Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of high power laser therapy on pain, functional disability, range of motion and pressure pain threshold in subjects with radicular low back pain due to intervertebral disc herniation

Protocol summary

Study aim

The purpose of this study is to evaluate the effect of active high-power laser compared to sham laser on pain, disability, range of motion, and pressure pain threshold in patients with radicular low back pain due to lumbar intervertebral disc herniation.

Design

The design of the present study is a randomized, double-blind, controlled clinical trial controlled by sham treatment, and random allocation will be performed by the variable block method, which includes four-letter blocks. Generatorslist.com is used to determine.

Settings and conduct

Target population: 36 patients with low back pain with radicular pain in one lower limb. Available community: Patients referred to the Poursina hospital, Rasht. When patients meet the criteria, afterward, they will fill out the relevant forms. Patients are randomly assigned to two groups: physiotherapy exercises with high power laser (n=18) and physiotherapy exercises with sham laser (n=18). The blinded people: assessors and patients

Participants/Inclusion and exclusion criteria

The criteria for inclusion in this Randomised controlled trial study are as follow: age between 25 and 60 years old, the patient has experienced clinical symptoms of L4-S1 herniation disc for 12 weeks at least, Diagnosis of lumbosacral disc herniation obtained by magnetic resonance imaging by neurologist; The criteria for exclusion are as follow: Patients with systemic conditions such as diabetes and cancer, etc., and a history of lumbar surgery and disorders that lead to symptoms of disc herniation (such as muscle trigger point or sacroiliac dysfunction)

Intervention groups

The treatment groups of this study are two groups: a) The first group is the real high-power laser group with motor control exercises. B) The second group is the unrealistic high power laser group with motor control exercises

Main outcome variables

The visual analog scale in resting in the last seven days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220410054486N1**
Registration date: **2022-06-23, 1401/04/02**
Registration timing: **prospective**

Last update: **2022-06-23, 1401/04/02**
Update count: **0**

Registration date

2022-06-23, 1401/04/02

Registrant information

Name

Seyed Mostafa Teymouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3255 8048

Email address

timouri.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-11, 1401/04/20

Expected recruitment end date

2023-01-10, 1401/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of high power laser therapy on pain, functional disability, range of motion and pressure pain threshold in subjects with radicular low back pain due to intervertebral disc herniation

Public title

The effect of high power laser therapy on radicular low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 25-60 years Diagnosis of radicular low back pain from the origin of the intervertebral disc herniation of the fourth lumbar to the first sacral vertebra by a neurosurgeon At least 12 weeks have passed since the symptoms Persistent pain or paraesthesia (numbness and/or tingling) in the lower back or both limbs due to herniation of the lumbar intervertebral disc in the path of the nerve root dermatome Patients on MRI stereotypes have protrusion or extrusion disc herniation

Exclusion criteria:

Local or systemic infection, rheumatic disease, diabetes Vertebral and sacroiliac joint dysfunction (Gillette test positive) Pregnancy History of previous surgery in the area Patients with MRI of spinal canal stenosis or spondylolisthesis Patients with vascular disorders, cancer and tumors and synovial cysts History of physiotherapy for at least the last 12 weeks sciatic nerve Contusion psychiatric illnesses Active trigger point of gluteus minimus muscle (diffuse sciatica-like pain)

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

All eligible patients with chronic radicular low back pain are randomly divided into two groups of treatment: high-intensity laser therapy and placebo high-intensity laser therapy groups with a 1: 1 ratio. Generatorslist.com is used to determine random allocation; This method is done with the help of four-digit blocks including even and odd numbers. For this purpose, 4-digit numbers are selected that have 2 even digits and 2 odd digits; Each digit represents each participant in the study. The random allocation process will be performed by someone outside the research team before the study begins. At the end of the random allocation, the numbers will be placed inside the numbered envelopes separately and after the initial evaluation by the examiner, the numbered envelopes will be given according to the ordinal number of each person entered in the study. Finally, after each participant enters the treatment sessions, the therapist opens the envelope of the participants and applies therapeutic interventions based on the number in the envelope. Patients are told not to provide information about their group to the assessor to prevent data contamination

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and assessor of outcomes are blind to treatment groups. First, the assessor measures the outcomes and then includes the study and the therapist performs the treatments of both groups, the assessor is not aware of the type of treatment during the study. Patients are first informed with a full explanation that the study is a clinical trial and has two groups and they will be in the intervention group or the control group, randomly. All patients wear a protective blindfold during treatment (due to laser treatment); To create real therapeutic conditions for the placebo group; The patient lies prone with a pillow under his abdomen and wears a protective blindfold. The difference is that the laser is off and an audio player turns on the sound of the laser device, to simulate the situation. At the end of the study, the examiner performs the final evaluation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Iran University of Medical Science

Street address

Maddakaran Alley, Shah Nazari St., Madar Square

City

Tehran

Province

Tehran

Postal code

19395- 5487

Approval date

2022-05-09, 1401/02/19

Ethics committee reference number

IR.IUMS.REC.1401.089

Health conditions studied

1

Description of health condition studied
Radicular low back pain
ICD-10 code
M54.17
ICD-10 code description
Radiculopathy, lumbosacral region

Primary outcomes

1

Description
Visual analog scale (VAS): Rated zero (painless) to 10 (most severe imaginable pain) of lumbar
Timepoint
The visual analog scale of pain is measured by the assessor before the intervention and every three sessions until the end of treatment, and one month after the end of treatment.
Method of measurement
In this study, pain is determined on a visual analog scale with a score of zero (painless) to 10 (the most severe pain imaginable for patients). The average pain in the last 7 days is the number of VAS.

