

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Compare the effectiveness of Positional Release Technique and Myofascial release technique with Foam Roller on Pain, ROM, Functional mobility and Quality of life in patients with piriformis syndrome.

Protocol summary

Study aim

Compare the effects of positional release technique and myofascial release technique with foam roller on Pain, Range of motion, Functional Mobility and Quality of Life in patients with piriformis syndrome.

Design

Parallel group randomized clinical trial and Randomization will be achieved through computer generated random allocation software.

Settings and conduct

Government General Hospital Faisalabad, National Hospital and Mujahid Hospital. Patients and outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Both male and female patients, Age group 25-40 years, A score of 8 or more out of 12 scoring system according to Clinical scoring system for the diagnosis of piriformis muscle syndrome Exclusion criteria: Mentally retarded, Any pathology or recent injury near the hip, sacroiliac joint, or lumbar spine, Limb length discrepancy, Recent buttock trauma and bladder/bowel dysfunction, Ischiogluteal/ischiofemoral bursitis or impingement, Referred pain from gastrointestinal or pelvic source

Intervention groups

Group A: They will receive Positional release technique and conventional treatment in the form of TENS and hot pack for 15 minutes then piriformis muscle and hamstring/calf muscle stretching will be performed (3 repetitions) for 5 minutes after the PRT. Session duration will be 30-35 minutes, twice a week and with 8 sessions over 4 weeks. Group B: They will receive Myofascial release technique with foam roller and conventional treatment in the form of TENS and hot pack for 15 minutes then piriformis muscle and hamstring/calf muscle stretching will be performed (3 repetitions) for a duration of 5 minutes after the MRT. Session duration will

be 30-35 minutes twice a week and with 8 sessions over 4 weeks.

Main outcome variables

Pain, range of motion, functional mobility and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230216057434N9**

Registration date: **2024-04-02, 1403/01/14**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-02, 1403/01/14**

Update count: **0**

Registration date

2024-04-02, 1403/01/14

Registrant information

Name

Zainab Sheraz

Name of organization / entity

Riphah International University, Faisalabad

Country

Pakistan

Phone

+92 301 7070941

Email address

zainab.48@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-18, 1402/12/28

Expected recruitment end date

2024-05-10, 1403/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effectiveness of Positional Release Technique and Myofascial release technique with Foam Roller on Pain, ROM, Functional mobility and Quality of life in patients with piriformis syndrome.

Public title

Effectiveness of two manual therapy technique in piriformis syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both male and female patients. Age group 25-40 years. A score of 8 or more than 8 out of 12 scoring system according to Clinical scoring system for the diagnosis of piriformis muscle syndrome

Exclusion criteria:

Mentally retarded Any pathology or recent injury near the hip, sacroiliac joint, or lumbar spine Limb length discrepancy Recent buttock trauma and bladder/bowel dysfunction Ischiogluteal/ischiofemoral bursitis or impingement Referred pain from gastrointestinal or pelvic sources (in particular colon cancer, endometriosis and interstitial cystitis)

Age

From **25 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through a computer software "Random allocation software Version 2. The total sample size will be entered with required number of participants to be allocated in two groups. An automated randomization list will be achieved with attrition rate included. The program starts running with the default settings. Users may run the program with the default settings or set the number of groups, the name of participants in each group and the sample size. Clicking the 'Generate' button produces the random sequence. Before generating the random sequence, the option window will be displayed and different randomization settings can be entered.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding will be done on part of outcome assessor who will be an experienced therapist. Patients will be assessed by him at the end of treatment session. He will be blinded about the type of intervention patient will receive. Patients will also be blinded about the type of intervention they will received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Riphah International University
Faisalabad

Street address

Riphah International University, Faisalabad

City

Faisalabad

Postal code

38000

Approval date

2024-03-01, 1402/12/11

Ethics committee reference number

RCRAHS/REC/24/10

Health conditions studied

1

Description of health condition studied

Piriformis syndrome

ICD-10 code

G57.00

ICD-10 code description

Lesion of sciatic nerve, unspecified lower limb

Primary outcomes

1

Description

Pain

Timepoint

Assessment will be performed at 0 week (baseline) and at completion of 4 weeks treatment.

Method of measurement

Numeric Pain Rating Scale

Secondary outcomes

1

Description

Range of motion

Timepoint

Assessment will be performed at 0 week (baseline) and at completion of 4 weeks treatment.

Method of measurement

Goniometer

2

Description

Functional mobility

Timepoint

Assessment will be performed at 0 week (baseline) and at completion of 4 weeks treatment.

Method of measurement

Time up and go test

3

Description

Quality of life

Timepoint

Assessment will be performed at 0 week (baseline) and at completion of 4 weeks treatment.

