

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the therapeutic potential of isometric exercises with and without diclofenac potassium spray in plantar-fasciitis

Protocol summary

Study aim

The basic purpose of this research will be to compare the effects of isometric exercises with and without diclofenac potassium in patients of planter-fascitis

Design

A concealed, randomized, double-blinded, randomized controlled clinical trial with a parallel group design of 30 patients, enrolled between 01 2021 and 01 2022, and followed for one year

Settings and conduct

The investigator and participant both were blind. Setting: Muhammad physical therapy clinic and rehabilitation Center, Multan Faiz Hospital, Multan, Pakistan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 2. Age 25 to 55 years 3. Patients with heel pain >3 months 4. Both genders 5. Heel pain 6. Bone spur Exclusion Criteria 7. Vascular neoplasia 8. Fibromyalgia 9. Rheumatoid arthritis 10. Radiculopathy 11. Neuropathy 12. Tumor 13. Fractures

Intervention groups

Group-A group will be treated with isometric exercises and four pumps of diclofenac potassium spray with phonophoresis were also given, we used 4 pumps of diclofenac potassium spray with phonophoresis and performed isometric exercises prior to phonophoresis with a frequency of 0.8MHz, an intensity of 1.5W/CM, and a mode of pulsatile (2:1) The regimen will be done for a 4-week period, 3 times per week, and each session lasted for about 5-7 mins. Group-B: control group will be treated with isometric exercises. The regimen will be done for a 4-week period, 3 times per week, and each session lasted for about 5-7 mins.

Main outcome variables

Pain,functional activities,ROMs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220408054449N1**

Registration date: **2022-04-28, 1401/02/08**

Registration timing: **retrospective**

Last update: **2022-04-28, 1401/02/08**

Update count: **0**

Registration date

2022-04-28, 1401/02/08

Registrant information

Name

Komal Ammar Bukhari

Name of organization / entity

Muhammad institute of medical and allied sciences,Multan,Pakistan

Country

Pakistan

Phone

+92 302 9132647

Email address

komalammarbukhari@mimas.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-08, 1399/10/19

Expected recruitment end date

2022-02-02, 1400/11/13

Actual recruitment start date

2020-08-08, 1399/05/18

Actual recruitment end date

2022-01-01, 1400/10/11

Trial completion date

2022-01-10, 1400/10/20

Scientific title

Evaluation of the therapeutic potential of isometric exercises with and without diclofenac potassium spray in

plantar-fasciitis

Public title

Effects of diclofenac potassium spray and isometric exercises

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 25 to 55 years Patients with heel pain >3 months
Both genders Heel pain

Exclusion criteria:

Vascular neoplasia Fibromyalgia Rheumatoid arthritis
Radiculopathy Neuropathy Fractures

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **19**

19 individuals in each group

Actual sample size reached: **30**

More than 1 sample in each individual

Actual sample size in each individual: **15**

15 individuals in each group

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation concealment occurs and patients will be recruited by using a simple randomization method by using a lottery method. The lottery method is carried out through sealed envelopes. Each participant randomly chooses the sealed envelopes and opens these sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

In a double-blinded study, participants and investigators will be blinded. participants will be unaware of the type of treatment that will receive and the investigator will be unaware of the type of treatment on which group which intervention will be given and for what purpose that will be evaluated after treatment. subjects will choose between two samples. both of the samples are in the same packing. In one sample, isometric exercises with diclofenac potassium spray. In another sample, liquid spray as a conventional treatment for the satisfaction of patients with isometric exercises will be given. subjects and investigators will be completely unaware of the effects of both interventions

Placebo

Not used

Assignment

Parallel

Other design features

participants pain will be assessed by using the NPRS

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

the Muhammad Institute of Medical and Allied Sciences' ethics committee in Multan, Pakistan

Street address

Bosan road Multan

City

Multan

Postal code

66000

Approval date

2020-09-18, 1399/06/28

Ethics committee reference number

2020/IRB/2/physio/05

Health conditions studied

1

Description of health condition studied

plantar fasciitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Decreased pain

Timepoint

after 3rd week

Method of measurement

NPRS 11 point numeric scale ranges from 0 representing one pain extreme(no pain)to 10 representing the other pain extreme severity

2

Description

Increased functional activity

Timepoint

After 3rd week

Method of measurement

11 point numeric scale ranges from 0 representing one pain extreme(no pain)to 10 representing the other pain extreme severity

Secondary outcomes

1

Description

ROMs improvement

Timepoint

After 3rd week

Method of measurement

11 point numeric scale ranges from 0 representing one pain extreme(no pain)to 10 representing the other pain extreme severity

Intervention groups

1

Description

Intervention group (group-A): Group-A group was treated with isometric exercises and four pumps of diclofenac potassium spray with phonophoresis were also given, we used 4 pumps of diclofenac potassium spray with phonophoresis and performed isometric exercises prior to phonophoresis with a frequency of 0.8MHz, an intensity of 1.5W/CM, and a mode of pulsatile (2:1) The regimen was done for a 4 week period, 3 times per week, and each session lasted for about 5-7 mins.

Category

Treatment - Other

2

Description

Control group (group-B): isometric exercises. The regimen was done for a 4 week period, 3 times per week, and each session lasted for about 5-7 mins.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Muhammad physical therapy clinic and rehabilitation Center, Multan Faiz Hospital,Multan,Pakistan

Full name of responsible person

Humera Tahir

Street address

Bosan road Multan

City

Multan

Postal code

66000

Phone

+92 302 9132647

Email

komalbukhari608@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Muhammad institute of medical and aied sciences,multan,pakistan

Full name of responsible person

Humera Tahir

Street address

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City

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Postal code

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Email

komalbukhari608@gmail.com

Grant name

Education

Grant code / Reference number

IRB/10

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

Yes

Title of funding source

Muhammad institute of medical and aied sciences,multan,pakistan

Proportion provided by this source

1

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

Muhammad institute of medical and allied sciences,Multan,pakistan

Full name of responsible person

Humera Tahir

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position

punjab

Latest degree

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Person responsible for updating data

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Position

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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