

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparative study of the effect of home(rehabilitation at home) and clinical interventions(rehabilitation treatment) on reducing pain and inflammation of plantar fascia

Protocol summary

Study aim

A comparative study of the effect of home and clinical interventions on reducing pain and inflammation of the plantar fascia

Design

Clinical trial with control group, cross-group, one-way blind, simple randomization

Settings and conduct

Clinical intervention will be performed in the rehabilitation center of Shahid Chamran Hospital by a therapist. Home intervention will be performed at home by the patient. Each intervention lasts for two weeks. Interventions include warming, massage, Passive ROM, Mobilization and stretching. The time of intervention sessions is 45 minutes per day. The study is one-way blind and the evaluator does not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with a diagnosis of plantar fasciitis by a specialist. Exclusion criteria: diseases that can cause pain in the heel area.

Intervention groups

Group A includes patients with plantar fasciitis who first receive clinical intervention for two weeks, then receive home intervention for two weeks. Group B includes patients with plantar fasciitis who first receive home intervention for two weeks, then receive clinical intervention for two weeks.

Main outcome variables

pain; hypersensitivity; satisfaction; range of motion;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210207050275N1**

Registration date: **2021-12-26, 1400/10/05**

Registration timing: **prospective**

Last update: **2021-12-26, 1400/10/05**

Update count: **0**

Registration date

2021-12-26, 1400/10/05

Registrant information

Name

narges ghamari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3623 4504

Email address

nargesghamari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of home(rehabilitation at home) and clinical interventions(rehabilitation treatment) on reducing pain and inflammation of plantar fascia

Public title

Comparative of home and clinical interventions on plantar fasciitis

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Inflammation of the plantar fascia No surgery or fracture in the last month
Exclusion criteria:
Reluctance to participate in the study People who have diseases that cause pain and inflammation in the foot

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Using Random Allocation Software and permutation block method and creating 10 blocks with a size of 6, a randomization table of sequence samples (from 1 to 60) will be made and the patients will be divided into A and B intervention groups. Allocation concealment will be conducted by using sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
Assessors are unaware of which group the participants belong to

Placebo
Not used

Assignment
Crossover

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

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Province

Fars

Postal code
7134814336

Approval date
2021-10-11, 1400/07/19

Ethics committee reference number
IR.SUMS.REC.1400.544

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

Timepoint

Pre intervention, 3,6,9,12,15,18,21 days after intervention

Method of measurement

pain analog scale

2

Description

hypersensitivity

Timepoint

Pre intervention, 3,6,9,12,15,18,21 days after intervention

Method of measurement

Numeric Analog Scale, McGill Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Home interventions include placing the foot up to the knee in warm water for 10 minutes, then using a home massager made by Abarteb for 5 minutes, then 15 minutes of passive movements and 15 minutes of stretching Which is adjusted according to the facilities of the house and the patient's ability.

Category

Rehabilitation

2

Description

Intervention group: Clinical treatment includes 10

minutes of hot pack on the muscles, 5 minutes of foot massage, 15 minutes of mobilization and 15 minutes of stretching .Interventions are performed using the equipment available in the clinic(Hot pack, Electric massager, Traband, Frame) or manually by the therapist.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Chamran Hospital

Full name of responsible person

narges ghamari

Street address

Bone and Joint Diseases Research Center,Shahid Chamran Hospital, Chamran Bolv.

City

Shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3623 4504

Fax

+98 71 3623 4504

Email

nargesghamari@yahoo.com

Web page address

<http://orthoresearch.sums.ac.ir/fa/index.html>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Mahtab Memarpor

Street address

Shahid Chamran Hospital,Chamran Bolv, Shiraz

City

shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3623 4504

Fax

+98 71 3623 4504

Email

nargesghamari@yahoo.com

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Grant name

No

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****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

narges ghamari

Position

consultant

Latest degree

Ph.D.

Other areas of specialty/work

Occupational Therapy

Street address

Shahid Chamran Hospital, Chamran Bolv, Shiraz

City

shiraz

Province

Fars

Postal code

7194815644

Phone

0098716234504

Email

nargesghamari@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

narges ghamari

Position

consultant

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

narges ghamari

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Province

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

it is to be shared the primary outcome measure

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

these data is available for people working in academic institutions or people working in businesses and they can apply to receive it

Under which criteria data/document could be used

Individuals can receive information via email at the discretion of the authors

From where data/document is obtainable

nargesghamari@yahoo.com

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

At the discretion of the authors, the documents will be available to the applicant within a week

Comments