

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of manual therapy with and without shockwave therapy on lumbar disc herniation in patients with sacroiliac joint dysfunction

#### Protocol summary

##### Study aim

To compare the effects of manual therapy with and without shockwave therapy on lumbar disc herniation in patients with sacroiliac joint dysfunction

##### Design

Two arm parallel group randomized trial with single blind about outcome assessment

##### Settings and conduct

This study will be conducted at University of Lahore teaching hospital .This study will be a single blinded study in which assessor was kept blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria • Participants aged  $\geq 18$  years • Both male and female patients • Chronic low back pain lasting over 3 months • Pain localized in unilateral sacroiliac joint • Presence of muscle spasm around the sacroiliac joint • Limited activity of lower limbs and inability to sit for extended periods • Positive findings on pelvic compression and separation tests, the "4" test, and one-foot standing test Exclusion Criteria: • Patients experiencing pain in the waist and legs from alternative etiologies • Pregnant individuals • Individuals with tuberculosis affecting the sacroiliac joint or spine • Participants with inflammatory conditions such as ankylosing spondylitis • Individuals with sacroiliac joint sprain characterized by symmetrical bone marks and no abnormalities observed in X-ray images

##### Intervention groups

All the screened and willing participants will be randomly allocated to two groups (Group A: Shockwave therapy with routine physical therapy group, Group B: Comparative Group / Manual therapy with routine physical therapy) by lottery method.

##### Main outcome variables

Pain , Disability and Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241019063426N1**  
Registration date: **2024-12-23, 1403/10/03**  
Registration timing: **retrospective**

Last update: **2024-12-23, 1403/10/03**

Update count: **0**

##### Registration date

2024-12-23, 1403/10/03

##### Registrant information

##### Name

Sana Sana

##### Name of organization / entity

University of Lahore

##### Country

Pakistan

##### Phone

+92 335 4552087

##### Email address

drsanasana986@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-07-03, 1403/04/13

##### Expected recruitment end date

2024-08-13, 1403/05/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of manual therapy with and without shockwave therapy on lumbar disc herniation in patients with

sacroiliac joint dysfunction

## Public title

Effect of manual therapy with and without shockwave therapy on lumbar disc herniation

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Participants aged  $\geq 18$  years Both male and female patients Chronic low back pain lasting over 3 months Pain localized in unilateral sacroiliac joint Presence of muscle spasm around the sacroiliac joint Limited activity of lower limbs and inability to sit for extended periods Positive findings on pelvic compression and separation tests, the "4" test, and one-foot standing test

### Exclusion criteria:

Patients experiencing pain in the waist and legs from alternative etiologies Pregnant individuals Individuals with tuberculosis affecting the sacroiliac joint or spine Participants with inflammatory conditions such as ankylosing spondylitis Individuals with sacroiliac joint sprain characterized by symmetrical bone marks and no abnormalities observed in X-ray images

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **72**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this randomized controlled trial ,stratified randomization will be used to ensure balanced allocation. A random sequence will be generated using statistical software and group assignments will be concealed in opaque , sealed and sequentially numbered envelopes prepared by an independent researcher. Envelops will be opened only after participant enrollment to maintain allocation concealment and avoid bias.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This study is single blinded study in which assessor will be remain unaware of the treatment group while assessing but patients will know about the whole procedure

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of University of Lahore

##### Street address

University of Lahore Teaching Hospital Lahore ,  
Punjab , Pakistan

##### City

Lahore

##### Postal code

55150

#### Approval date

2024-08-13, 1403/05/23

#### Ethics committee reference number

REC-UOL-/379/08/24

## Health conditions studied

### 1

#### Description of health condition studied

Sacroiliac joint dysfunction refers to abnormal movement or inflammation in the sacroiliac joint, causing pain in the lower back and pelvis. It often results from trauma, misalignment, or excessive stress on the joint.

#### ICD-10 code

S33.6XXA

#### ICD-10 code description

Sprain of sacroiliac joint, initial encounter

## Primary outcomes

### 1

#### Description

The pain VAS is a unidimensional measure of pain intensity, used to record patients' pain progression, or compare pain severity between patients with similar conditions.

#### Timepoint

4th week

#### Method of measurement

The simplest VAS is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptom, pain, health) orientated from the left (worst) to the right (best) .

### 2

#### Description

The Back Pain Functional Scale (BPFS) is a subjective measure developed by Stratford et al. in 2000 to assess physical function during the initial weeks of low back pain episodes.

#### Timepoint

4th week

#### Method of measurement

The total score out of 60 indicates physical abilities, with

a higher score representing greater functionality. Additionally, an 'Adjusted score' ranges from 0 to 60, reflecting the ability to perform activities, with 0 indicating inability and 60 indicating no difficulty.

### 3

#### **Description**

The SF-12 is a self-reported outcome measure assessing the impact of health on an individual's everyday life. It is often used as a quality of life measure.

#### **Timepoint**

4th week

#### **Method of measurement**

The SF-12 uses the exact two domains mental and physical health score as the SF-36. Patients fill out a 12-question survey which is then scored by a clinician or researcher.

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Patients in Group A will be received ESWT using the Shockwave Therapy Machine In the MT group, interventions will be as follows: Patients will be assumed a prone position, during which the operator will be administered a massage and apply pressure to the affected lumbosacral muscles (latissimus dorsi, erector spinae, multifidus, gluteus Maximus, gluteus medius, iliopsoas, lateral external oblique muscle, and internal oblique muscle) for approximately 10 minutes. When a cord-like painful nodule at the SIJ is touched, the operator will be flipped the nodule with their thumb and gently push it obliquely upward or downward until the nodule reduces or disappears. Subsequently, the patient will be transitioned to a supine position, and their lower limb will be straightened and subjected to a ring-like shaking motion 6-7 times. The patient's affected side will be then positioned beneath the operator's arm, and they will be received forward-bending traction for 1 minute, involving flexion of the knees and hip, as well as adduction of the hip joint. Finally, the operator will be positioned the patient in lateral decubitus on the healthy side and instruct them to flex their knees and hips. The operator will be then applying pressure and movement to the affected side of the sacroiliac joint (SIJ), followed by straightening the affected extremity. This treatment process will be repeated 3-5 times. Subsequently, the patients will be instructed to assume the prone position, and various assessments, including measuring the height of the posterior superior iliac spine, evaluating painful cord-like nodules, conducting the "4" test, and performing point of care testing, will be performed to assess the degree of SIJ dysfunction. And some lumbar stretching exercises (including bridges, knee to chest, press-up back extensions, and bird dogs) and exercises for strengthening core muscles (partial crunches, pelvic

tilts, wall sits, hip stretches) will be assigned to the patients for 10 minutes.

#### **Category**

Treatment - Other

#### 2

#### **Description**

Intervention group: In group B, patients will be received manual therapy only, following the interventions will be same, Patients will be assumed a prone position, during which the operator will be administered a massage and apply pressure to the affected lumbosacral muscles for approximately 10 minutes. When a cord-like painful nodule at the SIJ is touched, the operator will be flipped the nodule with their thumb and gently push it obliquely upward or downward until the nodule reduces or disappears. Subsequently, the patient will be transition to a supine position, and their lower limb will be straightened and subjected to a ring-like shaking motion 6-7 times. The patient's affected side will be then positioned beneath the operator's arm, and they will be received forward-bending traction for 1 minute, involving flexion of the knees and hip, as well as adduction of the hip joint. Finally, the operator will be positioned the patient in lateral decubitus on the healthy side and instruct them to flex their knees and hips. The operator will be then applying pressure and movement to the affected side of the sacroiliac joint (SIJ), followed by straightening the affected extremity. This treatment process will be repeated 3-5 times. And some lumbar stretching exercises (including bridges, knee to chest, press-up back extensions, and bird dogs) and exercises for strengthening core muscles (partial crunches, pelvic tilts, wall sits, hip stretches) will be assigned to the patients for 10 minutes.

#### **Category**

Treatment - Other

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

University of Lahore Teaching Hospital

##### **Full name of responsible person**

Dr. Asim Arif

##### **Street address**

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Punjab , Pakistan

##### **City**

Lahore

##### **Postal code**

55150

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+92 321 6597727

##### **Email**

asim.arif@uipt.uol.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

Asim Arif

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Drsanasana986@gmail.com

**Grant name**

None

**Grant code / Reference number**

None

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

No

**Title of funding source**

None

**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**

University of Lahore

**Full name of responsible person**

Sana

**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**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

Yes - There is 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

### Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining the confidentiality

### When the data will become available and for how long

Data will be available after the publication of findings till six months

### To whom data/document is available

Sana

### Under which criteria data/document could be used

For research purpose

### From where data/document is obtainable

To the corresponding author of the study, Sana and can contact on Drsanasana986@gmail.com , +92 335 4553087

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

Open access and there is the traditional public data release where anyone can get access to the data

### Comments