

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 assessor 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

###### Country

Pakistan

###### Phone

+92 332 1877045

###### Email address

drghanwa@gmail.com

##### 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 assessor 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**

The 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 were 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 lying on the abdomen. The examiner found the landmarks of greater trochanter and sacrum in S2, S3 and S4. He 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 20 seconds, 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 were 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

##### **Street address**

University of Lahore Teaching Hospital Lahore, Punjab, Pakistan

##### **City**

Lahore

##### **Postal code**

55150

##### **Phone**

+92 335 1450137

##### **Email**

asim.arif@uipt.uol.edu.pk

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

The University of Lahore

**Full name of responsible person**

Ghanwa Noor

**Street address**

1 km Defence Road , near Bhuptian Chowk , Lahore , Punjab

**City**

Lahore

**Postal code**

55150

**Phone**

+92 332 1877045

**Email**

Drnoor045@gmail.com

**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**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

1 km Defence Road , near Bhuptian Chowk , Lahore , Punjab

**City**

Lahore

**Province**

Punjab

**Postal code**

55150

**Phone**

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Drnoor045@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

The university of Lahore

**Full name of responsible person**

Ghanwa Noor

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data****Contact****Name of organization / entity**

The university of Lahore

**Full name of responsible person**

Ghanwa Noor

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Province**

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**Postal code**

55150

**Phone**

+92 332 1877045

**Email**

Drnoor045@gmail.com

**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 confidentiality

**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 can 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**