Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of manual therapy with and without shockwave therapy on lumber 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 lumber 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 ≥ 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

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Pakistan

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+92 335 4552087

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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 lumber disc herniation in patients with

sacroiliac joint dysfunction

Public title
Effect of manual therapy with and without shockwave therapy on lumber disc herniation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants aged ≥ 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

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
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Sana
Position
Consultant
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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 confidentially
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 correspondiong 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