

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the changes in the elastography of the para-spinal lumbar muscles on chronic low back pain patients after ozone injection

#### Protocol summary

##### Study aim

The purpose of this study is whether injection of ozone into the lumbar para-spinal muscles causes muscular tissue changes.

##### Design

Clinical trial without control group, before-after study, unblinded, non-randomized, phase 2 on 29 patients.

##### Settings and conduct

Twenty-nine patients who present to the Rasoul Akram Hospital Physical Medicine and Rehabilitation Department with a clinical diagnosis of chronic low back pain, after exclusion of other causes, and who meet the study inclusion criteria, will be enrolled after providing written informed consent. Initially, baseline data including the patient's pain level and functional impairment will be collected using a questionnaire. Paraspinal muscle elastosonography will then be performed and recorded, followed by paraspinal ozone injection at the same site, and appropriate follow-up will be conducted.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with complaints of back pain that lasted for more than 3 months. