Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Dry Needling in Addition to conventional Physical Therapy in Patients with Piriformis Syndrome

Protocol summary

Study aim
To compare the effects of dry needling and conventional physical therapy patients with piriformis syndrome
Design
Two arm parallel group randomized trails with blinded outcome assesor and with sample size of 86 enrolled
Settings and conduct
Participants were referred by the orthopedic physician of Nishtar hospital to the Physical Therapy Department
Participants/Inclusion and exclusion criteria
Inclusion criteria was as follows: • Aged between 30-50 years • Both Male and females • Patients with positive FAIR & Lasegue test • Having atleast 4 score of Numeric Pain Rating Scale Exclusion Criteria: • Patients with any abnormality in spine column • Patients with any systemic inflammatory disease (rheumatologic Conditions) • Recent fracture/dislocation in and around the Hip Joint • Patient with psychological impairment (Parkinson's disease) • Pregnancy
Intervention groups
All the screened and willing participants were randomly allocated to two groups (Group A: Experimental group / Dry needling group, Group B: Comparative Group / Conventional therapy group) by lottery method.
Main outcome variables
1. Pain (Numeric Pain Rating Scale) 2. Lower extremity Functional Scale (LEFS) 3. Range of Motion (Goniometry)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241125063847N1**
Registration date: **2025-02-19, 1403/12/01**
Registration timing: **retrospective**

Last update: **2025-02-19, 1403/12/01**
Update count: **0**
Registration date
2025-02-19, 1403/12/01

Registrant information
Name
Ghanwa Noor
Name of organization / entity
University of Lahore
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Pakistan
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+92 332 1877045
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-10-10, 1403/07/19
Expected recruitment end date
2025-02-15, 1403/11/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Dry Needling in Addition to conventional Physical Therapy in Patients with Piriformis Syndrome

Public title
Dry Needling in Addition to conventional Physical Therapy in Patients with Piriformis Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Aged between 30-50 years • Both Male and females • Patients with positive FAIR & Lasegue test • Having atleast 4 score of Numeric Pain Rating Scale

Exclusion criteria:

• Patients with any abnormality in spine column • Patients with any systemic inflammatory disease (rheumatologic Conditions) • Recent fracture/dislocation in and around the Hip Joint • Patient with psychological impairment (Parkinson's disease) • Pregnancy

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

0

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method will be used for randomization by an independent statistician. Randomization will be done by one of the research team members who will not involve in patient recruitment or assessment or data analysis. In this method Group names will be mentioned on separate slips of paper of same size, shape and color. They are folded and mixed up in a container. A blind fold selection will be made and each member of the population will be assigned a number. Randomization assignments will be kept in opaque, sealed envelopes and unsealed by a researcher after baseline testing. Outcome assessors will be unaware of group assignment.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is single blinded study in which accessor will be kept blind who will not involve in patient recruitment or assessment or data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of University of Lahore

Street address

University of Lahore Teaching Hospital Lahore , Punjab , Pakistan

City

Lahore

Postal code

55150

Approval date

2024-12-05, 1403/09/15

Ethics committee reference number

REC_UOL_/481/08/24

Health conditions studied

1

Description of health condition studied

Piriformis syndrome is a neuromuscular condition that occurs when the piriformis muscle , located in the buttock region , compresses the sciatic nerve. This can cause pain, numbness , and down the leg , often mimicking symptoms of sciatica

ICD-10 code

M62.838

ICD-10 code description

Other muscle spasm

Primary outcomes

1

Description

The Numeric pain rating scale in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line. The NPRS takes <1 minute to complete Scores range from 0-10 points, with higher scores indicating greater pain intensity. The NPRS can be administered verbally (therefore also by telephone) or graphically for self-completion

Timepoint

2nd week

Method of measurement

The Numeric pain rating scale in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line. The NPRS takes <1 minute to complete Scores range from 0-10 points, with higher scores indicating greater pain intensity.

2

Description

The Lower Extremity Functional Scale (LEFS) is a valid patient-rated outcome measure (PROM) used to assess lower extremity function. It was initially developed by Binkley et al. (1999) for patients with various musculoskeletal conditions.

Timepoint

2nd week

Method of measurement

This self-report questionnaire asks patients about their ability to perform twenty everyday activities, with five response options ranging from “Extreme Difficulty or Unable to Perform Activity” to “No Difficulty.” Patients’

scores are totaled, with a maximum score of 80 points indicating high function and a minimum score of 0 points indicating low function

3

Description

The term 'goniometry' is derived from the Greek words 'gonia' meaning angle and 'metron' meaning measure, therefore goniometry refers to the measurement of angles, which in rehabilitation settings refers to the measurement of angles in each plane at the joints of the body. T

Timepoint

2nd week

Method of measurement

he neutral zero method (0 to 180- degree system) is the most widely used method. The range of motion of each joint should be measured in isolation, to avoid trick movement (simultaneous movement of another joint) and muscle insufficiency which may alter the reading.

Secondary outcomes

empty

Intervention groups

1

Description

Dry Needling: Participants of Group A was received dry needling (DN). Acupuncture was applied to the trigger points, as described in previous studies by Itoh et al. Tight points or taut band was identified by palpation. The patient was laying on the abdomen. The examiner found the landmarks of greater trochanter and sacrum in S2, S3 and S4. He was inserted the needle vertically to the surface of trochanter, from the sciatic notch toward the pubis symphysis, directly to the stiffness points. Dry needling was performed deeply by a needle with the. 30mm in diameter and 65mm in length. Duration of needling in piriformis muscle was one minute. After the application of DN, mild stretching of piriformis was performed. This group was received dry needling at the end of 1st, 3rd and 5th sessions. Hip Abductor Strengthening: Subject's position was in side- lying with the affected side upward. Lower leg flexed at hip & knee. Pelvis was stabilized by therapist and upper leg kept out of couch at the level of ankle. One end of the elastic band was tied to the distal part of the affected leg while the other end tied around. The leg of that couch, keeping the elastic band perpendicular to the floor. Subjects were instructed to lift the upper leg towards the ceiling against the force of the resistance band. This strengthening exercise was performed 3 sets; 10 times per set. Sciatic Nerve Mobilization (Tensioning Technique): Sciatic nerve mobilization was given for 12-15 sessions including 30 sec hold and 1 min rest. The subjects were in supine lying position and straight leg raise was done for inducing longitudinal tension as the sciatic nerve runs posterior to hip and knee Joints while maintaining extension at the Knee. In order to induce Dural motion through the sciatic nerve; the leg was raised. At least past 35 degrees in order to take up Slack in the nerve. To introduce additional Traction (i.e., sensitization) into the proximal aspect of the sciatic nerve, hip adduction was added to the straight leg raise. The nerve sliding technique was applied for 20-30 repetitions in 2-3 sets per day, and the nerve tensioning technique was implemented in addition for 15-25 seconds in 5-7 repetitions.Piriformis Stretching: In supine lying position subject's tested leg was placed into flexion at the hip and knee so that the foot rests on the table lateral to the contra-lateral knee (the tested leg is crossed over the straight non-tested Leg). The non-tested side pelvis was stabilized during the test and the knee of the tested side was pushed into adduction, to place a stretch on piriformis. Holding time was 20seconds, with 5 seconds rest period and repeated for 5 times.

Category

Other

2

Description

Intervention group: In Group B all allocated participants received conventional therapy. Conventional therapy includes 15 minutes of heat therapy. All the patients of this group was treated by hip abductor muscle strengthening along with sciatic Nerve mobilization & piriformis stretching. Three sets of hip abductor muscle strengthening exercises with 10 sec hold for 10 repetitions were done 3 days per week for 2 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Lahore teaching hospital

Full name of responsible person

Dr.Asim Arif

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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Grant name
None

Grant code / Reference number
None

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
None

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
The university of Lahore
Full name of responsible person
Ghanwa Noor
Position
Consultant
Latest degree
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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

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

Title and more details about the data/document

Demographics data and data related to final outcome will be shared by maintaining the confidentially

When the data will become available and for how long

Data will be available after the publication of findings till six months

To whom data/document is available

Ghanwa Noor

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding author of the study, Ghanwa Noor and cane contact on +92 332 1877045 and Drnoo045@gmail.com

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

Open access and there is the traditional public data release where anyone can get access to the data

Comments