

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

“Comparison of extracorporeal shockwave and high intensity laser in reducing pain and improving function in chronic plantar fasciitis.”

Protocol summary

Study aim

By knowing the short and long term effects of ESWT(Extracorporeal shockwave therapy) and HILT(High intensity laser therapy) in patients of chronic plantar fasciitis, we can avoid the need of cortisone injection and surgery.

Design

A randomized controlled not blind trial. Samples will be divided into 2 groups.1 group will be treated with extra corporeal shock wave and 2nd will be treated with high intensity LASER therapy. Both groups will receive treatment for 3 weeks and than follow up will be taken after 2 months.

Settings and conduct

Setting: Lifeline Healthcare and Pain center, Opposite Jinnah hospital Lahore, Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: both genders, minimum age 18 and maximum 70, VAS >5 on first step in morning, Informed consent, Symptoms duration more than 6 months.
Exclusion criteria: Previous surgery of plantar fasciitis, Pregnancy, Pacemaker fitted, Bleeding disorder, Any tumor of treatment site, calcaneus stress fracture checked by squeeze test.

Intervention groups

Patients will be randomly divided into two groups 15 subjects in each group. After taking baseline assessment Group 1 will be treated with BTL-6000 Shockwave therapy Intensity= 2.0 Bar, Frequency =10Hz, Number of Shocks=2000. The ESWT will be applied in a circular motion on the insertion site of the plantar fascia (1,000 shocks) and along the fascia (1,000 shocks). (9) twice a week for 3 weeks. Group 2 will receive Diowave 60W Class IV Laser three times per week for 3 weeks for a total of 9 sessions at wavelength of 980nm, a laser output of 30 Watts and energy dose of 10,000 Joules. Scanning method will be used. Both groups will be given some exercises to follow for home plan.

Main outcome variables

Pain (VAS) Function of foot by Foot functional Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200317046798N1**

Registration date: **2020-04-17, 1399/01/29**

Registration timing: **prospective**

Last update: **2020-04-17, 1399/01/29**

Update count: **0**

Registration date

2020-04-17, 1399/01/29

Registrant information

Name

Saba Riaz

Name of organization / entity

Riphah International University Lahore, Pakistan

Country

Pakistan

Phone

+92 42 35225100

Email address

sabariaz317@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-10, 1399/02/21

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"Comparison of extracorporeal shockwave and high intensity laser in reducing pain and improving function in chronic plantar fasciitis."

Public title

"Comparison of extracorporeal shockwave and high intensity laser in reducing pain and improving function in chronic plantar fasciitis."

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Both genders minimum age 18 and maximum 70 Visual analogue Scale >5 on first step in morning Informed consent Symptoms duration more than 6 months

Exclusion criteria:

Previous surgery of plantar fasciitis, Pregnancy Pacemaker fitted Bleeding disorder, Any tumor of treatment site calcaneus stress fracture checked by squeeze test

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by lottery method. Allocation concealment through sealed envelopes

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Non-probability convenient sampling technique will be used to recruit the individuals for the study and then randomization will be done by lottery method to divide the individuals into 2 treatment groups. Sealed envelopes will be used for allocation concealment.

Secondary Ids

empty

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

Riphah College of Rehabilitation Sciences (RCRS)
Research Ethical Committee (REC)

Street address

near Hajj Complex, I-14, Islamabad, Islamabad Capital Territory

City

Islamabaad

Postal code

46000

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

RCRS-RE-MS-OMPT/SPring 19/ 033

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

Plantar Fasciitis is one of the most common causes of heel pain. It involves inflammation of a thick band of tissue that runs across the bottom of your foot and connects your heel bone to your toes

ICD-10 code

M72.2

ICD-10 code description

Plantar fascial fibromatosis

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

Pain

Timepoint

before treatment. than after treatment (3 weeks), Follow Up (after 2 months)

Method of measurement

Visual Analogue scale , Foot functional Index (Short version)

2**Description**

Functional Status

Timepoint

before treatment. than after treatment (3 weeks), Follow Up (after 2 months)

Method of measurement

Foot functional Index (Short version)

Secondary outcomes

empty

Intervention groups**1****Description**

After taking baseline assessment Group 1 will be treated

with BTL-6000 Extracorporeal Shockwave therapy
Intensity= 2.0 Bar, Frequency =10 Hz , Number of
Shocks=2000. The ESWT will be applied in a circular
motion on the insertion site of the plantar fascia (1,000
shocks) and along the fascia (1,000 shocks). twice a
week for 3 weeks

Category

Treatment - Devices

2

Description

After taking baseline assessment group 2 will receive
Diowave 60W Class IV Laser three times per week for 3
weeks for a total of 9 sessions at wavelength of 980 nm ,
a laser output of 30 Watts and energy dose of 10,000
Joules. Scanning method will be used.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Lifeline Health Care and Pain Center , opposite Jinnah
hospital Lahore, Pakistan

Full name of responsible person

Saba Riaz

Street address

150-HBFC, Opp. Emergency Gate Jinnah
Hospital,Lahore

City

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sabariaz317@gmail.com

Web page address

<http://www.lifelinehealthcare.org/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lifeline Healthcare and pain center

Full name of responsible person

Saba Riaz

Street address

150-HBFC, opp Jinnah Hospital Emergency Gate,
Lahore Pakistan

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Web page address

<http://www.lifelinehealthcare.org/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Lifeline Healthcare and pain center

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University Lahore, Pakistan

Full name of responsible person

Saba Riaz

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Riphah College of Rehabilitation Sciences (RCRS)

Full name of responsible person

SABA RIAZ

Position

student
Latest degree
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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

Yes - There is 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

study protocol, Statistical analysis, results

When the data will become available and for how long

after completion of study

To whom data/document is available

People working in Healthcare providing centers and
academic institutes regarding healthcare.

Under which criteria data/document could be used

According to Profession

From where data/document is obtainable

Different search sites

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

Registration on specific site

Comments