Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the clinical effects of percutaneous laser disc decompression in the treatment of Lumbar Intervertebral Disc

Protocol summary

Study aim

This study aims to determine the clinical effects of percutaneous disc decompression with laser in the treatment of lumbar discopathy compared to routine drug treatments.

Design

Clinical trial with a control group, with factorial groups, and a blind strain, on 36 patients

Settings and conduct

The study will be conducted in the form of a thesis of the Department of Neurosurgery of the University of Medical Sciences on the target population of all patients referred to Imam Reza Hospital clinic with radicular pain caused by intervertebral disc herniation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Age 35-70 years 2) Symptoms of radicular pain in the lower limbs 3) Lumbar disc herniation by CT scan, magnetic resonance imaging (MRI) or myelogram 4) No improvement after 3 months of conservative treatment Exit criteria: 1) Patients with previous spinal surgery 2) cauda equina syndrome 3) Bone disorders 4) Generalized bulging disc 5) Nervous disorders (movement disorders, urinary and fecal incontinence) 6) Pregnancy 7) Any history of coagulopathy 8) reducing the height of the disc by more than 50%

Intervention groups

Patients in the intervention group, after determining the affected areas of the lumbar spine, taking a history, physical examination, imaging such as MRI, CT scan and electromyography - nerve conduction velocity (EMG-NCV), in an outpatient setting, with injection A one-step needle into the disc space will be treated. Disc material is not removed. Instead, the nucleus pulposus will be vaporized by laser. When finished, the tip of the needle should be in the center of the disc. Analgesic treatment is prescribed to both intervention and control groups in the same way.

Main outcome variables

PLDD as an alternative treatment for patients with lumbar disc herniation can be performed in an outpatient setting with rapid recovery and return to daily routine.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231121060129N1**
Registration date: **2023-12-11, 1402/09/20**
Registration timing: **prospective**

Last update: **2023-12-11, 1402/09/20**
Update count: **0**

Registration date

2023-12-11, 1402/09/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the clinical effects of percutaneous laser disc decompression in the treatment of Lumbar Intervertebral Disc

Public title

Laser therapy in lumbar discopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) Age 35-70 years 2) Symptoms of radicular pain in the lower limbs 3) Confirmation of lumbar disc herniation with CT scan, magnetic resonance imaging (MRI) or myelogram 4) No improvement after 3 months of conservative treatment

Exclusion criteria:

1) Patients with a history of previous spinal surgery 2) cauda equina syndrome 3) Bone disorders 4) Generalized disc bulging 5) Nervous disorders (movement disorders, urinary and fecal incontinence) 6) Pregnancy 7) Any history of coagulopathy 8) reducing the height of the disc by more than 50%

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The target population includes all patients referred to the Imam Reza Hospital clinic with radicular pain caused by intervertebral disc herniation. Subjects are included in the study by considering the entry and exit criteria through non-random sampling. Then they are divided into intervention and control groups using RAS software using random block method with 2 and 4 blocks. Flow chart (Loss to follow up) will be mentioned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

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Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

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Approval date

2023-10-04, 1402/07/12

Ethics committee reference number

IR.TBZMED.REC.1402.485

Health conditions studied

1

Description of health condition studied

Lumbar discopathy

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description

The Persian version of the Roland-Morris Disability Questionnaire and Oswestry Disability Index is one of the main assessment tools used in the assessment of spinal disabilities. The RDQ has been validated and extensively evaluated in a variety of clinical studies and has been reported to exhibit good psychometric properties. 1 The questions in this questionnaire are designed to provide the physician with information about how Pacemaker pain affects the patient's ability to perform daily tasks.

Timepoint

Investigations are conducted and recorded before the intervention, immediately after the intervention and one week after the intervention.

Method of measurement

The amount of pain is determined using the VAS tool. The VAS tool is in the form of a graduated ruler from 0 to 10, and the patient indicates one of the numbers listed on the ruler according to the intensity of pain from the lowest to the highest.

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the intervention group, after determining the affected areas of the lumbar spine, taking a history, physical examination, imaging such as MRI, CT scan and electromyography - nerve conduction velocity (EMG-NCV), in an outpatient setting, with injection A one-step needle into the disc space will be treated. Disc material is not removed. Instead, the nucleus pulposus will be vaporized by laser. Patients are treated with a 1000 J 980 nm diode laser (a product of LaserStar Technologies Corp, manufactured in Germany with a 200 micron fiber) at a power of 5 watts. After sterile skin preparation and dressing, the disc space is identified with the help of a C-arm fluoroscope. The craniocaudal movement of the fluoroscope tube defines the margin of the disc. The fluoroscope tube is rotated obliquely to bring the superior articular process to the midline, and a 7-inch 18-gauge needle is inserted immediately anterior to the superior articular process and superior to the transverse process through a triangular safe zone. Advancement with the C-fluoroscope arm is observed to be strong enough and of good quality to provide an overview of the area. When finished, the tip of the needle should be in the center of the disc.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital

Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Investigation of the clinical effects of percutaneous laser disc decompression in the treatment of Lumbar Intervertebral Disc

Grant code / Reference number
71378

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

Title of funding source
Tabriz 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

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Professor

Latest degree
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Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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