# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 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

**City**

Yazd

**Province**

Yazd

**Postal code**

8915887857

**Phone**

+98 35 3822 4000

**Email**

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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

**Street address**

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## Person responsible for scientific 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**

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## Person responsible for updating data

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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**