Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

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 fasiatis

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 fascists

Public title
Effect of night splint Strassburg Sock in plantar fascists

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 size
Target 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
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2016-06-09, 1395/03/20
Ethics committee reference number
Ir.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
Street address
Sofeh Ave , Hakinnezami St , Esfahan
City
Esfahan
Province
Isfehan
Postal code
8173696969
Phone
+98 31 3792 5016
Fax
+98 31 3668 7270
Email
Alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Hezarjib St ,. Azadi Sq ,. Esfahan University of Medical Sciences
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0042
Fax
Email
Mui@mui.ac.ir

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
Street address
Azadi Sq ,, Hezarjrib St
City
Esfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 5016
Email
Tahmasebi@rehab.mui.ac.ir

Person responsible for scientific 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 Prosthtics
Street address
Hezarjrib St ., Azadi Sq ., Esfahan University of Medical Sciences
City
Esfahan
Province
Isfehan
Postal code
81746734461
Phone
+98 31 3668 0042
Email
Tahmasebi@rehab.mui.ac.ir

Person responsible for updating data

Tahmasebi@rehab.mui.ac.ir

Contact

Name of organization / entity
Esfahan University of Medical Sciences

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Tahmoures Tahmasebi

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Province
Isfehan

Postal code
8174673461

Phone
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Email

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