

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of interdiscal ozone injection and Laser disc decompression in discogenic low back pain

Protocol summary

Summary

In this clinical trial, 40 patients with radiating low back pain to the lower limbs were selected. They had been diagnosed as disc herniation in physical exam and lumbar spinal disc imaging. The patients were randomly divided into two equal groups for intradiscal interventions. 20 patients in the laser group (L) was irradiated 1500 J Laser ray inters Disc. 20 patients in the ozone Group: (O) volume of 6 mL of 30 micrograms ozone, was injected into the disc. In both groups, 20 mg of triamcinolone was injected by transforaminal approach around the involved nerve root. Patients were followed for pain score on the visual Analog Scale (VAS) and improved performance in life based on Oswestry disability index and satisfaction levels, for six months

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011910599N7**

Registration date: **2016-07-30, 1395/05/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-30, 1395/05/09

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran University Of Medical School

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2016-04-03, 1395/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of interdiscal ozone injection and Laser disc decompression in discogenic low back pain

Public title

Comparison of the efficacy of interdiscal ozone injection and Laser disc decompression in discogenic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :age 20 -70 ,ASA(American Society of Anesthesia) I,II ,root irritation secondary to herniated disc ,pain score more than 4 , valid consent Exclusion criteria ; disc sequestration ,involve more than two disc ,cuda equina syndrome ,favism in ozone group

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University Of Medical School

Street address

Hemmat exp way

City

tehran

Postal code

Approval date

2016-06-01, 1395/03/12

Ethics committee reference number

IR.IUMS.REC.1395.27280

Health conditions studied

1

Description of health condition studied

Low Back Pain

ICD-10 code

G55.1

ICD-10 code description

Nerve root and plexus compressions in intervertebral disc disorders

Primary outcomes

1

Description

reduce pain & disability

Timepoint

one week ,1,3 ,6 month

Method of measurement

(visual analogue scale(VAS) , Oswestry disability index(ODI)

Secondary outcomes

1

Description

satisfactory ratio

Timepoint

6 month

Method of measurement

Patient relief

Intervention groups

1

Description

Ineradiscal 1500 J laser beam

Category

Treatment - Surgery

2

Description

ozone 30 mic interadiscal 6 ml injected

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasol Akram Hospital

Full name of responsible person

Mohmad Ghahremani MD

Street address

Satar Chan Ave ,Niaish St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research ,Iran University of medical Sciences

Full name of responsible person

Dr Musavi

Street address

Hemat I Exp Way,Iran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research ,Iran University of medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Pain Research Center

Full name of responsible person

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Pain Fellowship

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty