Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Fasciiate 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)

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+98 21 2271 8021

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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 Fasciiate 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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Postal code
1989934148
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+98 21 2271 8021
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+98 21 2274 9221
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
City
Tehran
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1989934148
Phone
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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
Shohadaye Tajrish Hospital, Tajrish, Tehran
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Maryam Barati

Position
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Latest degree
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Person responsible for updating data

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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