Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Oswerty 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

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Lahore

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74000

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+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

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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

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Person responsible for scientific inquiries

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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
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