Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+92 302 9132647

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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
Bosan road Multan
City
Multan
Postal code
66000
Phone
+92 302 9132647
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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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