Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone

+98 921 749 9821

Email address

hadighobadi124@gmail.com

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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target 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 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.

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
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1625
Fax
+98 21 6658 1625
Email
Imamhospital@tums.ac.ir

2

Recruitment center
Name of recruitment center
Dr. Shariati Hospital
Full name of responsible person
Ensieh Taftian
Street address
North Kargar St
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
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
City
Tehran
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
Physical Medicine
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Tehran
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Person responsible for scientific inquiries

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Full name of responsible person
Hadi Ghobadi Marallu
Position
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Medical doctor
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City
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Province
Tehran
Postal code
1417913191
Phone
+98 21 6696 5500
Email
hadighobadi124@gmail.com

Person responsible for updating data

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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Street address
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Tehran
Province
Tehran
Postal code
1417913191
Phone
+98 21 6696 5500
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