

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the efficacy of Extracorporeal shockwave therapy and high-level laser therapy in patients with plantar fasciitis

Protocol summary

Study aim

The aim of this study will be to determine and compare the effectiveness of extracorporeal shockwave therapy and high power laser therapy on pain, heel thickness and quality of life in patients with plantar fasciitis.

Design

The laser therapy group will use a gallium arsenide diode laser (model K-laser-cube 4) with a wavelength of 1064 nm, an output power of 8 watts, and an average energy intensity of 6-10 joules per square centimeter. The laser wave is of continuous type and will be applied by scanning method. The total duration of treatment in each session will be 5-7 minutes. All patients will be treated for 3 consecutive weeks (6 sessions)

Settings and conduct

This study will be performed as a single blind (evaluator will be blinded of the type of intervention) in patients referred to Besat Hospital in Hamedan with plantar fasciitis.

Participants/Inclusion and exclusion criteria

The subjects of patients with plantar fasciitis are 18 to 65 years old. Inclusion criteria: The duration of diagnosis is at least 3 months and the minimum pain intensity is greater than 3 according to the VAS criteria. Comorbidity with other ankle and heel diseases such as tarsal tunnel syndrome, osteomyelitis, malignancy, Recent history of surgery or trauma of the ankle or heel, vascular disease, treatment with corticosteroids now or during the past 4 months and treatment with NSAIDs will be the exclusion criteria.

Intervention groups

ESWT Group: This group will receive an ESWT one session for three weeks consecutively. ESWT will be performed in laying position on a quiet bed at the point where the greatest intensity of tenderness is found. Device settings: frequency 4 Hz, pulse 1500, energy 0.15 mj / mm².

Main outcome variables

The main outcome of treatment includes changes in pain

intensity and heel thickness, which will be assessed with the VAS scale and ultrasound, respectively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N15**

Registration date: **2021-07-16, 1400/04/25**

Registration timing: **prospective**

Last update: **2021-07-16, 1400/04/25**

Update count: **0**

Registration date

2021-07-16, 1400/04/25

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the efficacy of Extracorporeal shockwave therapy and high-level laser therapy in patients with plantar fasciitis

Public title
Comparison of the therapeutic effect of laser and extracorporeal shock waves in plantar fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of plantar fasciitis according to clinical criteria and para -clinical imaging by a specialist physician The duration of diagnosis is at least 3 months Age 65-18 years Minimum pain intensity > 3 according to VAS scale
Exclusion criteria:
 Comorbidity other ankle and heel diseases such as tarsal tunnel syndrome, osteomyelitis, malignancy History of recent ankle or heel surgery or trauma Vascular diseases Treatment corticosteroid past 4 months NSAID treatment

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

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
60 patients with inclusion will be selected by convenience sampling. The samples will be randomly coded with computer software in two groups E and L and the relevant codes will be entered in the raw checklists. Upon patient referral, one of the checklists will be randomly assigned to each patient. If the selected code is E, the patient will be in the ESWT treatment group and if it is L, he/she will be in the laser treatment group

Blinding (investigator's opinion)
Single blinded

Blinding description
The evaluator of intervention outcome will be blinded to the patients' group

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Science

Street address

Shahid Fahmideh Ave

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Postal code

6517838697

Approval date

2021-01-16, 1399/10/27

Ethics committee reference number

IR.UMSHA.1399.877

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

Plantar fascia thickness

Timepoint

3, 6 and 12 weeks after treatment

Method of measurement

Ultrasound examination of the heel in prone position

2

Description

Severity of plantar pain

Timepoint

3, 6 and 12 weeks after treatment

Method of measurement

with Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Life Quality

Timepoint

Before, 3. 6 and 12 weeks after intervention

Method of measurement

2**Description**

Treatment Complications

Timepoint

3, 6 and 12 weeks after the intervention

Method of measurement

Examination and observation

Intervention groups1**Description**

Intervention group: Group A will be allocated to ESWT by a physical therapist for 3 consecutive weeks and one session per week. ESWT will be performed while the patient is lying on a quiet bed at the point where the greatest intensity of tenderness is found. Device settings: frequency 4 Hz, pulse 1500, energy 0.15 mj / mm². will be done

Category

Treatment - Devices

2**Description**

Control group: Patients in group B will receive powerful laser therapy. In this group, gallium aluminum arsenide diode laser (model K-laser-cube 4) with a wavelength of 1064 nm, output power of 8 watts, and an average energy intensity of 6-10 joules per square centimeter will be used. The laser wave is of continuous type and will be applied by scanning method. The total duration of treatment in each session will be 5-7 minutes. All patients will be treated for 3 consecutive weeks (6 sessions).

Category

Treatment - Devices

Recruitment centers1**Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Mohammad Reza Niko

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Email**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

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Full name of responsible person

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Person responsible for scientific inquiries

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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