

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

+98 21 7756 7840

Email address

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 \geq 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

Street address

Shahid Madani street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

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

City

Tehran

Province

Tehran

Postal code

1985717434

Phone

+98 21 2243 9951

Email

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

Street address

Shahid Madani street-Imam Hossein Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

m.taheri@sbmu.ac.ir

Person responsible for scientific 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

Street address

Shahid Madani street-Imam Hossein Hospital

City

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Province

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Postal code

1617763141

Phone

+98 21 7343 0000

Email

m.taheri@sbmu.ac.ir

Person responsible for updating data

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

Street address

Shahid Madani street-Imam Hossein Hospital

City

Tehran

Province

Tehran

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Email

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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