

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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 fibrosis) 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/cm<sup>2</sup> or 300 mW/cm<sup>2</sup> 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

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54590

**Phone**

+92 42 35322501

**Email**

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**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

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**Province**

Punjab

**Postal code**

75500

**Phone**

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**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**

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**Province**

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**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**