# 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)

**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
**Street address**
Enghelab Square,borhani alley , enghelab dorm
**City**
Tehran
**Province**
Tehran
**Postal code**
1344619546
**Phone**
+98 921 749 9821
**Email**
hadighobadi124@gmail.com

## Person responsible for scientific 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
**Street address**
Enghelab square
**City**
Tehran
**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**
Physical Medicine
**Street address**
Enghelab square
**City**
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**