

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effect of corticosteroid injection versus high intensity laser on pain and function in patients with chronic plantar fasciitis referred to Imam Khomeini and Shariati hospitals , a single-blind clinical trial.

Protocol summary

Study aim

Comparing the effect of corticosteroid injection versus high intensity laser on pain and function in patients with chronic plantar fasciitis referred to Imam Khomeini and Shariati hospitals.

Design

The sample size (about 20 patients in each group, 40 in total) was divided into two groups using simple randomization.

Settings and conduct

This study is a randomized, single-blind clinical trial that will be conducted in the orthopedic and physical medicine departments of Imam Khomeini and Shariati hospitals in Tehran. Patients will be divided into two groups using a simple randomization method: group A will be treated with novin med company high intensity laser device for 8 sessions (2 or 3 sessions weekly) . Group B will be treated with injection of combination of 1 ml triamcinolone 40 mg and 2 ml lidocaine 2% in maximum pain location.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age 18-65 years, clinical diagnosis confirmed by a physician, failure to respond to conservative treatment, plantar fasciitis up to 2 months and ability to cooperate in the study Exclusion criteria:History of surgery within the last year for plantar fasciitis, injection therapy, laser or shockwave therapy within the last 2 months and use of Plavix within the last week

Intervention groups

Group A:High intensity laser therapy with determinate protocol Group B: Corticosteroid injection(A combination of 1 ml Triamcinolone 40 mg and 2 ml Lidocaine 2%) in maximum pain location

Main outcome variables

The results of this study can help physicians choose the

most appropriate treatment for patients with chronic plantar fasciitis, leading to improved treatment outcomes and reduced costs of care.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260419069106N1**

Registration date: **2026-07-29, 1405/05/07**

Registration timing: **registered_while_recruiting**

Last update: **2026-07-29, 1405/05/07**

Update count: **0**

Registration date

2026-07-29, 1405/05/07

Registrant information

Name

Hadi Ghobadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 921 749 9821

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-04, 1405/02/14

Expected recruitment end date

2028-07-31, 1407/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of corticosteroid injection versus high intensity laser on pain and function in patients with chronic plantar fasciitis referred to Imam Khomeini and Shariati hospitals , a single-blind clinical trial.

Public title

Comparing the effect of corticosteroid injection and high intensity laser in patients with chronic plantar fasciitis.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-65 years Clinical diagnosis confirmed by a physician Failure to respond to conservative treatment Plantar fasciitis up to 2 months Ability to cooperate in the study

Exclusion criteria:

History of surgery within the last year for plantar fasciitis Injection therapy Laser or shockwave therapy within the last 2 months Use of Plavix within the last week

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be divided into two groups using a simple randomization method: - Group A: High intensity laser therapy with determinate protocol Group B: Corticosteroid injection (A combination of 1ml triamcinolone 40 mg and 2 ml lidocaine 2%) in maximum pain location

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is designed as a single-blind study. Patients will not be aware of the type of intervention. The physician will inevitably be aware of the technique, but the clinical assessor (who will record VAS and FFI at subsequent visits) will be completely unaware of the group allocation of patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee Research Ethics Committee of Dr. Shariati Hospital

Street address

Three ways of Jalal Al-Ahmad

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2025-12-31, 1404/10/10

Ethics committee reference number

IR.TUMS.SHARIATI.REC.1404.140

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

Plantar fasciitis/heel spur

ICD-10 code

M72.2

ICD-10 code description

Plantar fascial fibromatosis

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

Determination and comparison of the mean pain score (VAS) at 2 weeks and 12 weeks after the end of procedure in patients with plantar fasciitis in two groups of high intensity laser and corticosteroid injection

Timepoint

Change in mean pain and function intensity score based on the Visual Analogue Scale (VAS) from baseline to 2 weeks and 12 weeks after corticosteroid injection or using of high intensity laser

Method of measurement

The Visual Analog Scale (VAS) will be used to assess the severity of patients' pain, and the Foot Function Index (FFI) questionnaire will be used to assess foot function. Scores for both instruments will be collected and recorded through direct patient questionnaires. Visual Analog Scale (VAS): This instrument is used to measure pain severity and is designed based on the Likert scale. In this scale, pain severity is reported as a number from 0 to 10, with 0 indicating complete absence of pain and 10 indicating the most severe pain imaginable. Foot Function Index (FFI): This questionnaire is used to assess

the degree of foot dysfunction and consists of 17 questions categorized into three subscales: pain (5 questions), disability (9 questions), and mobility limitation (3 questions). Each question is scored numerically from 0 to 10. The final score for each subscale is calculated from the sum of the scores for its questions and determines the patient's level of pain, disability, and mobility limitation.

2

Description

Determination and comparison of the mean function score (FFI score) at 2 weeks and 12 weeks after the end of procedure in patients with plantar fasciitis in two groups of high intensity laser and corticosteroid injection.

Timepoint

Change in mean pain and function intensity score based on the Visual Analogue Scale (VAS) from baseline to 2 weeks and 12 weeks after corticosteroid injection or using of high intensity laser

Method of measurement

The Visual Analog Scale (VAS) will be used to assess the severity of patients' pain, and the Foot Function Index (FFI) questionnaire will be used to assess foot function. Scores for both instruments will be collected and recorded through direct patient questionnaires. Visual Analog Scale (VAS): This instrument is used to measure pain severity and is designed based on the Likert scale. In this scale, pain severity is reported as a number from 0 to 10, with 0 indicating complete absence of pain and 10 indicating the most severe pain imaginable. Foot Function Index (FFI): This questionnaire is used to assess the degree of foot dysfunction and consists of 17 questions categorized into three subscales: pain (5 questions), disability (9 questions), and mobility limitation (3 questions). Each question is scored numerically from 0 to 10. The final score for each subscale is calculated from the sum of the scores for its questions and determines the patient's level of pain, disability, and mobility limitation.

