

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of abdominal hypopressive exercise on pain intensity, functional disability, transversus abdominis muscle thickness and quality of life in Primiparous female with Sacroiliac hypermobility dysfunction

Protocol summary

Study aim

To find the effect of abdominal hypopressive exercise on pain intensity in primiparous female with sacroiliac hypermobility dysfunction To assess the effects of abdominal hypopressive exercise on functional activities of primiparous female with sacroiliac hypermobility dysfunction. To evaluate the effects of abdominal hypopressive exercise on sonographic change in transversus abdominis muscle thickness in primiparous female with sacroiliac hypermobility dysfunction To find the change in quality of life in primiparous female with sacroiliac hypermobility dysfunction

Design

Randomized, single blinded, parallel group

Settings and conduct

The Physical therapy department, ULTH, The University of Lahore It will be a single blinded trial in which the assessor will be kept blind. Assessor will be senior physiotherapist who will take measurements after giving consent to participate in the study. He will be blind, not confirmed about the group of intervention

Participants/Inclusion and exclusion criteria

- Primiparous Female aged between 18-30 years
- Patient with vaginal delivery
- Within one year after post-partum
- Unilateral sacroiliac dysfunction
- Positive SI joint dysfunction test
- Exclusion Criteria:
- Pregnancy
- History of Cardiopulmonary Disease
- History of Spondyloarthropathies

Intervention groups

Abdominal hypopressive exercise group Conventional physical therapy

Main outcome variables

Pain Intensity functional disability Muscle thickness changes

General information

Reason for update

Acronym

AHE

IRCT registration information

IRCT registration number: **IRCT20241222064127N1**

Registration date: **2025-02-24, 1403/12/06**

Registration timing: **registered_while_recruiting**

Last update: **2025-02-24, 1403/12/06**

Update count: **0**

Registration date

2025-02-24, 1403/12/06

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-20, 1403/12/02

Expected recruitment end date

2025-08-20, 1404/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of abdominal hypopressive exercise on pain intensity, functional disability, transversus abdominis muscle thickness and quality of life in Primiparous female with Sacroiliac hypermobility dysfunction

Public title

Effects of abdominal hypopressive exercise on pain intensity, functional disability, transversus abdominis muscle thickness and quality of life in Primiparous female with Sacroiliac hypermobility dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with vaginal delivery Within one year after post-partum Unilateral sacroiliac dysfunction Sacroiliac Forward Flexion Test (= or more than 5mm difference will suggest sacral torsion) Positive SI joint dysfunction test (= or more than 3 tests +ve) The SIJ and posterior elements of the pelvic girdle can be examined using the P4 posterior pelvic pain provocation test, Patrick's FABER (flexion, abduction, external rotation of the hip) test, active straight leg raise, palpation of the long dorsal sacroiliac ligament and Gaenslen's test VAS score equal or greater than 4 • Modified Oswestry disability index score equal or greater than 15

Exclusion criteria:

Pregnancy History of Cardiopulmonary Disease History of Spondyloarthropathies History of Femoral acetabular impingement History of Ischiofemoral impingement History of Lumbar disc herniation History of Lumbar facet syndrome History of traumatic injury to lumbar spine, sacroiliac joint or hip joint Diagnosed by physician with any disease other than iliosacral dysfunction Previous surgical history of back

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

4

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients having diagnosed Sacroiliac dysfunction will be recruited in the study by purposive sampling, and the patients who fulfill the inclusion and exclusion criteria will be selected, with similar baseline characteristics. The consent will be taken from the subjects to participate in the study. The subjects will be randomly assigned to one of two groups by using a table of random numbers generated the randomization sequence, using a restricted randomization scheme to assure equal

numbers in each group. Random allocation to all groups will be ensured, from all study personnel and participants by entry of data into computer randomization program immediately. Group assignments will be sealed in opaque envelopes and opened sequentially by the investigators.

