

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of Primal Reflex Release Technique and Stretching Exercises in Coccydynia

Protocol summary

Study aim

Effects of primal reflex release technique and stretching exercises on pain and function in patients with coccydynia.

Design

A randomized controlled not blind trial. Sample size 46 divided in 2 groups. Total 12 treatment sessions will be given to subjects.

Settings and conduct

Setting: District Head Quarter (DHQ) Hospital, Sargodha.

Participants/Inclusion and exclusion criteria

1) pain in or around coccyx without radiation 2) tenderness on palpation over coccyx 3) age group above 20 including both male and females 4) difficulty in pain free sitting for long duration
Exclusion 1) Patients with cancer or cysts in pelvic area 2) Any tumor, surgery or fracture, recent trauma 3) Pain in coccyx region referred from lumbar spine, pelvic floor muscles, degenerative disc, bony spurs, cysts, or infections etc. 4) neurologic signs/conditions, sensory paresthesia or motor paresis.

Intervention groups

Patients will be randomly divided into two groups with 23 patients in each group. After taking baseline assessment both group A and B will be treated with hot pack for 10 minutes and then PRRT will be performed. Maximal muscle contraction for 10 seconds against manual force will be applied in a diagonal of hip flexion adduction followed by relaxation of 30 seconds. 1 set of 6 repetitions of contract relax each treatment session and 3 sessions/week on alternate days will be given for 4 weeks. Stretching will be performed for piriformis and iliopsoas for group B. 3 sessions/week on alternate days will be given for 4 weeks. Treatment time of each session will be approximately 20-25 minutes.

Main outcome variables

Pain (Numeric Pain Rating Scale), Functional performance (Dallas Pain Questionnaire), Pain free sitting duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200513047421N2**

Registration date: **2021-08-10, 1400/05/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-10, 1400/05/19**

Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Pakeeza Seemal

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 48 3256502

Email address

pakeezaseemal212@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Primal Reflex Release Technique and Stretching Exercises in Coccydynia

Public title

Comparison of Primal Reflex Release Technique and Stretching Exercises in Coccydynia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pain in or around coccyx without radiation Tenderness on palpation over coccyx Age group above 20 including both male and females Difficulty in pain free sitting for long duration

Exclusion criteria:

Patients with cancer or cysts in pelvic area Any tumor, surgery or fracture, recent trauma Pain in coccyx region referred from lumbar spine, pelvic floor muscles, degenerative disc, bony spurs, cysts, or infections etc. Pregnancy and coccyx dislocation If any overt neurologic signs/conditions, such as sensory paresthesia or motor paresis, present during the initial evaluation

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Written informed consent will be taken. After enrollment into study, patient will be allocated either to Group A or Group B by lottery method. No. of Chits will be equal to total sample size, odd Numbers will be allocated to Group A and even number will be allocated to Group B. Each patient will be requested to draw a chit from the box and after that patient will be recruited into either Group A or Group B.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Sargodha Institute of Health Sciences(SIHS) Research Ethical Committee (REC)

Street address

117-C, Zafar Ullah Road, Satellite Town, Sargodha

City

Sargodha

Postal code

40100

Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

SIHS/21/160

Health conditions studied**1****Description of health condition studied**

Coccygodynia, is also referred as coccydynia, coccygeal neuralgia, coccalgia, or tailbone pain, is the term that describes the symptoms of pain occurring in the coccyx region. During sitting position pain is most commonly started, but may happen if individual changes his position from sitting to standing. Conservative, manual, surgical and other treatments are used to treat coccydynia depending on severity of condition.

ICD-10 code

M53.3

ICD-10 code description

Sacrococcygeal disorders, not elsewhere classified

Primary outcomes**1****Description**

Pain

Timepoint

Before treatment, after treatment (4 weeks)

Method of measurement

Numeric Pain Rating Scale (NPRS)

2**Description**

Functional performance

Timepoint

Before treatment, after treatment (4 weeks)

Method of measurement

Dallas Pain Questionnaire (DPQ)

3**Description**

Pain

Timepoint

Before treatment, after treatment (4 weeks)

Method of measurement

Pain free sitting duration

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After taking baseline measures, Group A will be treated with hot pack for 10 minutes. A gluteal set will be performed while the physical therapist karate chops the gluteal musculature bilaterally from the sacrum to the coccyx. The first coccyx release technique will be performed 10 times for duration of 30 seconds each treatment session. In second coccyx release technique maximal muscle contraction for 10 seconds against manual force applied in a diagonal of hip flexion adduction. The patient relaxes for 30 seconds. Thus, the contract-relax ratio will be 10:30. It will be performed at 1 set of 6 repetitions of contract relax each treatment session

Category

Treatment - Other

2

Description

Intervention group: After taking baseline measures group B will be treated with hot pack for 10 minutes. Stretching will be performed for Piriformis and Iliopsoas. It will be applied 5 times alternately for both sides for 30 second each with 10 second relaxation between each application.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

District Head Quarter (DHQ) Hospital, Sargodha.

Full name of responsible person

Pakeeza Seemal

Street address

Khushab Road, Sargodha, Punjab

City

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40100

Phone

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Web page address

<https://www.punjab.gov.pk/node/880>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

District Head Quarter (DHQ) Hospital, Sargodha.

Full name of responsible person

Pakeeza Seemal

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Grant name

Grant code / Reference number

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

No

Title of funding source

District Head Quarter (DHQ) Hospital, Sargodha

Proportion provided by this source

100

Public or private sector

Public

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

Sargodha Institute of Health Sciences (SIHS)

Full name of responsible person

Pakeeza Seemal

Position

Senior lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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House# 411, street#07, Al Farooq colony, Sargodha.

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

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Position

Senior Lecturer

Latest degree

Master

Other areas of specialty/work

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

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Full name of responsible person

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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

There is no further decision and information decided yet

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