Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 theray) 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, calcaneous 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 calcaneous 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 envelops

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 envelops 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

Lahore

Postal code

54770

Phone

+92 42 35236690

Email

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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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

Street address

House No: 124, Sector SW, NFC Society, Phase 1, Near Wapda Town Lahore, Pakistan.

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sabariaz317@gmail.com

Web page address

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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
Bachelor

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

Contact

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Riphah College of Rehabilitation Sciences (RCRS)

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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