

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of Low Intensity Pulsed Ultrasound on Clinical and Radiological Outcomes in Patients with Early Stage Lumbar Spondylolysis: A Randomized Controlled Trial

Protocol summary

Study aim

To compare the effect of routine physical therapy with routine physical therapy and low intensity pulsed ultrasound on clinical and radiological outcomes in patients with early stage lumbar spondylolysis.

Design

A concealed, randomized, blinded, controlled clinical trial with a parallel group design of 34 patients, enrolled between May 2020 and November 2020, and followed for one year

Settings and conduct

The list of diagnosed cases will be obtained from the department of orthopedics, patients will be randomly selected and will be approached by principal investigator after informed consent taken and their approval and ethical approval they will be included in the study. The principal investigator will be known to the type of treatment but the assessor here will be kept blinded by labeling treatment A and treatment B to either group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age: 20-40 years, Both Gender, Married living with their spouse as Oswestry Low Back Pain Disability Questionnaire is consisted of a part based on sexual activity, Diagnosed cases of early stage spondylolysis on x-ray and Symptomatic low-back pain since more than 4 weeks. Exclusion Criteria: History of neurological or autonomic deficits, History of other fracture or bony abnormalities, History of rheumatic disease, History of other spinal problems, History of post-menopausal female, History of osteoporosis, History of osteopenia

Intervention groups

Group A: will receive the routine physical therapy alone.
Group B: will receive the routine physical therapy and low intensity pulsed ultrasound.

Main outcome variables

Pain, Quality of Life, Muscle Strength, Functional

Disability and X-ray findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200206046396N1**

Registration date: **2020-05-02, 1399/02/13**

Registration timing: **prospective**

Last update: **2020-05-02, 1399/02/13**

Update count: **0**

Registration date

2020-05-02, 1399/02/13

Registrant information

Name

Fahad Tanveer

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 42 35184348

Email address

fahadtanveer3.pt@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-15, 1399/02/26

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effects of Low Intensity Pulsed Ultrasound on Clinical and Radiological Outcomes in Patients with Early Stage Lumbar Spondylolysis: A Randomized Controlled Trial

Public title
Effects of Low Intensity Pulsed Ultrasound on Clinical and Radiological Outcomes in Patients with Early Stage Lumbar Spondylolysis: A Randomized Controlled Trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age: 20-40 years Both Gender Married living with their spouse as Oswestry Low Back Pain Disability Questionnaire is consisted of a part based on sexual activity Diagnosed cases of early stage spondylolysis on x-ray Symptomatic low-back pain since more than 4 weeks
Exclusion criteria:
 History of neurological or autonomic deficits History of other fracture or bony abnormalities History of rheumatic disease History of other spinal problems History of post-menopausal female History of osteoporosis History of osteopenia

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Lottery method

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor will be blind as the treatment groups will be named as group A or group B. Assessor will not aware about group A and group B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of University Institute of Physical Therapy, The University of Lahore

Street address

1 Km Off Raiwind Road, Lahore

City

Lahore

Postal code

54792

Approval date

2020-01-22, 1398/11/02

Ethics committee reference number

IRB-UOL-FAHS/690/2020

Health conditions studied

1

Description of health condition studied

Early Stage Lumbar Spondylolysis

ICD-10 code

M43.06

ICD-10 code description

Spondylolysis, lumbar region

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and 8, 20 weeks after intervention

Method of measurement

Numeric Pain Rating Scale

2

Description

Quality of Life

Timepoint

Before intervention and 8, 20 weeks after intervention

Method of measurement

World Health Organization Quality of Life-Bref

3

Description

Functional Disability

Timepoint

Before intervention and 8, 20 weeks after intervention

Method of measurement

Oswestry Disability Index

4

Description

Muscle Strength
Timepoint
Before intervention and 8, 20 weeks after intervention
Method of measurement
Hand Held Dynamometry

5

Description
Radiological Union
Timepoint
Before intervention and 8, 20 weeks after intervention
Method of measurement
X-ray

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group- will get Routine Physical Therapy + Low Intensity Pulsed Ultrasound 60 minutes of session, Alternative three days/ week for 12 weeks.
Category
Treatment - Other

2

Description
Control Group- will get Routine Physical Therapy 40 minutes of session, Alternative three days/ week for 12 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Orthopedic Surgery, University of Lahore Teaching Hospital, Lahore.
Full name of responsible person
Dr. Imran Salim Malik
Street address
1 Km off Defense Road, Lahore
City
Lahore
Postal code
74000
Phone
+92 42 37553435
Email
imransmalik@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
Full name of responsible person
Prof Dr Ashfaq Ahmad
Street address
1 Km Off Raiwind Road, Lahore
City
Lahore
Postal code
54792
Phone
+92 42 35322501
Email
ashfaaqpt@gmail.com
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
The University of Lahore
Full name of responsible person
Fahad Tanveer
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
1 Km Off Raiwind Road, Lahore
City
Lahore
Province
Punjab
Postal code
54792
Phone
+92 42 35184348
Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Fahad Tanveer

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

1 Km Off Raiwind Road, Lahore

City

Lahore

Province

Punjab

Postal code

54792

Phone

009235184348

Email

fahadtanveer3.pt@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Fahad Tanveer

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

1 Km Off Raiwind Road, Lahore

City

Lahore

Province

Punjab

Postal code

54792

Phone

+92 42 35184348

Email

fahadtanveer3.pt@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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

after publication of the study

To whom data/document is available

people working in academic institutions and researchers

Under which criteria data/document could be used

on informed request from the investigator

From where data/document is obtainable

via email / telephonic contact with investigator

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

on email request data will be provided within week

Comments