3

Description

Determination and comparison of possible treatment side effects at 2 weeks and 12 weeks after the end of procedure in patients with plantar fasciitis in two groups of high intensity laser and corticosteroid injection

Timepoint

Change in mean pain and function intensity score based on the Visual Analogue Scale (VAS) from baseline to 2 weeks and 12 weeks after corticosteroid injection or using of high intensity laser

Method of measurement

The Visual Analog Scale (VAS) will be used to assess the severity of patients' pain, and the Foot Function Index (FFI) questionnaire will be used to assess foot function. Scores for both instruments will be collected and recorded through direct patient questionnaires. Visual Analog Scale (VAS): This instrument is used to measure pain severity and is designed based on the Likert scale. In this scale, pain severity is reported as a number from

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4

Description

Determination and comparison of patients satisfaction at 2 weeks and 12 weeks after the end of procedure in patients with plantar fasciitis in two groups of high intensity laser and corticosteroid injection

Timepoint

Change in mean pain and function intensity score based on the Visual Analogue Scale (VAS) from baseline to 2 weeks and 12 weeks after corticosteroid injection or using of high intensity laser

Method of measurement

The Visual Analog Scale (VAS) will be used to assess the severity of patients' pain, and the Foot Function Index (FFI) questionnaire will be used to assess foot function. Scores for both instruments will be collected and recorded through direct patient questionnaires. Visual Analog Scale (VAS): This instrument is used to measure pain severity and is designed based on the Likert scale. In this scale, pain severity is reported as a number from 0 to 10, with 0 indicating complete absence of pain and 10 indicating the most severe pain imaginable. Foot Function Index (FFI): This questionnaire is used to assess the degree of foot dysfunction and consists of 17 questions categorized into three subscales: pain (5 questions), disability (9 questions), and mobility limitation (3 questions). Each question is scored numerically from 0 to 10. The final score for each subscale is calculated from the sum of the scores for its questions and determines the patient's level of pain, disability, and mobility limitation.

5

Description

Determination and comparison of the distribution of demographic and clinical characteristics at the beginning of the study in patients of group of corticosteroid injection and group of high intensity laser

Timepoint

in the begginig of sessions

Method of measurement

The Visual Analog Scale (VAS) will be used to assess the severity of patients' pain, and the Foot Function Index (FFI) questionnaire will be used to assess foot function. Scores for both instruments will be collected and recorded through direct patient questionnaires. Visual Analog Scale (VAS): This instrument is used to measure pain severity and is designed based on the Likert scale. In this scale, pain severity is reported as a number from

0 to 10, with 0 indicating complete absence of pain and 10 indicating the most severe pain imaginable. Foot Function Index (FFI): This questionnaire is used to assess the degree of foot dysfunction and consists of 17 questions categorized into three subscales: pain (5 questions), disability (9 questions), and mobility limitation (3 questions). Each question is scored numerically from 0 to 10. The final score for each subscale is calculated from the sum of the scores for its questions and determines the patient's level of pain, disability, and mobility limitation.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: laser therapy with novin med High intensity laser therapy device in 2 or 3 sessions weekly for 8 sessions. first to fourth sessions protocol is :/area : 49 /fr : 30 /total 735j / time 4':05" Mode: pulsed / peak power :8 / average power : 3 / dose : 15 j/cm²• fifth to eights sessions protocol is :/area : 49 /fr : 30 /total 1470j / time 4':54" Mode: pulsed / peak power :15 / average power : 5 / dose : 30 j/cm²

Category

Treatment - Other

2

Description

Intervention group: After obtaining informed consent, Corticosteroid injection with palpitation technique will be perform in maximum pain location. Injection will be in 1 session and is combination injection of 1 ml triamcinolone 40 mg and 2 ml lidocaine 2%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Ensieh Taftian

Street address

End of Keshavarz Boulevard

City

Tehran

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Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6658 1625

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Email

lmamhospital@tums.ac.ir

2

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Ensieh Taftian

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North Kargar St

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Province

Tehran

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1411713135

Phone

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Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ensieh Taftian

Street address

keshavarz blvd, gods crossing,poursina street,medical faculty

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Province

Tehran

Postal code

1461884513

Phone

+98 21 8895 3003

Email

deanmed@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hadi Ghobadi Marallu
Position
Physical Medicine and Rehabilitation Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Email
hadighobadi124@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After deidentifying people, all the data obtained from the research, including the demographic information of the samples, clinical information and the results of the intervention can be shared.

When the data will become available and for how long

It is possible to access the results after nine to twelve months from the publication of the results.

To whom data/document is available

Researchers in academic centers and scientific research centers.

Under which criteria data/document could be used

In order to data comparison in similar studies, the researchers of academic centers and scientific research centers have the possibility to receive data and re-analyze it if they comply with the principles of ethics in research.

From where data/document is obtainable

dr.hadi ghobadi marallu with email of :
hadighobadi124@gmail.com and phone number of
09217499821

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

Researchers should send a written request to receive

data to the relevant email address.A week after receiving an email , it will take action.

Comments