Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of adding caudal neuroplasty to percutaneous laser disc decompression(PLDD) in the management of lumbar radiculopathy, a double-blind randomized clinical trial

Protocol summary

Study aim

A- General Objectives: To evaluate the effect of adding caudal neuroplasty to PLDD in controlling lumbar radiculopathy pain. B- Specific Objectives: -To determine the effect of PLDD on the pain score, ODI, Lasegue test , amount of painkillers consumption after procedure, in patients with lumbar radiculopathy. -To determine the effect of adding caudal neuroplasty to PLDD on the pain score, ODI, Lasegue test (positive or negative), amount of painkillers consumption .

Design

Clinical trial, Parallel group, double-blind, randomized, phase II on 44 patients. Block randomization method was used for randomization.

Settings and conduct

Total of 44 patients diagnosed with lumbar radiculopathy will be included in this clinical trial. They will be divided into 2 groups of 22 patients each, and the procedures will be conducted in the prone position under local anesthesia and fluoroscopy. Group A will undergo PLDD, Group B will receive the addition of caudal neuroplasty to PLDD. The evaluator and The pain management specialist responsible for the therapeutic intervention will be blind to the grouping and the materials used.

Participants/Inclusion and exclusion criteria

Including criteria: Age between 30-70 years old, low back pain radiating to the lower limb for 3 months without response to maintenance treatmentDisc buldging in MRI,Informed consent Excluding criteria: Previous surgery at the same disc level,Caudaequina syndrome,Vertebral listhesis,Tumor,Infection,Vertebral fracture,Pregnancy,Severe mental and physical illness,Dissatisfaction

Intervention groups

Group A: Lumbar disc decompression laser. Group B: Adding caudal neuroplasty to lumbar disc decompression laser.

Main outcome variables

Pain Intensity, Level of function in activities of daily living, Lasegue test, amount of painkillers consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241015063370N1**
Registration date: **2025-03-14, 1403/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-14, 1403/12/24**
Update count: **0**

Registration date

2025-03-14, 1403/12/24

Registrant information

Name

Katayoon Anoushirvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 3504

Email address

ktynshrvni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of adding caudal neuroplasty to percutaneous laser disc decompression(PLDD) in the management of lumbar radiculopathy, a double-blind randomized clinical trial

Public title
Effect of adding caudal nerve block to lumbar disc laser
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30-70years old low back pain radiating to the lower limb for 3 months without response to maintenance treatment Disc buldging in MRI Informed consent
Exclusion criteria:
Previous surgery at the same disc level Caudaequina syndrome Vertebral listhesis Tumor Infection Vertebral fracture Pregnancy Severe mental and physical illness Dissatisfaction
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization: Block randomization is conducted. At the time of the first visit to the pain clinic, one of the colleagues will place the code for the first 20 patients in one envelope as Group A and the code for the next 20 patients in another envelope as Group B. This colleague will not participate in the follow-up of patients. Blinding: Another colleague of the project, who is responsible for evaluation, data collection, and follow-up, will be unaware (blind) of the method of patient group randomization. Another project colleague, responsible for the therapeutic intervention, will be unaware (blind) of the grouping or the materials used.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding: Another colleague of the project, who is responsible for evaluation, data collection, and follow-up, will be unaware (blind) of the method of patient group randomization. Another project colleague, responsible for the therapeutic intervention, will be unaware (blind) of the grouping or the materials used. Patients will be unaware and blinded to the type of treatment method. They will know that they will be randomly assigned to one of the two study groups, but they will not know which treatment method will be provided in each group. Patients will be allocated to one of the two groups using a random number table. The data collector, analyst, and outcome evaluator will gather and analyze information based on Groups A and B and will remain unaware of the type of treatment in the groups, maintaining their blinding.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Iran University of Medical Science
Street address
Hemat Highway next to Milad Tower،Ethic Committee of Iran University of Medical Science
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2024-01-01, 1402/10/11
Ethics committee reference number
IR.IUMS.REC.1402.878

Health conditions studied

1

Description of health condition studied
The effect of adding caudal neuroplasty to percutaneous laser disc decompression in the management of lumbar radiculopathy a double-blind randomized clinical trial
ICD-10 code
M54.1
ICD-10 code description
Radiculopathy

Primary outcomes

1

Description
Assessment of Pain Intensity
Timepoint

before intervention, two weeks after, one month after, three months after intervention

Method of measurement

Visual Analogue Scale

2

Description

lasegue

Timepoint

before intervention, two weeks after, one month after, three months after intervention

Method of measurement

The test in which raising the leg creates pain in the lower limb and the angle at which the pain is generated is recorded.

