Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of intradiscal ozone injection on various types of herniated lumbar disc

Protocol summary

Study aim
Effect of intradiscal ozone injection on various types of herniated lumbar disc

Design
A total of 128 patients with radicular back pain (Based on MRI and MSU Classification criteria), are divided into 8 groups of 16 patients. All patients are given written consent (After explaining about the method of work and possible complications).

Settings and conduct
According to inclusion and exclusion criterias, 128 patients are divided into 8 groups of 16 people. All patients are given written consent (After explaining about the method of work and possible complications). Then inside the nucleus pulposus (Under fluoroscope guidance), a mixture of ozone + oxygen is injected at a concentration of 29-32 µg / ml (within 15 to 20 seconds). For all patients, the severity of pain (VAS) and the degree of disability (ODI)(Oswestry Disability Index) is assessed, before and one month and three months after injection. The physician who evaluates the patients after ozone injection is unaware of the type of herniated disc of the patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: VAS (Visual Analogue Scale) larger or equal to 5;Radicular pain for more than 4 weeks and less than one year;CT scan or MRI findings with dermatomal distribution of pain and disc herniation at one level;SLR is less than 45 ° positive exclusion criteria:Hemorrhagic diseases;Local infection;Uncontrolled diabetes; Pregnancy;Hyperparathyroidism;G6PD (Glucose-6-phosphate dehydrogenase) Deficiency;Unwillingness of the patient; Cauda equina syndrome symptoms

Intervention groups
According to the type of disk herniation (MSD classification), patients are divided into 8 different groups.

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130518013364N5**
Registration date: **2018-02-04, 1396/11/15**
Registration timing: **retrospective**

Last update: **2018-02-04, 1396/11/15**
Update count: **0**

Registration date
2018-02-04, 1396/11/15

Registrant information

Name
Mehrdad Taheri
Name of organization / entity
Shahid Beheshti University of Medical Science
Country
Iran (Islamic Republic of)
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+98 21 7756 7840
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m.taheri@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-04, 1396/01/15

Expected recruitment end date
2017-12-21, 1396/09/30

Actual recruitment start date
2017-04-25, 1396/02/05

Actual recruitment end date
2018-01-16, 1396/10/26

Trial completion date
empty

Scientific title
Effect of intradiscal ozone injection on various types of herniated lumbar disc

Public title
Effect of intradiscal ozone injection
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having VAS ≥ 5 Radicular pain for more than 4 weeks and less than one year CT scan or MRI findings with dermatomal distribution of pain and disc herniation at one level SLR is less than 45 ° positive
Exclusion criteria:
Hemorrhagic diseases Local infection Uncontrolled diabetes Pregnancy Hyperparathyroidism G6PD Deficiency Unwillingness of the patient Cauda equina syndrome symptoms
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **128**
Actual sample size reached: **128**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The physician who evaluates the patients after ozone injection is unaware of the type of herniated disc of the patient.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway
City
Tehran
Province
Tehran
Postal code
1617763141
Approval date
2017-05-21, 1396/02/31
Ethics committee reference number
IR.SBMU.RETECH.REC.1396.111

Health conditions studied

1

Description of health condition studied
disk herniation
ICD-10 code
M54.40
ICD-10 code description
Lumbago with sciatica, unspecified side

Primary outcomes

1

Description
pain
Timepoint
At the beginning of the study, 1 and 3 months after the ozone injection
Method of measurement
VAS

2

Description
disability
Timepoint
At the beginning of the study, 1 and 3 months after the ozone injection
Method of measurement
ODI (Oswestry Disability Index)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Inside the nucleus pulposus (Under fluoroscope guidance), a mixture of ozone + oxygen is injected at a concentration of 29-32 µg / ml (within 15 to 20 seconds).
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Mehrdad Taheri

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Shahid Madani street

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m.taheri@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research and Technology of Shahid Beheshti University Of Medical Sciences

Street address
Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway

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1985717434

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mpd@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mehrdad Taheri

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Information on the initial and main implications
When the data will become available and for how long
Since 2018
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
There are no special conditions
From where data/document is obtainable
Mehrdad Taheri taheri.1352@yahoo.com
What processes are involved for a request to access data/document
Send a request by e-mail
Comments