatory drugs and use at night for 6 hours so that foot and leg are in 90 angle and fingers in Dorsi Flex position.

Category

Rehabilitation

2**Description**

Control group: People in the study participated . They receive conventional treatments(Physiotherapy and Drugs) but have not received splint.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Tahmoures Tahmasbi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

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

Tahmoures Tahmasebi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and Prosthetics

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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