

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of Low Level Laser Therapy in Discogenic Lumbar Radiculopathy; A Double Blind Randomized Controlled Clinical Trial

Protocol summary

Study aim

To determine the effectiveness of conventional physical therapy with and without Low Level Laser Therapy on pain, functional disability, ROM and Straight Leg Raise in patients with discogenic lumbar radiculopathy.

Design

Double Blind Randomized Controlled Trial with a parallel group design of 140 patients will have random allocation by Sealed Envelope Method.

Settings and conduct

Patients from the Physical Therapy Departments of Polyclinic, NIRM and Rawal hospitals, Islamabad Pakistan. The patients and outcome assessor will be kept blind during the whole trial regarding the treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria □ Age group between 25- 50 years □ Both male and female patients □ Newly diagnosed cases of discogenic lumbar radiculopathy □ Patients with at least moderate score (21% - 40%) in Oswestry Disability Index □ Patients with positive SLR or Lasègue's test
Exclusion Criteria □ Patients receiving treatment by other methods for the last 3 months □ Lumbar spine surgery within the past year □ Spondylolisthesis □ Ankylosing spondylitis □ Cauda equina syndrome □ Any co-morbid diseases

Intervention groups

Patients will be randomly assigned to a treatment group by Sealed Envelope Method, either an Experimental Group (Low level Laser Therapy and Conventional Physical Therapy) or a Control Group (Conventional Physical Therapy alone). The treatment procedures for both groups will be repeated for 3 sessions per week for 6 weeks (18 sessions) and a follow up consultation over a maximum period of Four weeks. The readings will be taken for two times (Pre-Treatment and Post-Treatment) during the whole session.

Main outcome variables

□ Visual Analogue Scale for Pain Intensity. □ Dual Inclinator for L-ROM □ Oswestry Disability Index) for

Functional Disability □ Straight Leg Raise or Lasègue's Test for Lumbar Radiculopathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190707044128N2**

Registration date: **2020-03-13, 1398/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-13, 1398/12/23**

Update count: **0**

Registration date

2020-03-13, 1398/12/23

Registrant information

Name

Ishaq Ahmed

Name of organization / entity

The university of Lahore

Country

Pakistan

Phone

+92 42 37592112

Email address

ishaqpt786@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-15, 1398/11/26

Expected recruitment end date

2020-04-15, 1399/01/27

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effectiveness of Low Level Laser Therapy in Discogenic Lumbar Radiculopathy; A Double Blind Randomized Controlled Clinical Trial

Public title
Low Level Laser Therapy in Discogenic Lumbar Radiculopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group between 25- 50 years Both male and female patients Newly diagnosed cases of discogenic lumbar radiculopathy Patients with at least moderate score (21%-40%) in Oswestry Disability Index Patients with positive SLR or Lasegue's test

Exclusion criteria:

Patients receiving treatment by other methods like vapocoolants, dry needling, laser acupuncture, subdural steroid injections etc. for the last 3 months Lumbar spine surgery within the past year Spondylolisthesis Ankylosing spondylitis Vascular, neurological or rheumatic disorders Clinical evidence of any myelopathy or joint disorders Recent fracture of the lumbar vertebral spine Cauda equina syndrome Osteoporosis Clinical evidence of any tumor or any space occupying lesion. Any co-morbid diseases

Age
From **25 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be allocated into two groups i.e. an Experimental Group and a Control Group by Randomization through Sealed Envelope Method. The Experimental Group patients will be treated with Low Level Laser Therapy along with Conventional Physical Therapy while those in the Control Group will be given Conventional Physical Therapy alone.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and the outcome assessor will be kept blind. Allocation of patients into the Experimental and Control group will be random through Sealed Envelope Method.

Placebo
Not used

Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Board of Advanced Studies and Research, The University of Lahore

Street address

1-km Defence Road, Off Bhotatian Chowk

City

Lahore

Postal code

54590

Approval date

2019-06-05, 1398/03/15

Ethics committee reference number

UOL/UIPT/BSAR/DPTH02163001

Health conditions studied

1

Description of health condition studied

Lumbar disc herniation is a displacement / protrusion of disc material (nucleus pulposus or annulus fibrosus) beyond the intervertebral disc space. The prolapsed nucleus pulposus will often come in contact with the nearby spinal nerves, results in the compression of these nerves which in turn results in severe radicular pain. Herniated discs are the common cause of lower back pain (LBP), hip and leg pain. The onset of pain may begin suddenly or gradually after injury. Typically, the pain is located bilaterally at the posterior belt line. The pain pattern is usually referred rather than radicular with a sharp, shooting pain running down the lower back, buttocks and down the thigh along with numbness or tingling sensations. The pain is aggravated by prolonged sitting, standing, forward bending or twisting movements and is relieved by walking, lying down, rest and a recumbent position.

