

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparative efficacy of Phonophoresis with Nitroglycerin and Phonophoresis with Hydrocortisone in the treatment of plantar fasciitis, A randomized clinical trial

Protocol summary

Study aim

The purpose of this study is to compare the effect of Phonophoresis with Hydrocortisone and Phonophoresis with Nitroglycerin in the treatment of Plantar Fasciitis.

Design

A double-blind randomized controlled clinical trial with parallel groups and consist of 60 patients.

Settings and conduct

The 60 patients who refer to Isfahan physical medicine and rehabilitation centers and have clinical diagnosis of Plantar Fasciitis will enrolled in the study. 30 patients will participate in Phonophoresis with Hydrocortisone group and 30 patients in Phonophoresis with Nitroglycerin group. In each group 10 sessions of Phonophoresis will be done every other day in Amin Hospital. The amount of pain based on visual analogue scale and the amount of activity limitation based on modified Roles and Maudsley score and thickness of plantar fascia will be assessed in each group. This study is a double-blind clinical trial that the patients don't know their treatment and The statistical consultant does not know the two methods of treatment and the name of the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients between 18 to 65 years with clinical diagnose of plantar fasciitis and ability to express the pain. exclusion criteria include pregnancy and breastfeeding, allergy to nitrate, hypertension and coronary artery disease, any pathology in foot and ankle, Diabetes and peripheral neuropathy, chronic pain syndrome and atrophy, scar or wounds in heel.

Intervention groups

In this study, 30 patients with plantar fasciitis will participate in Phonophoresis with Hydrocortisone group and 30 patients in Phonophoresis with Nitroglycerin group. In each group 10 sessions of Phonophoresis will be done every other day.

Main outcome variables

The amount of pain based on (VAS) and the amount of activity limitation based on modified Roles and Maudsley score (RMS) and thickness of plantar fascia.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190824044598N2**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-02, 1398/12/12**

Update count: **0**

Registration date

2020-03-02, 1398/12/12

Registrant information

Name

Razieh Maghroori

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of Phonophoresis with Nitroglycerin and Phonophoresis with Hydrocortisone in the treatment of plantar fasciitis, A randomized clinical trial

Public title

Comparison of Phonophoresis with Hydrocortisone and Phonophoresis with Nitroglycerin in treatment of Plantar Fasciitis.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between 18 to 65 years old with clinical diagnose of Plantar Fasciitis. Ability to express pain

Exclusion criteria:

pregnancy and breastfeeding allergy to nitrate Diabetes and peripheral neuropathy any pathology in foot and ankle atrophy , scar or wound in the heel hypertension and coronary artery disease Chronic Pain Syndrome

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random allocation: In this study, a specific code will be given to each of the individuals who are eligible for inclusion and exclusion criteria. Then 30 people will be allocated in the group of phonophoresis with nitroglycerin and 30 people in the group of phonophoresis with hydrocortisone.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the main executor is considered as a physician who knows the goals of the study and the types of treatments. The patients don't know their treatment (Phonophoresis with Hydrocortisone or Nitroglycerin) and they will not be aware of how the treatments will be compared. The statistical consultant does not know the two methods of treatment and the name of the patients and he/she randomizingly assigne the codes to the patients and analyze the results. Therefore, this study is a double blind clinical trial.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St.

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Postal code

8514933373

Approval date

2019-06-18, 1398/03/28

Ethics committee reference number

IR.MUI.MED.REC.1398.154

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

plantar fasciitis

ICD-10 code

M77.3

ICD-10 code description

Calcaneal spur

Primary outcomes**1****Description**

The amount of pain

Timepoint

Before starting the study, after last session of Phonophoresis ,three weeks after the last session of Phonophoresis and two months after the last session of Phonophoresis.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : 30 patients participate in Phonophoresis with Nitroglycerin group and will treated with ultrasound (pulse mode, 0.8 MHZ frequency and 1.5 W/CM intensity) for 10 minutes in 10 sessions every other day. Maximum site of pain in heel will be embarrassed with 1 gr Nitroglycerin 2% ointment before ultrasound therapy.

Category

Treatment - Drugs

2

Description

Intervention group : 30 patients participate in Phonophoresis with Hydrocortisone group and will treated with ultrasound (pulse mode, 0.8 MHZ frequency and 1.5 W/CM intensity) for 10 minutes in 10 sessions every other day. Maximum site of pain in heel will be embarrassed with 2 gr Hydrocortisone 1% ointment before ultrasound therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Shiva Fakhari

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Sonbolestan Aly., Ebnesina Ave., Shohada Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Shiva Fakhari

Position

Resident, Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Position

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Latest degree

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Other areas of specialty/work

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

Esfahan University of Medical Sciences

Full name of responsible person

Shiva Fakhari

Position

Resident, Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available