Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Pakistan

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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 Ferozepur 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/cm2 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
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Sponsors / Funding sources

1

Sponsor

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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
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Position
Physiotherapist
Latest degree
Bachelor
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Person responsible for updating data

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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