

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Assessment of the Effect of Low Level Laser Therapy in Plantar Fasciitis Patients

Protocol summary

Study aim

Study of the effect of low-level laser therapy in patients with Plantar fasciitis referring to Imam Hossein Hospital and Shohadaye Tajrish Hospital

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients in Shohada Tajrish and Emam hosein hospital with plantar fasciitis confirmed by Standard diagnostic methods were selected in 20-65 years old patients and divided into two groups of low-level laser and control group. All patients were randomly assigned based on random numbers into two groups. The group assigned to the subject is buried in dark envelopes. The envelope will be opened by a doctor only after the initial assessment of each person, and the patient and the clinical evaluator of his treatment group won't be informed

Participants/Inclusion and exclusion criteria

All patients with Plantar Fasciite In the age range of 65-20 years At least three months from the onset of pain Their pain levels are higher than VAS4 And clinically diagnosed by a specialist. Dissatisfied patient to participate in the study. In Radiography: Local Bone Disorders and Spur Patients with history of injection or heel surgery Patients with a history of malignancy and bone defects. Patients with systemic Articular diseases like RA and diabetes Patients with lumbar radiculopathy lesions and disseminated pains

Intervention groups

Intervention group: In the case group, is given an IR-type laser with a wavelength of 940 (nm) and a power of 10 J/cm2 in a three-way heel in 12 sessions .

Main outcome variables

VAS (Visual analogue scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180417039342N1**

Registration date: **2018-05-24, 1397/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-24, 1397/03/03**

Update count: **0**

Registration date

2018-05-24, 1397/03/03

Registrant information

Name

Maryam Barati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

m.barati@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the Effect of Low Level Laser Therapy in Plantar Fasciitis Patients

Public title

Assessment of the Effect of Low Level Laser Therapy in Plantar Fasciitis Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with Plantar Fasciite In the age range of 65-20 years At least three months from the onset of pain Their pain levels are higher than VAS4 And clinically diagnosed by a specialist

Exclusion criteria:

Dissatisfied patient to participate in the study. In Radiography: Local Bone Disorders and Spur Patients with history of injection or heel surgery Patients with a history of malignancy and bone defects. Patients with systemic Articular diseases like RA and diabetes Patients with lumbar radiculopathy lesions and disseminated pains

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients are divided into two groups according to the Table of random numbers. The group assigned to the study is packed in succession in dark letters. This package is opened by a doctor only after an initial assessment of each person. The patient and clinical evaluator will not be informed from his clinic.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research will be conducted in a clinical trial. all patients are divided into two groups according to the Table of random numbers. The group assigned to the study is packed in succession in dark letters. This package is opened by a doctor only after an initial assessment of each person. The patient and clinical evaluator will not be informed from his clinic.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2018-01-21, 1396/11/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.979

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

Plantar fasciitis , also called foot pain syndrome, Heel spur syndrome and painful heel syndrome, is also caused by inflammation of plantar fascia.

ICD-10 code

M72.2

ICD-10 code description

Plantar fascial fibromatosis Plantar fasciitis

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

VAS (Visual analogue scale)

Timepoint

Before laser therapy and 2, 4 and 8 weeks after laser treatment

Method of measurement

In the form of numbers from zero to ten

2**Description**

PFPS (plantar fasciitis pain scale)

Timepoint

In the form of numbers from zero to ten

Method of measurement

As a number

3

Description

FAOS (foot & Ankle outcome score)

Timepoint

In the form of numbers from zero to ten

Method of measurement

In the form of numbers 0 to 4

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the case group, is given an IR-type laser with a wavelength of 940 (nm) and a power of 10 J/cm2 in a three-way heel in 12 sessions .

Category

Treatment - Devices

2

Description

Control group: In the control group by SHAM Laser, which includes the use of the device and complete laser surgery for the patient with a silent, non-laser light-emitting device. For both groups, basic therapies such as medical shoes, medical exercises and rest are used to prevent the control group from being treated.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada - Tajrish hospital

Full name of responsible person

Maryam Barati

Street address

Tajrish Sq. Shohada - Tajrish hospital

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Fax

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Email

dr.baaraati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST.
Yemen street, Shahid Chamran highway, Tehran

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1989934148

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Email

dr.Baaraati@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Barati

Position

Non-faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Maryam Barati

Position

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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