Method of measurement

Sf-36

Intervention groups

1

Description

Intervention group A (Positional release technique) 22 patients will receive TENS and hot pack for 15 minutes on gluteal region as conservative treatment in prone lying position before the application of the Positional Release Technique (PRT) that uses Speicher's protocol. In this protocol, patients will be in prone position with their hip flexed at 60 to 90 degrees and abducted. The affected leg will hang off the table, with the bent knee resting on the thigh of the therapist. To locate the piriformis muscle, the therapist will use one hand to feel for the coccyx and the other hand to locate the greater trochanter. The trigger point will then palpate in the belly of the piriformis muscle, roughly halfway between the base of the sacrum and the greater trochanter. Once the most significant tender point is identified, the therapist will use one hand to apply gentle, sustained pressure with their fingertips directly on the trigger point for two minutes, or until the patient reports a significant reduction in pain. The therapist's other hand will adjust the patient's hip position, depending on the trigger point location, to maintain the position of least discomfort. This process will be repeated throughout the PRT treatment sessions until the patient experiences a significant reduction or complete elimination of pain. Three repetitions of PRT will be performed for a period of 10

minutes at two sessions a week for 4 weeks. The total duration of treatment session will be 30-35 minutes. Furthermore, the stretching of piriformis, hamstring and calf muscles will be carried out by the therapist after the administration of PRT. For piriformis stretching, patients will be in supine position with both knees flexed at 90 degrees. The foot of the unaffected leg resting on a table with the ankle of the involved leg placed on the opposite knee. Then patients will gently pull the unaffected thigh towards their chest until a stretch is perceived in the buttock and along the lateral aspect of the hip on the affected leg. This stretch will be maintained for 60 seconds before gradually returning to the initial position. For hamstring and calf stretching, patients will be instructed to stand upright and lean forward, placing the palms of both hands on the wall. They will stretch the hamstring and calf muscles of the affected lower limb by positioning the foot of the affected limb behind and the foot of the unaffected limb in front, with both knees fully extended. As the heels of both lower limbs reach the floor, the knee of the unaffected limb will be flexed forward toward the wall to increase the stretch on the soleus of the affected limb. The upper body will then be swung left and right to ensure the stretching of the entire hamstring muscle group.

Category

Treatment - Other

2

Description

Intervention group Group B (myofascial release technique with foam roller): 22 patients will receive TENS and hot pack for 15 minutes on gluteal region as conservative treatment in prone position before the application of myofascial release technique with foam roller. In this technique, patients will be instructed to position themselves on the floor in a long sitting position, bending the hip and knee with the foot that placed on the floor. Then they will place the moderate density foam roller under their hip with the knee straight for the intervention. After that, patients will initiate their own roller massage technique for 2 minutes. Session duration will be 30-35 minutes, twice a week and there will be 8 sessions over 4 weeks. Furthermore, the stretching of piriformis, hamstring and calf muscles will be carried out by the therapist after the administration of MRT with foam roller. For piriformis stretching, patients will be in supine position with both knees flexed at 90 degrees. The foot of the unaffected leg resting on a table with the ankle of the involved leg placed on the opposite knee. Then patients will gently pull the unaffected thigh towards their chest until a stretch is perceived in the buttock and along the lateral aspect of the hip on the affected leg. This stretch will be maintained for 60 seconds before gradually returning to the initial position. For hamstring and calf stretching, patients will be instructed to stand upright and lean forward, placing the palms of both hands on the wall. They will stretch the hamstring and calf muscles of the affected lower limb by positioning the foot of the affected limb behind and the foot of the unaffected limb in front, with both knees fully extended. As the heels of both lower limbs reach the

floor, the knee of the unaffected limb will be flexed forward toward the wall to increase the stretch on the soleus of the affected limb. The upper body will then be swung left and right to ensure the stretching of the entire hamstring muscle group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Government General Hospital, Faisalabad

Full name of responsible person

Amna Aslam

Street address

93P8+3PP, Hospital rd, Block A Samnabad, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Phone

+92 320 7678354

Email

shahzadamna636@gmail.com

2

Recruitment center

Name of recruitment center

National Hospital, Faisalabad

Full name of responsible person

Ayesha Shafiq

Street address

C3C7+75R, Gulberg Road, Jinnah Colony, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Phone

+92 306 7233233

Email

shafiqayesha567@gmail.com

3

Recruitment center

Name of recruitment center

Mujahid Hospital

Full name of responsible person

Fatima Batool

Street address

P-103 Z Block Madina Town, Susan Road, Faisalabad

City

Faisalabad

Postal code

38000

Phone

+92 307 5592087

Email

fb5252774@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University, Faisalabad

Full name of responsible person

Zainab Sheraz

Street address

House no. 32, street no. 2, Rehman Town, adjacent Shahzad Colony, Satyana Road, Faisalabad

City

Faisalabad

Postal code

38000

Phone

+92 335 6600141

Email

zainab.48@hotmail.com

Web page address

<https://www.riphahfsd.edu.pk/>

Grant name

N/A

Grant code / Reference number

N/A

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

No

Title of funding source

N/A

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, Faisalabad

Full name of responsible person

Zainab Sheraz

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House no. 32, street no. 2, Rehman Town, adjacent

Shahzad Colony, Satyana Road, Faisalabad

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 335 6600141

Email

zainab.48@hotmail.com

Web page address

<https://www.riphahfsd.edu.pk/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Riphah International University, Faisalabad

Full name of responsible person

Zainab Sheraz

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House no. 32, street no. 2, Rehman Town, adjacent
Shahzad Colony, Satyana Road, Faisalabad

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 335 6600141

Email

zainab.48@hotmail.com

Web page address

<https://www.riphahfsd.edu.pk/>

Person responsible for updating data

Contact

Name of organization / entity

Riphah International University, Faisalabad

Full name of responsible person

Zainab Sheraz

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House no. 32, street no. 2, Rehman Town, adjacent
Shahzad Colony, Satyana Road, Faisalabad

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 335 6600141

Email

zainab.48@hotmail.com

Web page address

<https://www.riphahfsd.edu.pk/>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Real patient is involved

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available