ICD-10 code

M54.16

ICD-10 code description

Radiculopathy, lumbar region

Primary outcomes

1

Description

Pain Intensity

Timepoint

At the start of treatment and then after 18 treatment

sessions for each patient.

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Functional Disability

Timepoint

At the start of treatment and then after 18 treatment sessions for each patient.

Method of measurement

ODI (Oswestry Disability Index)

3

Description

Lumber Range of Motion

Timepoint

At the start of treatment and then after 18 treatment sessions for each patient.

Method of measurement

Dual Inclinator

Secondary outcomes

1

Description

Sciatic Nerve mobility

Timepoint

At the start of treatment and then after 18 treatment sessions for each patient.

Method of measurement

Straight Leg Raise or Lasegue's Test

Intervention groups

1

Description

Intervention group: Group-A of 70 patients will be treated with Low level Laser Therapy (LLLT) -830nm, 0.67 W/cm² or 300 mW/cm² at (Lumber-4,5 and Sacral-1 area) and Conventional Physical Therapy – McKenzie technique (1 set of 5 repetitions), Hot Pack (10 mins), Hold Relax with sustained stretch (1 set of 5 repetitions with 15 seconds hold), Sciatic nerve mobilizations in 1 set of 5 repetitions.

Category

Treatment - Other

2

Description

Control group: Group-B of 70 patients will be treated with Conventional Physical Therapy alone – McKenzie technique (1 set of 5 repetitions), Hot Pack (10 mins), Hold Relax with sustained stretch (1 set of 5 repetitions with 15 seconds hold), Sciatic nerve mobilizations in 1 set of 5 repetitions.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Poly Clinic Hospital

Full name of responsible person

Dr. Daud Niazi

Street address

44 Luqman Hakeem Rd, G-6/2 G 6/2 G-6, Islamabad, Islamabad Capital Territory

City

Islamabad

Postal code

44000

Phone

+92 51 9218300

Email

info@fgpc.com.pk

2

Recruitment center

Name of recruitment center

National Institute of Rehabilitative Medicine

Full name of responsible person

Dr. Zahoor Ahmed

Street address

Street 9, Sector G-8/2, Islamabad.

City

Islamabad

Postal code

44000

Phone

+92 51 9262213

Email

info@nirm.com.pk

3

Recruitment center

Name of recruitment center

Rawal Hospital

Full name of responsible person

Dr. Nadia Shaheen

Street address

Lehtrar Rd, Taramri, Tarlai Kalan

City

Islamabad

Postal code

45550

Phone

+92 51 2617381

Email

info@rgh.com.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

Dr. Ashfaq Ahmed

Street address

1-Km Defence Road, Off Bhabatian Chowk

City

Lahore

Postal code

54590

Phone

+92 42 35322501

Email

info@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**

The University of Lahore

Full name of responsible person

Dr. Ishaq Ahmed

Position

Assistant Professor/ Head of Physical Therapy

Department

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

6.7-Km, Japan Road, Sihala, Zone-5

City

Islamabad

Province

Punjab

Postal code

75500

Phone

+92 51 4486422-6

Email

ishaqpt786@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

The university of Lahore

Full name of responsible person

Ishaq Ahmed

Position

Assistant Professor/Head of Department

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Japan Road, Sihala

City

Islamabad

Province

Punjab

Postal code

75500

Phone

+92 42 37592112

Fax**Email**

ishaqpt786@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

The university of Lahore

Full name of responsible person

Ishaq Ahmed

Position

Assistant Professor/Head of Department

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Japan Road, Sihala

City

Islamabad

Province

Punjab

Postal code

75500

Phone

+92 42 37592112

Fax**Email**

ishaqpt786@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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Consent form, Clinical Study Report, Statistical Plan files
can be shared
**When the data will become available and for how
long**

2 months after Publication
To whom data/document is available
People working in academic institutions or people
working in businesses can also apply to receive it
Under which criteria data/document could be used
Intervention Purpose
From where data/document is obtainable
ishaqpt786@gmail.com
**What processes are involved for a request to access
data/document**
Full description about the purpose/aim of using the
documents, Insight about the disorder and Intervention
of the research
Comments