Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the High Intensity laser Therapy (HILT) with Extra corporeal Shock Wave Therapy (ESWT) in the treatment of patients with plantar fasciitis

Protocol summary

Study aim

Provide less invasive methods in the treatment of patients with plantar fasciitis; Providing the best non-invasive treatment in patients with plantar fasciitis Provide a new proposal to physicians to reduce the rate of invasive measures Provide results for larger studies in the field of shock wave and laser therapy and determine the appropriate therapeutic dose;

Design

without control group, with parallel groups, one-way blind, randomized, on 56 patients.Online randomization will be used for randomization, which will be done using the site www.random.org/integres. Then a random sequence of numbers generated on the web will be recorded and the random allocation will be hidden by presenting a sealed envelope containing the treatment code to the participants.

Settings and conduct

Referrals to the Physical Medicine and Rehabilitation Clinic of Sadoughi Hospital in Yazd with a diagnosis of plantar fasciitis are placed in one of the treatment groups and are treated with therapeutic modality according to the group.

Participants/Inclusion and exclusion criteria

Age over 18 years and under 55 years, plantar fasciitis confirmed by physical and orthopedic specialists, failure to respond to conservative treatments including ice and rest and stretching and insole and NSAIDS after 1 week

Intervention groups

Group A: Stretching exercises, insole administration and shock wave Group B Stretching exercises, insole administration and high power laser

Main outcome variables

Reduce pain and tenderness;Improve the quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210913052465N1**
Registration date: **2021-10-22, 1400/07/30**
Registration timing: **retrospective**

Last update: **2021-10-22, 1400/07/30**
Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

Marzieh Zarebidoki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3253 2476

Email address

zarebidoki.ma@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-14, 1399/02/25

Expected recruitment end date

2020-10-23, 1399/08/02

Actual recruitment start date

2020-05-22, 1399/03/02

Actual recruitment end date

2020-12-26, 1399/10/06

Trial completion date

2021-03-27, 1400/01/07

Scientific title
Comparison of the High Intensity laser Therapy (HILT) with Extra corporeal Shock Wave Therapy (ESWT) in the treatment of patients with plantar fasciitis

Public title
Effect of high power laser in treatment of plantar fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Plantar fasciitis confirmed by specialists in physical medicine and orthopedics Failure to respond to conservative therapies including ice, rest, traction, insole, and NSAIDS after 6 weeks

Exclusion criteria:

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **56**
Actual sample size reached: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Online randomization sampling method will be used, which will be done using the site www.random.org/integres, then the random sequence of numbers generated on the web will be recorded and hiding the random assignment of participants to One of the two treatment groups will be performed. To hide the random allocation, the researcher chooses 28 envelopes for the high-power laser group and the same number for the extra corporal shock wave (ESWT) group, and the type of treatment is written inside these envelopes. And the generated codes are written in these envelopes. These envelopes are then handed over to the research colleagues who have no benefit from the research to give to the patients at random.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, only the participants did not know which group they were in

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid sadughi University of Medical School

Street address
Ebne Sina Alley,Yadregare emam Ave, Mazvirabad

City
Mehriz

Province
Yazd

Postal code
8981855515

Approval date
2020-05-11, 1399/02/22

Ethics committee reference number
IR.SSU.MEDICINE.REC.1399.017

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
Pain relief

Timepoint
Before treatment and two weeks after treatment and three months after

Method of measurement
Visual Analogue Scale

2

Description
Quality of life

Timepoint
Before and 3 months after

Method of measurement
36-item quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Radial shock wave modality, 3 weeks and 3 sessions in the week

Category

Treatment - Devices

2

Description

Intervention group: high level laser therapy modality , 3 weeks and 3 sessions in the week

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadooghi Hospital, Yazd

Full name of responsible person

Marzieh zare

Street address

Ebne Sina Ave, Shahid Ghandi Blvd, Safaieh

City

Yazd

Province

Yazd

Postal code

8915887857

Phone

+98 35 3822 4000

Email

Zarebidoki.ma@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Zare Marzieh

Street address

Ebne Sina Ave, Shahid Ghandi Blvd, Safaieh

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8915887857

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Sadoughi University of Medical sciences

Proportion provided by this source

1

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

Yazd University of Medical Sciences

Full name of responsible person

Zare Marzieh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Ebne sina Alley, Yadegare Emam Ave, Mazvirabad

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

No - There is not 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

Total data

When the data will become available and for how long

Starting access period from 6 months after printing

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions who research related cases

From where data/document is obtainable

By sending a request to the email zarebidoki.ma @gmail .com

What processes are involved for a request to access data/document

After sending the researcher's request to the e-mail along with providing documents regarding the verification of real and legal identity and confirmation of conducting research in the relevant field, information will be sent within three months.

Comments