

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of ozone therapy on pain and function of patients with lumbar disc herniation

Protocol summary

Study aim

Evaluation of the efficacy of ozone therapy on the treatment of patients with lumbar disc herniation

Design

Randomize clinical trial with control group

Settings and conduct

Patients who are candidates for ozone therapy are hospitalized and Ozone is injected in fluoroscopic guidance in the operation room

Participants/Inclusion and exclusion criteria

Patients with lumbar disc herniation who do not currently have canal Stenosis And they did not respond to non-intervention therapy

Intervention groups

Ozone therapy in the intervention group
Exercise Therapy in the Control Group

Main outcome variables

Pain; function; disc regression

Iran (Islamic Republic of)

Phone

+98 21 6312 1297

Email address

dr_hshafiei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ozone therapy on pain and function of patients with lumbar disc herniation

Public title

The effect of ozone gas on lower back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lumbar disc herniation

Exclusion criteria:

Spinal Stenosis History of surgery in the Spine area
History of malignancy in the Spine area

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046174N1**

Registration date: **2020-03-20, 1399/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-20, 1399/01/01**

Update count: **0**

Registration date

2020-03-20, 1399/01/01

Registrant information

Name

Hossein Shafiei

Name of organization / entity

Country

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the fact that the treatment was different in the two intervention and control groups, there was no possibility of blinding the participants. Physician helping patients fill out questionnaires and the Physician who checks the MRI blinded. The analyzer was also blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

First floor Building No. 4 Sina Hospital Imam Khomeini Hospita

City

Tehran

Province

Tehran

Postal code

۱۱۳۶۷۶۹۱۱

Approval date

2018-07-25, 1397/05/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.274

Health conditions studied

1

Description of health condition studied

Back Pain; Lumbar disc - Lumbar disc herniation

ICD-10 code

M51.16

ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

Primary outcomes

1

Description

Pain

Timepoint

In baseline, 2 weeks 1 month and 3 months after ozone injection

Method of measurement

Visual Analogue Scale

2

Description

Function

Timepoint

In baseline and 3 months after ozone injection

Method of measurement

Sf36

3

Description

Regression of herniated disc

Timepoint

In baseline and 3 months after ozone injection

Method of measurement

MSU Classification

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of ozone at a concentration of 40 mg / DL in the operating room

Category

Treatment - Drugs

2

Description

Control group: Physiotherapy and drug treatment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Farhad Mahdavi

Street address

First floor Building No. 4 Sina Hospital Imam Khomeini

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fmahdavi075@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Sahraian
Street address
Imam Khomeini Ave Sina Hospital Orthopedic
Department
City
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Province
Tehran
Postal code
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Phone
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Email
farhadmahdavi6889@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

1

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
Tehran University of Medical Sciences
Full name of responsible person
Farhad Mahdavi
Position
Assistant
Latest degree

Medical doctor
Other areas of specialty/work
Orthopedics
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Imam Khomeini Ave Sina Hospital Orthopedic
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Not applicable

Title and more details about the data/document

All the study database will be accessible except the participants personal data.

When the data will become available and for how long

The database will be accessible 6 months after result publication

To whom data/document is available

The database will be accessible for academic researchers

Under which criteria data/document could be used

Use of database in academic researches is permitted by reference to the source

From where data/document is obtainable

For database access the request must be sent to farhadmahdavi6889@gmail.com

What processes are involved for a request to access data/document

Upon sending an email the request will be reviewed by the hospital research center and will be sent to the applicant academic research center immediately after verification of the identity.

Comments