Blinding (investigator's opinion)

Single blinded

Blinding description

It will be a single blinded trial in which the assessor will be kept blind. Assessor will be senior physiotherapist who will take measurements after giving consent to participate in the study. He will be blind, not confirmed about the group of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

single blinded, single setting

Secondary Ids

empty

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

Research Ethics committee, Faculty of Allied Health Sciences, The University Of Lahore

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1-km defence road, off bhoptian chowk, Lahore
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Lahore

Postal code

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Approval date

2023-12-20, 1402/09/29

Ethics committee reference number

REC-UOL-616-12-2023

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

Sacroiliac hypermobility dysfunction

ICD-10 code

M53.2X

ICD-10 code description

Spinal instabilities

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

Pain intensity

Timepoint

before intervention, 4 and 8 weeks after intervention

Method of measurement

Visual Analogue Scale

2**Description**

Functional Disability

Timepoint

before intervention, 4 and 8 weeks after intervention

Method of measurement

Modified Oswestry disability index (MODI)

3**Description**

thickness of transverses abdominus muscle

Timepoint

before and after the intervention

Method of measurement

Sonography

Secondary outcomes**1****Description**

quality of life

Timepoint

before and after treatment

Method of measurement

SF-12 questionnaire

Intervention groups**1****Description**

Intervention group: In abdominal hypopressive exercise group the participants will receive 3 sessions of exercises per week over the period of two months. Participants will learn the posture and breathing techniques in the first week. AHT involves 3 cycles of normal breathing followed by total air expiration and gradual contraction of the TrA and intercostal muscle with the rise of the hemi diaphragm and apnea. In 8 weeks the participant will learn performing abdominal hypopressive exercise in different postures in progressive manner. Postures will be repeated three times and apnea will be maintained for an average of 30 seconds. Conventional Physiotherapy which included US with a frequency of 1 MHz and intensity of 0.8 W/cm² for 5 minutes followed by Corrective exercises.

WEEKS EXERCISES

Week 1: Standing posture and Tailor Sitting posture

Week 2: Semi-Sitting posture and Tailor Sitting posture

Week 3: Supine position and Tailor Sitting posture

Week 4: Kneeling posture, Quadruped posture and Genupectoral Sitting posture

Week 5: Standing posture and Tailor Sitting posture

Week 6: Kneeling posture and Quadruped posture

Week 7: Semi-Sitting posture and Supine position

Week 8: Tailor sitting posture and Genupectoral

Sitting posture

Category

Rehabilitation

2**Description**

Control group: Conventional Physiotherapy includes Ultra sound with a frequency of 1 MHz and intensity of 0.8 W/cm² for 5 minutes followed by Corrective exercises. Corrective Exercises

The following low back corrective exercises will be given:

1. To stretch the tight lower back muscles- Seated Forward Bend- hold for 5 sec and repeat for 3 times, once a day
2. To stretch the tight lower back muscles- Full Squat hold for 5 sec and repeat for 3 times, once a day
3. To strengthen the weak lower abdomen- Draw in holding for 3 seconds, repeat 5 times, once a day
4. To strengthen the weak lower abdomen- Reverse Crunch- holding for 2 sec, repeating 5 times, twice a day
5. To stretch the tight hip flexors: Standing Hip Flexor Stretch- hold for 10-15 seconds repeat 5 times on both legs, once a day
6. To strengthen the weak gluteus: Toed in Glutei Squeeze- hold for 3 sec, repeat 10 times, once a day
7. To strengthen the weak gluteus: Bridge both single and double leg- hold for 3 seconds, repeat 10 times, once a day
8. To stretch the tight quadriceps: Standing Quadriceps Stretch- hold for 3 seconds, Repeat 5 times on each side, once a day
9. To strengthen weak hamstrings: Kick Butts -hold for 2 sec, repeat 8 times, once a day, progression 2 times per day

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

The Physical therapy department, ULTH, The University of Lahore

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

The University of Lahore

Full name of responsible person

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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
 The University of Lahore
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

all collected IPD for all outcome measures

When the data will become available and for how long

starting in February, 2025 6 months after publication

To whom data/document is available

persons in academic institutes and researchers

Under which criteria data/document could be used

it could be used on permission from investigator

From where data/document is obtainable

through email to investigator

Halimashoukat92@gmail.com

What processes are involved for a request to access data/document

through email to investigator

Halimashoukat92@gmail.com and Call Halima Shoukat
0923244257755

Comments

Data will be provided on request