

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1560

Email address

bbabakhani@sina.tums.ac.ir

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

Street address

Reyhaneh Building, Imam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1560

Email

drbabakhani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 8889 6692

Email

gsia@tums.ac.ir

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

Full name of responsible person

Babak Babakhani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Pain management

Street address

Reyhaneh Building, Imam Khomeini Hospital
Complex, Tohid Squire, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1560

Email

drbabakhani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Babak Babakhani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Pain management

Street address

Reyhaneh Building, Imam Khomeini Hospital,
Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1560

Email

drbabakhani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Babak Babakhani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pain

Street address

Reyhaneh Building, Brain and Spinal Cord Injury
Research Centre, Emam Khomeini Hospital, Keshavarz
Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1560

Fax**Email**

drbabakhani@yahoo.com

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