

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Therapeutic Ultrasound versus Muscle Energy Techniques of piriformis and iliopsoas for coccydynia in pregnant females

#### Protocol summary

##### Study aim

To compare the effects of therapeutic ultrasound and muscle energy techniques of piriformis and iliopsoas for coccydynia in pregnant females

##### Design

The study is a concealed, randomized, blinded, clinical trial with a parallel group design. Randomization is done by lottery method. In this method, the researcher gives each participant of the trial a number. Researchers draw numbers from the box randomly to allocate participants in two groups.

##### Settings and conduct

This study is conducted at Arif Memorial Hospital. In this trial participants are blinded through concealment to avoid biasness.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20-40 years pregnant females  
Idiopathic coccydynia  
Subjects willing to undergo muscle energy techniques of piriformis and iliopsoas  
Exclusion criteria: Tumors  
Trauma  
Subjects with history of spinal surgery

##### Intervention groups

The individuals are grouped in 2 categories; Group A will receive Therapeutic ultrasound. Group B will receive muscle energy techniques of piriformis and iliopsoas

##### Main outcome variables

Pain is measured before the application of techniques using Numeric Pain Rating Scale (NPRS).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220626055285N1**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**

Update count: **0**

##### Registration date

2023-01-21, 1401/11/01

##### Registrant information

###### Name

Rehana Niazi

###### Name of organization / entity

Rashid Latif medical college

###### Country

Pakistan

###### Phone

+92 333 4734783

###### Email address

rehana.niazi@rlmc.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-28, 1401/11/08

##### Expected recruitment end date

2023-05-28, 1402/03/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Therapeutic Ultrasound versus Muscle Energy Techniques of piriformis and iliopsoas for coccydynia in pregnant females

##### Public title

Effect of Therapeutic Ultrasound versus Muscle Energy Techniques on coccydynia in pregnant females

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Idiopathic coccydynia Subjects willing to undergo muscle energy techniques of piriformis and iliopsoas Age 20-40 years pregnant females

### Exclusion criteria:

Tumors Trauma Subjects with history of spinal surgery Lumbar disc prolapse

## Age

From **20 years** old to **40 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **26**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients were allocated into two groups i.e.; Group A and Group B, by lottery method. Lottery method is a type of simple random sampling. In this method, each participant of the trial is assigned a unique number. In the next step these numbers are written on separate cards which are physically similar in shape, size, color etc. 35 cards were used. Then they are placed in a basket and thoroughly mixed. In the last step the slips are taken out randomly without looking at them and are placed into two sets randomly. Total of 26 cards were taken out, 13 participants in each group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The blinding is achieved by concealment in which the treatment allocation for each patient is not revealed to the patient. This is done to avoid biasness.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Institutional Review Board of Rashid Latif Medical College

##### Street address

35-Km Ferozpur road Lahore

##### City

Lahore

## Postal code

54600

## Approval date

2022-10-05, 1401/07/13

## Ethics committee reference number

IRB/2022/052

## Health conditions studied

### 1

#### Description of health condition studied

coccydynia

#### ICD-10 code

M53.3

#### ICD-10 code description

Sacrococcygeal disorders, not elsewhere classified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Pre and Post 1 Month

#### Method of measurement

Pain is measured before the application of techniques using Numeric Pain Rating Scale (NPRS).

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Group A will receive Therapeutic ultrasound. Therapeutic ultrasound is used with the intensity of 1.5W/cm<sup>2</sup> for 3-5 min with the use of ultrasonic gel and this procedure is done by approaching the patient posteriorly using irregular probe.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Group B will receive muscle energy techniques of piriformis and iliopsoas. For piriformis MET, ask patient to Lay the patient in the supine position and bend the knee of affected side and place the foot of that side on the lateral aspect of the opposite knee. The therapist was at the side of the patient. The therapist will push the knee medially until meeting the restrictive barrier. Ask the patient push against the therapist's resistance for 3 to 5 sec, allow for a period of isometric relaxation, then engage a new barrier and repeat three times. Then, return the patient to a neutral position. For Iliopsoas MET, Patient position is Supine lying with lower

leg hanging off the end of the plinth. The patient flexes the contralateral hip and knee to hug the lower extremity to the chest. Therapist position is Standing on the ipsilateral side of the dysfunction. By Using one hand to keep the contralateral leg flexed, the other hand will provide a downward force immediately proximal to knee until reaching the restrictive barrier. Continue to engage the restrictive barrier and instruct the patient to bring the knee up toward the ceiling to achieve hip flexion for 3 to 5 sec. Instruct the patient to relax and move the hip further into extension by providing a downward force proximal to the knee. Repeat the last two steps 3 to 5 times. After last repetition passively return the patient's leg to a neutral position.

#### Category

Treatment - Other

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Arif Memorial Hospital

###### Full name of responsible person

Amber Iqbal

###### Street address

35-Km Ferozepur road Lahore

###### City

Lahore

###### Postal code

54600

###### Phone

+92 321 4632209

###### Email

iqbalamber50@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Rashid Latif Medical College

###### Full name of responsible person

Rehana Niazi

###### Street address

35-Km Ferozepur road Lahore

###### City

Lahore

###### Postal code

54600

###### Phone

+92 333 4734783

###### Email

rehana.niazi@rlmc.edu.pk

###### Grant name

###### Grant code / Reference number

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

Yes

###### Title of funding source

Rashid Latif Medical College

###### 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

Rashid Latif Medical College

##### Full name of responsible person

Amber Iqbal

##### Position

Physiotherapist

##### Latest degree

Bachelor

##### Other areas of specialty/work

Physiotherapy

##### Street address

35-Km Ferozepur road Lahore

##### City

Lahore

##### Province

Punjab

##### Postal code

54600

##### Phone

+92 321 4632209

##### Email

iqbalamber50@gmail.com

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rashid Latif Medical College

##### Full name of responsible person

Rehana Niazi

##### Position

Professor

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

35-Km Ferozepur road Lahore

##### City

Lahore

##### Province

Punjab

##### Postal code

54600

##### Phone

+92 333 4734783

**Email**

rehana.niazi@rlmc.edu.pk

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rashid Latif Medical College

**Full name of responsible person**

Rehana Niazi

**Position**

Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

35-Km Ferozepur road Lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

54600

**Phone**

+92 333 4734783

**Email**

rehana.niazi@rlmc.edu.pk

**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