Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Investigating the effect of Tacar treatment on improving symptoms and performance of patients with plantar fasciitis and comparing it with drug treatment

Protocol summary

Study aim

Determining the therapeutic effect of Tecar on improving the symptoms and performance of patients with plantar fasciitis

Design

A parallel blind randomized clinical trial study in 1402-1403 on 60 patients diagnosed with plantar fasciitis who were randomly assigned to one of 2 intervention groups.

Settings and conduct

In this blinded study, plantar fasciitis patients who have pain for at least one month and VAS score more than 3 and are referred to physical medicine clinics of Isfahan University of Medical Sciences in 1402-1403 will be treated randomly (with information and agreement of the treatment method considered by each patient) and after the completion of sampling of all data by an analyst who is not aware of the division of groups and treatment methods, the results will be analyzed.

Participants/Inclusion and exclusion criteria

1-Diagnosis of plantar fasciitis (worsening of the pain in the inner part of the heel in the morning after waking up and also after a lot of activity during the day) by a specialist in physical medicine and rehabilitation with a physical examination (33)). 2. Heel pain for at least 4 weeks 3. Age between 18 and 68 years 4. Presence of VAS more than 3 5. Informed written consent to participate in the study

Intervention groups

1- Intervention group: tacar therapy (8 sessions: 2 days per week) and exercise (including stretching of the plantar calf muscles, passive dorsiflexion of the fingers, strengthening of the intrinsic foot and rolling muscles, 9 times a day including 3 times in the morning, 3 times in the afternoon, 3 times in the evening load 30 seconds) and (Soft medial longitudinal arch support or Silicon Heel Pad) along with medicine (Celecoxib 200 mg, once a day for 15 days) are prescribed. 2- Control group: All previous cases except tacar therapy (8 sessions: 2 days per week)

Main outcome variables

pain and function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231105059968N1**
Registration date: **2024-01-22, 1402/11/02**
Registration timing: **prospective**

Last update: **2024-01-22, 1402/11/02**
Update count: **0**

Registration date

2024-01-22, 1402/11/02

Registrant information

Name

Fatemeh Izadi najafabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3772 5602

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-19, 1403/12/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Tacar treatment on improving symptoms and performance of patients with plantar fasciitis and comparing it with drug treatment

Public title

The therapeutic effect of Tecar on patients with plantar fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of plantar fasciitis (worsening of the pain in the inner part of the heel in the morning after waking up and also after a lot of activity during the day and the presence of local tenderness in the lower inner part of the calcaneus) by a physical medicine and rehabilitation specialist with a physical examination Heel pain for at least 4 weeks Age between 18 and 68 years Presence of VAS greater than 3 Informed written consent to participate in the study

Exclusion criteria:

History of inflammatory joint disease Achilles tendon or nerve damage History of heel surgery or injection in the last 6 months History of injury to the affected heel The presence of diseases mimicking the symptoms of plantar fasciitis Contraindications of the Tecar device (pregnancy, pacemaker, insulin pump, growth plate, cancer, open wound and skin lesions, skin sensitivity, insensitivity to heat) Patients with intense physical activity or sports who are unable to reduce their activity level

Age

From **18 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who will enter the study phase will be randomly assigned to one of the two intervention groups. The randomization method is that 25 random numbers from 1 to 50 are created by random number generation software, which are assigned to the first intervention group, and then the remaining 25 numbers are assigned to the second group.

Blinding (investigator's opinion)

Single blinded

Blinding description

data analysts are unaware of which group each patient was placed in.

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 Science

Street address

Hezarjerib ave, Isfahan University of Medical Science

City

isfahan

Province

Isfehan

Postal code

7346181746

Approval date

2023-10-19, 1402/07/27

Ethics committee reference number

IR.MUI.MED.REC.1402.264

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

The severity of symptoms and performance of patients before the treatment will be measured again immediately after the end of the treatment and 2 months after the end of the treatment.

Method of measurement

Pain level of patients by Visual Analogue Scale questionnaire - intensity of symptoms and performance of patients by RM(The modified Roles and Maudsley) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Tecarotherapy (8 sessions: 2 days a week) and exercise (including stretching of calf muscles, plantar fascia, passive dorsiflexion of fingers, strengthening of intrinsic foot muscles and rolling soles, 9 times a day, including 3 times in the morning, 3 times in the afternoon, 3 times in the evening, 30 seconds each time) and (Soft medial longitudinal arch support or Silicon Heel Pad) is prescribed along with medicine (Celecoxib 200 mg, once a day for 15 days).
Category
Treatment - Other

2

Description
Control group: Exercise (including stretching of calf muscles, plantar fascia, passive dorsiflexion of fingers, strengthening of intrinsic foot muscles, rolling soles, 9 times a day, including 3 times in the morning, 3 times in the afternoon, 3 times at night, 30 seconds each time) along with medicine (Celecoxib 200 mg, once a day) for 15 days) and (Soft medial longitudinal arch support or Silicon Heel Pad) are prescribed. After the completion of the treatments, the pain level of the patients by VAS), the severity of the symptoms and the performance of the patients by the RM questionnaire will be measured again immediately after the end of the treatment and 2 months after the end of the treatment and with the other group and also at the beginning of the treatment under Comparison will be made.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
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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