Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Public title

Low Level Laser Therapy in Discogenic Lumber 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 Bhobatian 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 Inclinometer

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

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2

Recruitment center

Name of recruitment center

National Institute of Rehabilitative Medicine

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Rawal Hospital

Full name of responsible person

Dr. Nadia Shaheen

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Lehtrar Rd, Taramri, Tarlai Kalan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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

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