

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Golgasht St., Daneshgah St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

##### Phone

+98 41 3334 7056

##### Email

info@imamreza.tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Abolghasem Jouyban

##### Street address

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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

##### Phone

+98 41 3335 7310

##### Email

research-vice@tbzmed.ac.ir

##### 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

##### Street address

N15, Shahriyar 3 Alley, Etesami St., Vali-e-asr

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Tabriz

##### Province

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5166614766

##### Phone

+98 41 3333 2803

##### Email

Ghaderi.payam@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Hossein Daghighi

##### Position

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiology

**Street address**

N16, Hooman Alley, Foroughi St., Vali-e-asr

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mh\_daghighi@yahoo.com

+98 41 3333 2803

**Email**

Ghaderi.payam@gmail.com

**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 obtainable**Dr. 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

**Street address**

N15, Shahriyar 3 Alley, Etesami St., Vali-e-asr

**City**

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**Province**

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