Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 abdominus 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

Halima Shoukat

Name of organization / entity

Government College University, Faisalabad

Country

Pakistan

Phone

+92 324 4257755

Email address

halimashoukat92@gmail.com

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 Oswetry 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 Ischeofemoral impingement History of Lumar 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

Street address
1-km defence road, off bhoptian chowk, Lahore Pakistan

City
Lahore

Postal code
0544

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 Wcm2 for 5 minutes followed by Corrective exercises.WEEKS EXERCISES Week 1: Standing posture and Tailor Sitting postureWeek 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 Wcm2 for 5 minutes followed by Corrective exercises. Corrective ExercisesThe 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 day2. To stretch the tight lower back muscles- Full Squat hold for 5 sec and repeat for 3 times, once a day3. To strengthen the weak lower abdomen- Draw inholding for 3 seconds, repeat 5 times, once a day4. 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 day8. To stretch the tight quadriceps: Standing Quadriceps Stretch- holdfor 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
Asim Arif
Street address
1-km defence road, off bhoptian chowk, Lahore
City
lahore
Postal code
54000
Phone
+92 42 35322501
Email
asim.pt@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
Full name of responsible person

Ashfaq Ahmad
Street address
1-km defence road, off bhoptian chowk, Lahore
City
Lahore
Postal code
54000
Phone
+92 42 35322501
Email
ashfaq.ahmad@uipt.uol.edu.pk
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
Name of organization / entity
government college university, faisalabad
Full name of responsible person
Halima Shoukat
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
kotwali road, Gurunanakpura,
City
faisalabad
Province
punjab
Postal code
38000
Phone
+92 41 9200952
Email
halimashoukat92@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Government College University, Faisalabad
Full name of responsible person
Halima Shoukat
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
kotwali road, gurunanakpura
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 41 9200953
Email
Halimashoukat92@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
government college university, faisalabad
Full name of responsible person
Halima Shoukat
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
kotwali road, Gurunanakpura,
City
faisalabad
Province
punjab
Postal code
38000
Phone
+92 41 9200952
Email
halimashoukat92@gmail.com

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