

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of magnetic resonance imaging (MRI) findings before and after intradiscal ozone injection in patients with lumbar disc herniation

Protocol summary

Study aim

The effect of intradiscal ozone injection in patients with lumbar disc herniation using magnetic resonance imaging (MRI) findings

Design

An uncontrolled before-after study with a single group design of 50 patients referred to Imam Reza Hospital with lumbar pain due to disc herniation.

Settings and conduct

Patients with lumbar disc herniation will undergo intradiscal intraforaminal injection of 8-10 ml ozone with the paravertebral approach in Imam Reza Hospital by an experienced pain specialist. magnetic resonance imaging (MRI) will be taken from all patients before injection and 6 months after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with lumbar pain due to disc herniation with any intensity; proven lumbar disk herniation using magnetic resonance imaging (MRI).
Exclusion criteria: history of lumbar disc herniation for more than 2 months; previous lumbar disc interventions, including surgery; ozone injection contraindications such as G6PD deficiency, uncontrolled hyperthyroidism, pregnancy, and leukemia.

Intervention groups

Intervention group: Intradiscal and intraforaminal injection of 10 cc of ozone (mixture of o2-o3) at a concentration of 30 µg/ml under fluoroscope guide with the paravertebral approach for one session

Main outcome variables

Type of lumbar disc herniation; grade of disc degeneration; location of lumbar disc herniation; grade of nerve root compression; grade of central spinal canal stenosis; grade of neuroforaminal stenosis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170910036107N3**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Naseh Yousefi

Name of organization / entity

Iran university of medical science and health services

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 6574

Email address

nasehusefi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-26, 1397/10/05

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of magnetic resonance imaging (MRI) findings before and after intradiscal ozone injection in patients with lumbar disc herniation

Public title

The effect of ozone on the lumbar disc herniation using magnetic resonance imaging findings

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with lumbar pain due to disc herniation with any intensity Proven lumbar disk herniation using magnetic resonance imaging (MRI)

Exclusion criteria:

History of lumbar disc herniation for more than 2 months
Previous lumbar disc interventions, including surgery
Ozone injection contraindications such as G6PD deficiency, uncontrolled hyperthyroidism, pregnancy, and leukemia

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences central building, Golgasht St., Azadi St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2018-12-25, 1397/10/04

Ethics committee reference number

IR.TBZMED.REC.1397.758

Health conditions studied**1****Description of health condition studied**

Lumbar disc herniation

ICD-10 code

M51

ICD-10 code description

Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders

Primary outcomes**1****Description**

Type of lumbar disc herniation

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

2**Description**

Grade of disc degeneration

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

3**Description**

Location of lumbar disc herniation

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

4**Description**

Grade of nerve root compression

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

5**Description**

Grade of central spinal canal stenosis

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

6

Description

Grade of neuroforaminal stenosis

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging (MRI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intradiscal and intraforaminal injection of 10 cc of ozone (mixture of o2-o3) at a concentration of 30 µg/ml under fluoroscope guide with the paravertebral approach for one session

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Payam Ghaderi

Street address

Golgassht St., Daneshgah St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

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3rd floor, Central building N2, Tabriz University of Medical Sciences, Golgasht St., Azadi St.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Payam Ghaderi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr. Mohammad Hossein Daghighi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the patient's data will be shared without mentioning their names and profile.

When the data will become available and for how long

Start accessing 6 months after publishing the results.

To whom data/document is available

For scholars working in academic centers.

Under which criteria data/document could be used

It can be evaluated and published by other people by mentioning the source.

From where data/document is obtainableDr. Payam Ghaderi, 00989124791387,
Ghaderi.payam@gmail.com**What processes are involved for a request to access data/document**

Upon authentication, data will be available to the applicants

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Payam Ghaderi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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