3

Description

Level of function (disability) in activities of daily living

Timepoint

before intervention, two weeks after, one month after, three months after intervention

Method of measurement

The Oswestry Disability Index (ODI) a questionnaire which gives a subjective percentage scorelevel of function (disability) in activities of daily living in those rehabilitating from low back pain

4

Description

Amount Of Painkillers Consumption

Timepoint

before intervention, two weeks after, one month after, three months after intervention

Method of measurement

It is recorded by a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: After IV access for crystalloids injection, midazolam (1 mg) is initially administered intravenously for sedation. Initial standard monitoring with non-invasive arterial blood pressure, electrocardiogram, and pulse oximetry is performed. The patient is positioned prone on the operating room table under sterile conditions, and with C-arm imaging guidance, the target disc is identified. After local anesthesia, an 18-gauge disc needle is advanced through the skin in an oblique view with C-arm guidance into the disc. The correct placement of the needle tip is confirmed with AP and lateral views of the C-arm. Then, the needle mandrel is removed, and a laser fiber is inserted through the needle into the disc. The laser is applied with the following specifications: wavelength of 980 nanometers, power of 7 watts, pulse duration of 60 seconds, and interval of 1 second, until a total energy of 1500 joules is delivered. Following the laser energy application, 40 micrograms of ozone in 10 milliliters is injected into the disc through the same needle, and the needle is then withdrawn. This concludes the lumbar disc decompression procedure. Afterward, if the patient has stable hemodynamics, no sensory or motor disturbances, is conscious, can tolerate fluids, and has no complications, they are discharged from recovery. Upon discharge, all patients are prescribed pregabalin 75 mg and vitamin B-1 with a dose of 300 mg. Analgesics are recommended for pain above 3, including oral diclofenac 100 mg, up to 2 tablets per day.

Category

Treatment - Other

2

Description

Intervention group B: All procedures are the same as in the first group, with the only difference being that after the injection of ozone into the disc, caudal neuroplasty is performed as follows. In the lateral view of the C-arm, under local anesthesia, an 18-gauge caudal needle is inserted into the sacral hiatus, and after the injection of 1 ml contrast agent (Visipaque), the caudal neuroplasty injection solution, which includes 5 ml of 0.2% ropivacaine and 5 ml of normal saline containing 80 mg of triamcinolone, and 1500 units of hyaluronidase, is administered.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital pain clinic

Full name of responsible person

Katayoon Anoushirvani

Street address

No 5, Hemmati Alley, Kabkanian St, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۵۹۹۴۶۶۷

Phone

+98 21 8896 3504

Email

ktynshrvni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Majid Safa, Vice President of Research and Technology of Iran University of Medical Sciences

Street address
Tehran, Hemat Highway, next to Milad Tower, Iran University Of Medical Science, Department of Research and Technology

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 8670 2503

Email
Research@iums.ac.ir

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
Prof. Dr. Farnad Imani

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pain Management Fellow

Street address
Anesthesiology And Pain Management Research Center,Rasoul Akram Hospital, Niyayesh St,Sattarkhan St

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2107

Email
farnadimani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Prof. Dr. Farnad Imani

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pain Management Fellow

Street address
Anesthesiology And Pain Management Research Center,Rasoul Akram Hospital, Niyayesh St,Sattarkhan St

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2107

Email
farnadimani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Prof. Dr. Farnad Imani

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pain Management Fellow

Street address
Anesthesiology And Pain Management Research Center,Rasoul Akram Hospital, Niyayesh St,Sattarkhan St

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2107

Email
farnadimani@yahoo.com

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
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is shareable.

When the data will become available and for how long
Access period will begin 6 months after the publication of results.

To whom data/document is available
It will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Any use that aids patients and advances medical science, while adhering to medical ethics, is permissible.

From where data/document is obtainable
For obtaining the documents, contact ktynshrvni@gmail.com or visit the Pain Research Center at Rasoul Akram Hospital, located in Tehran, Sattarkhan Street, Niyayesh Street, Dr. Farnad Imani.

What processes are involved for a request to access data/document
After submitting a clear written request and stating the purpose of data access, the data will be provided within 2 weeks upon approval.

Comments