

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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 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

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 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

**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 W/cm<sup>2</sup> 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/cm<sup>2</sup> 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**

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**

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## Person responsible for updating data

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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