Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of percutaneous intradiscal hyalase injection, percutaneous intradiscal ozone injection, and percutaneous laser disc decompression in radiculopathy of patients with herniated lumbar disc

Protocol summary

Study aim

The purpose of this study is to compare the effectiveness of percutaneous laser disc decompression (PLDD), intradiscal ozone injection and intradiscal hyaluronidase injection in reducing pain and improving function of patients with radiculopathy following lumbar intervertebral disc herniation.

Design

A controlled, parallel-group, double blind, randomized, phase 3 clinical trial on 30 patients. Random allocation software is used for randomization.

Settings and conduct

Outcome assessor, statistician and the researcher are all blind to treatment group allocation. Subjects will be randomly allocated in 3 groups. The study will take place in Modava pain clinic, Tehran.

Participants/Inclusion and exclusion criteria

Patients with lumbar radiculopathy whose duration of symptoms is between 6 weeks and 6 months and did not respond properly to conservative treatments, the minimum VAS questionnaire score of participants is 5, and in MRI, confirmed disc herniation in one level with grade 1A, 2A, 1B 2B based on the MSU classification. Exclusion criteria include cauda equina syndrome, major neurological defects, pregnancy and breastfeeding, spondylodiscitis, spondylolisthesis, spinal canal stenosis, previous history of spine surgery.

Intervention groups

Intervention group 1: 10 patients are treated with intradiscal laser and a maximum of 1000 joules of energy is used. Intervention group 2: 10 patients are treated with 1500 mg of hyaluronidase inside the nucleus pulposus. Intervention group 3: A maximum of 10 cc of ozone with a concentration of 40 µg/ml is used for intradiscal injection. In all groups, 3 cc of 2% lidocaine and 40 mg of triamcinolone are injected immediately after the needle exits the disc in the infraneural position.

Main outcome variables

Assessment of lumbar pain, assessing the patient's performance and disability in daily tasks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N36**
Registration date: **2024-04-12, 1403/01/24**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-12, 1403/01/24**
Update count: **0**

Registration date

2024-04-12, 1403/01/24

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-26, 1402/12/07

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of percutaneous intradiscal hyalase injection, percutaneous intradiscal ozone injection, and percutaneous laser disc decompression in radiculopathy of patients with herniated lumbar disc

Public title

Comparison of percutaneous hyaluronidase injection, percutaneous laser disc decompression (PLDD) and percutaneous ozone injection in radiculopathy of patients with herniated lumbar disc.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lumbar radiculopathy whose duration of symptoms is between 6 weeks and 6 months and has not responded well to conservative treatment (NSAIDs, physiotherapy or epidural injection) The minimum VAS score of all participants is considered 5. In MRI, confirmed disc herniation in one level with grade 1A, 2A, 1B, 2B based on the Michigan State University (MSU) classification

Exclusion criteria:

Cauda equina syndrome The presence of any defect in motor function. Major neurological deficit Allergy to bovine proteins in patient treated with hyaluronidase Pregnancy and breastfeeding Spondylodiscitis Spondylolisthesis Spinal canal stenosis more than 50% Reduction of disc height Previous history of spine surgery

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

in this clinical trial study, 30 patients with a diagnosis of lumbosacral radiculopathy will be included in the study randomly .For random allocation of individuals in the study groups, the method of random allocation with block method (Block Randomization) will be used In this method, blocks with size of six (including two people in in each of the three groups with a ratio of 1:1:1 will be used. Random allocation software (RAS) will be used to generate random sequences. For concealment, the random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified with three types of cards which are identified by the letters A (intradiscal laser recipient group), B (hyaluronidase recipient group) and C (intradiscal ozone recipient group). Cards will be recorded and these cards will be placed in sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the researcher, the data analyst, and the outcome evaluator are kept blind and are not aware of the intervention performed on each group of patients, and only the final data are assigned to the first, second, and third groups of random numbers. Due to the different intervention in the three groups, it is not possible to blind the participants and the Care provider.

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

Street address

Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.SBMU.LASER.REC.1402.007

Health conditions studied

1

Description of health condition studied

Lumbosacral radiculopathy

ICD-10 code
M54.16
ICD-10 code description
Radiculopathy, lumbar region

Primary outcomes

1

Description
Assessment of lumbar pain
Timepoint
At the beginning of the study (before intervention) and 4 weeks, 12 weeks and 24 weeks after the intervention
Method of measurement
Visual analogue scale (VAS)

2

Description
Evaluation of pain, function and return to activity
Timepoint
At the beginning of the study (before intervention) and 4 weeks, 12 weeks and 24 weeks after the intervention
Method of measurement
Using the Modified Macnab questionnaire

3

Description
Assessment of the patient's disability in daily living
Timepoint
At the beginning of the study (before intervention) and 4 weeks, 12 weeks and 24 weeks after the intervention
Method of measurement
Using the Oswestry low back disability (ODI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: includes 10 patients who are treated with intradiscal laser (VELAS, 30W, 980 nm, diode laser) and a maximum of 1000 joules of energy was used. Immediately after exiting the Chiba needle (15 cm, G20) from the disc, 3 cc of 2% lidocaine and 40 mg of triamcinolone are injected infraneurally.
Category
Treatment - Drugs

2

Description
Intervention group: includes 10 patients who are treated with 1500 mg of hyaluronidase inside the nucleus pulposus. Immediately after exiting the Chiba needle (15 cm, G20) from the disc, 3 cc of lidocaine 2% and 40 mg of triamcinolone are injected infraneurally.
Category
Treatment - Drugs

3

Description
Intervention group: includes 10 patients who are treated with a maximum of 10 cc of ozone with a concentration of 40 µg/ml (intradiscal injection). Immediately after exiting the Chiba needle (15 cm, G20) from the disc, 3 cc of lidocaine 2% and 40 mg of triamcinolone are injected infraneurally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Modava pain clinic
Full name of responsible person
Seyed Ahmad Raeissadat
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Modava pain clinic, Gulban Street, Tarbiat Moalem Street, Farahzadi Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

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

No

Title of funding source

Laser Application in Medical Sciences Research Center(LAMSRC) 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

Ali Nazari Nodoushan

Position

Resident 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

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Full name of responsible person

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Position

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Latest degree

Specialist

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

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Email

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

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

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

From where data/document is obtainable

By sending an email to alin7093@gmail.com

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

The given request should contain information about his/her affiliation, phone number, e-mail and the reason for his/her request. If these items are presented and the information related to the applicant's plan is registered and confirmed in the PROSPERO system, the information will be provided to the applicant.

Comments