Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Pakistan
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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
Sargodha
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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
Street address
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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

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Physiotherapy
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Person responsible for updating data

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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