Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Naseh Yousefi

Name of organization / entity
Iran university of medical science and health services

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Iran (Islamic Republic of)

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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
Street address
3rd floor, Central building N2, Tabriz University of Medical Sciences, Golgasht St., Azadi St.
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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
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Person responsible for scientific inquiries

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Professor

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Person responsible for updating data

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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 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