Secondary outcomes

1

Description
Functional disability
Timepoint
Before the start of treatment by the assessor and the end of treatment and one month after the end of treatment
Method of measurement
In this study, the functional disability of the score obtained from the localized and Persianized Oswestry questionnaire, which was validated by Mousavi et al. In 2006.

2

Description
Pressure pain threshold
Timepoint
Before the start of treatment by the assessor and the end of treatment and one month after the end of treatment
Method of measurement
In this study, an algorithm will be used to measure the pressure threshold of pain. The algometer will record each point three times and an average of numbers per point will be written finally. 2 and 5 cm outside the first lumbar vertebra, 2 and 5 cm outside of the third lumbar vertebra,2 cm outside of the fifth lumbar vertebra bilaterally, on the common peroneal nerve (which comes from behind the fibula bone and reaches the front of the neck bone) and tibial nerve (outside the tibial artery) and the sciatic nerve (between the ischial tuberosity and the large trochanter deep in the gluteus maximus muscle), obtained at the moment of pain onset by participants, by algometer, in Newtons per square centimeter.

3

Description
Range of motion
Timepoint
Before the start of treatment by the assessor and the end of treatment and one month after the end of treatment
Method of measurement
In this study, the range of motion is the active movement of the lumbar region forward (using Schubert test) and the SLR range of motion of the affected lower limb (using a goniometer).

Intervention groups

1

Description
Intervention group: high-intensity laser therapy as the patient sleeps prone and a pillow will be placed under the abdomen and he wears a protective blindfold, the laser scanner is placed at a distance of 50 cm from the skin and the area under the 12th ribs to the upper part of the iliac crest from 4.2 cm outside the spine spinous process. Also, the sciatic, tibial and peroneal nerve pathways are laser irradiated. GaAlAs laser device with an average power of 1.6 watts and a wavelength of 808nm. The duty cycle is 80%. At the beginning of treatment with 10 joules per square centimeter and according to the patient's subjective symptoms, after every 3 sessions, 2 joules will be added to the previous dose; The final indication for a therapeutic dose is 16 joules per square centimeter and the treatment of motor control exercises is the basic treatment for all patients: The transverse abdominis and multifidus contractions will be done separately and also will be done as co-contractions in various positions. Contractions are initially performed up to a maximum of 10 repetitions per movement. Hold the contraction for 10 seconds. From the third week, the patient should be able to easily perform 10 repetitions and hold the contraction for 10 seconds and increase it. So, the exercises are progressive. Correction of activities including how to sleep, sit and stand properly, and how to carry loads are taught to the patient.
Category
Rehabilitation

2

Description
Control group: Unrealistic high-power laser as the patient lies prone with a pillow under his abdomen and wears a protective blindfold. The difference is that the laser is off and an audio player turns on the sound of the device to

simulate the situation and the treatment of motor control exercises is the basic treatment for all patients: The transverse abdominis and multifidus contractions will be done separately and also will be done as co-contractions in various positions. Contractions are initially performed up to a maximum of 10 repetitions per movement. Hold the contraction for 10 seconds. From the third week, the patient should be able to easily perform 10 repetitions and hold the contraction for 10 seconds and increase it. As a result, the exercises are progressive. Correction of activities including how to sleep, sit and stand properly, and how to carry loads are taught to the patient.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Poursina hospital

Full name of responsible person
Mohammadreza Pourahmadi

Street address
Crossroads of Poursina, Rasht

City
Rasht

Province
Guilan

Postal code
4193712194

Phone
+98 13 3332 5783

Fax
+98 13 3333 9842

Email
Poursina@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Reza Pourahmadi

Street address
Maddakaran Alley, Shah Nazari St, Madar Square

City
Tehran

Province
Tehran

Postal code
4391-15875

Phone
+98 21 2222 2059

Fax

Email
pourahmadipt@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

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
Iran University of Medical Sciences

Full name of responsible person
Mohammad Reza Pourahmadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Department of Physiotherapy, Faculty of Rehabilitation Sciences of Iran University of Medical Sciences, Maddakaran St., Shah Nazari St., Madar Sq., Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
4391-15875

Phone
+98 21 2222 2059

Email
pourahmadipt@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Reza Pourahmadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address

Department of Physiotherapy, Faculty of Rehabilitation Sciences of Iran University of Medical Sciences, Maddakaran St., Shah Nazari St., Madar Sq., Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
4391-15875

Phone
+98 21 2222 2059

Email
pourahmadipt@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Reza Pourahmadi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Department of Physiotherapy, Faculty of Rehabilitation Sciences of Iran University of Medical Sciences, Maddakaran St., Shah Nazari St., Madar Sq., Mirdamad Blvd.

City
Tehran

Province
Tehran

Postal code
4391-15875

Phone
+98 21 2222 2059

Email
pourahmadipt@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
Deidentified individual participant data collected for the primary and secondary outcome measures will be shared if necessary.

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
The data will be available for physical therapists working in academic institutions and also clinicians working in the field of musculoskeletal disorders

Under which criteria data/document could be used
The raw data and results of this study can be used in future relevant systematic reviews. Thus, the raw data and results of this study will be available for researchers working in the field of low back pain.

From where data/document is obtainable
Applicants can contact Dr. Mohammad Reza Pourahmadi (PT, PhD) by email. Email address: pourahmadipt@gmail.com

What processes are involved for a request to access data/document
Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may takes 10-12 working days.

Comments