

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the efficacy of interadiscal 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

Iran (Islamic Republic of)

###### Phone

+98 21 6650 9059

##### Email address

p-rahimzadeh@tums.ac.ir

##### 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 interadiscal ozone injection and Laser disc decompression in discogenic low back pain

##### Public title

Comparison of the efficacy of interadiscal 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**

Mohamad Ghahermani MD

**Position**

Pain Fellowship

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**Web page address**

**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*