Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Therapeutic effects of laser assisted intradiscal nucleoplasty with and without adjuvant intradiscal ozone in patients with lumbar discopathy in terms of quality of life

Protocol summary

Study aim

Objective: to determine the superiority of laser assisted intradiscal nucleoplasty with or without Ozone in controlling pain and disability in patients with lumbar discopathy

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment.

Settings and conduct

The study will be done in Brain and Spinal Cord Injury Research Center, Neuroscience Institute, Tehran University of Medical Science. After informed consent, the patients will be included in the study. The responsible doctor, operation theater staff (other than the surgeon who performs the procedure) and statistical consultant will be blind to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: radicular low back pain with evidence of discopathy/discopathies of L3-L4, L4-L5 or L5-S1 in MRI in patients who fail to respond to conservative therapy and peri-root therapy. Exclusion criteria: Previous back surgery, bleeding tendency, drug abuse, non-controlled psychiatric disorders, lower extremity weakness, sphincter disorder, disc protrusion more than one third of anterior-posterior spinal column diameter in MRI, disc extrusion or sequestration in MRI

Intervention groups

In both groups A and B, intradiscal nucleoplasty will be done using Diode laser PW 3.5-5 W 1200-1500 J. In group B, after completion of nucleoplasty, 2 ml of Ozone 45 mcg/ml will be injected into the disc(s).

Main outcome variables

NRS (Numerical rating scale): Simple tool that tells us the patient's perceived intensity of pain. Patients are given a scale from 0 (no pain) to 10 (worst pain). Oswestry Disability Index (ODI) is an index derived from the Oswestry Low Back Pain Questionnaire used by clinicians and researchers to quantify disability for low back pain.

General information

Reason for update

Acronym

OLINT (Ozone Laser Intradiscal Nucleoplasty Trial)

IRCT registration information

IRCT registration number: **IRCT20200107046039N1**
Registration date: **2020-06-09, 1399/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-09, 1399/03/20**
Update count: **0**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name
Babak Babakhani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of laser assisted intradiscal nucleoplasty with and without adjuvant intradiscal ozone in patients with lumbar discopathy in terms of quality of life

Public title

Therapeutic effects of laser assisted intradiscal nucleoplasty with and without adjuvant intradiscal ozone on lumbar discopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Low back pain With lower limb radicular symptoms Spinal MRI indicates inter-vertebral disc(s) protrusion of L3-L4, L4-L5 or L5-S1 Failure of conservative treatments and peri-root injection

Exclusion criteria:

Previous back surgery Coagulation disorder Drug abuse Known non-treated psychiatric disorders Lower extremity weakness Sphincter disorder Disc protrusion more than one third of anterior-posterior spinal column in MRI Sequestration or extrusion of inter-vertebral disc in MRI

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups by computer randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In group one, after prep and drape, patients receive intradiscal nucleoplasty of responsible disc(s) after local anesthesia under C-Arm vision in prone position using diode laser. Patients in group two receive such a treatment, but before removal of intradiscal needle, 2 ml of 45 micro-gram/ml Ozone will be injected into the disc with a speed less than 0.5 ml/sec. The surgeon will be aware of the group allocation, while the patient, researcher and analyzer remain blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Neuroscience Institute, Tehran University of Medical Sciences

Street address

Reyhaneh Building, Emam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-08-08, 1398/05/17

Ethics committee reference number

IR.TUMS.NI.REC.1398.005

Health conditions studied

1

Description of health condition studied

Lumbar radiculopathy, Lumbar discopathy, Low back pain

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy

2

Description of health condition studied

lumbar radiculopathy

ICD-10 code

M54.16

ICD-10 code description

Radiculopathy, lumbar region

Primary outcomes

1

Description

Numeric Rating Scale (NRS): An 11-point numeric rating scale is a simple tool that tells us the patient's perceived intensity of pain. Patients are given a scale from 0 (no pain) to 10 (worst pain).

Timepoint

Before intervention, one, six and 12 month after intervention

Method of measurement
An 11-point numeric rating scale is a simple tool that tells us the patient's perceived intensity of pain. Patients are given a scale from 0 (no pain) to 10 (worst pain) and they select a number.

2

Description
(Oswestry Disability Index (ODI): self-filled questionnaire by patient which indicates disability from low back pain.
Timepoint
Before intervention, one, six and 12 month after intervention
Method of measurement
The self-completed questionnaire contains ten topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel. Each topic category is followed by 6 statements describing different potential scenarios in the patient's life relating to the topic. The patient then checks the statement which most closely resembles their situation. Each question is scored on a scale of 0–5 with the first statement being zero and indicating the least amount of disability and the last statement is scored 5 indicating most severe disability.The scores for all questions answered are summed, then multiplied by two to obtain the index (range 0 to 100). Zero is equated with no disability and 100 is the maximum disability possible.

Secondary outcomes

empty

Intervention groups

1

Description
The patient receives intradiscal nucleoplasty of responsible disc(s) in prone position using diode laser PW 3.5 to 5 W 1200 to 1500 j.Before removal of intradiscal needle, 2 ml of ozone 45 micro-gram/ml will be injected into the disc with a speed less than 0.5 ml/sec. Dressing of puncture site will be done.
Category
Treatment - Surgery

2

Description
Control group: The patient receives intradiscal nucleoplasty of responsible disc(s) in prone position using diode laser PW 3.5 to 5 W 1200 to 1500 j. The needle will be removed and dressing of puncture site will be done.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Brain and Spinal Cord Injury Research Center, Neuroscience Institute, Imam Khomeini Hospital, Tehran
Full name of responsible person
Babak Babakhani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
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Postal code
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Phone
+98 21 8889 6692
Email
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Web page address
https://www.tums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
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Position
Assistant professor
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Pain management
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Collected deidentified IPD, IPD collected for the primary outcome measure (NRS and ODI)
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Medical research and studies
From where data/document is obtainable
Reyhaneh Building, Brain and Spinal Cord Injury Research Centre,Emam Khomeini Hospital, Keshavarz Blvd., Tehran Dr Babak Babakhani Email: bbabakhani@sina.tums.ac.ir
What processes are involved for a request to access data/document
Sending Email
Comments