

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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

#### 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

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

## 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

113746911

#### 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

**City**  
Tehran  
**Province**  
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+98 21 6312 1297  
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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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**Phone**  
+98 21 6312 1297  
**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  
**Street address**  
Imam Khomeini Ave Sina Hospital Orthopedic  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Assistant  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Farhad Mahdavi  
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Assistant  
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113746911  
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63121297  
**Email**  
farhadmahdavi6889@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**

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**