

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of high-intensity laser therapy compared to low-intensity laser therapy in improving the symptoms of lumbosacral disc herniation patients with radiculopathy

Protocol summary

Study aim

Investigating the effect of high-intensity laser therapy in improving the symptoms of lumbosacral discopathy patients with radiculopathy and comparing its effect with low-intensity laser therapy

Design

A two-group, single-blind, phase 3 clinical trial on 50 patients

Settings and conduct

This study will be conducted on patients who come to the physical medicine and rehabilitation clinic of Shohad Tajrish Hospital in Tehran with complaints of low back pain.

Participants/Inclusion and exclusion criteria

Eligibility criteria: Patients who have lumbosacral discopathy based on history, examination and MRI findings. Exclusion criteria: a) Non-cooperation and failure to complete the 10-session treatment course b) Questionnaires that are incompletely completed or more than one question is answered. c) History of spinal fracture or surgery d) History of epidural steroid injection in the previous 4 weeks e) Presence of malignancy g) Pregnancy h) Having a cardiac pacemaker

Intervention groups

Dividing into two groups, one group is treated with high-intensity laser therapy and the other group is treated with low-intensity laser therapy.

Main outcome variables

a) Examining the effect of treatments performed on reducing patients' pain, b) Examining the effect of treatments performed on reducing patients' disability, c) Examining the effect of treatments performed on improving quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240115060701N1**

Registration date: **2024-01-23, 1402/11/03**

Registration timing: **prospective**

Last update: **2024-01-23, 1402/11/03**

Update count: **0**

Registration date

2024-01-23, 1402/11/03

Registrant information

Name

Abdoljabbar Mozaffari Komsh Tappeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

jabbarmozaffari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of high-intensity laser therapy

compared to low-intensity laser therapy in improving the symptoms of lumbosacral disc herniation patients with radiculopathy

Public title

Evaluation of the effect of high-intensity laser therapy compared to low-intensity laser therapy in improving the symptoms of lumbosacral disc herniation patients with radiculopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who attend the physical medicine and rehabilitation clinic with low back pain

Exclusion criteria:

History of spinal fracture or surgery
History of epidural steroid injection within 4 weeks before
Presence of Malignancy
Pregnancy
Having a cardiac pacemaker

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, according to the design, the patient is subjected to standard treatment, only the patient is not informed whether the treatment is high-power or low-power laser to reduce bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of Shahid Beheshti University of Medical Sciences and Healthcare Services

Street address

Shahid Beheshti University of Medical Sciences, Shahid Arabi Street, Yaman Street, Shahid chamran

Highway,

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

IR.SBMU.MSP.REC.1402.175

Health conditions studied

1

Description of health condition studied

Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Low Back Pain

Timepoint

At the beginning of the study (before the start of the treatment) and 1 months after treatment

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Degree of disability

Timepoint

At the beginning of the study (before the start of the treatment) and 1 months after treatment

Method of measurement

Oswestry Disability Index (ODI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 25 patients with low back pain who will be treated with 10 session of High Intesity Laser Therapy, 5 session per week with a frequency of 25 Hz, power of 10 watts, with a dose of 12 j/cm2 in the lumbar region for 4 minutes in biostimulation mode, followed by continuous mode for 6 minutes with a power of 7 watts and a dose of 10 j/cm2

Category

Treatment - Devices

2

Description

Intervention group: 25 patients with low back pain who will be treated with 10 session of Low Intesity Laser Therapy, 5 session per week, GaAlAs infrared radiation, wavelength 808 nm, power 160 mV and penetration depth 4 cm

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohad Tajrish Hospital

Full name of responsible person

Dariush Eliaspour

Street address

Shohada Tajrish Hospital, Shahrdari Street, Tajrish Square

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d.eliaspour@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Ali Ziaei

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abdoljabbar Mozaffari Komsh Tappeh

Position

Residentt of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Darioush Eliaspour

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Title and more details about the data/document

All the data of people participating in this study can be shared after deidentifying people

When the data will become available and for how long

The access period starts one year after the results are published.

To whom data/document is available

Data of this study will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

In the goal of the researchers is to conduct a systematic review and meta-analysis on the data, the non-identifiable data of patients will be provided to the researchers.

From where data/document is obtainable

By Sending an email to jabbarmozaffari@sbmu.ac.ir

What processes are involved for a request to access data/document

Sending an email requesting information and explaining the purpose and how to use the data

Comments