Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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

Ŝhahid Fahmideh Ave

City

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Province

Hamadan

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

SF-12 Questionnaire

Besat@Umsha.ac.ir

2

Description
Treatment Complications
Timepoint
3, 6 and 12 weeks after the intervention
Method of measurement
Examination and observation

Intervention groups

1

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 centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Mohammad Reza Niko
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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
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
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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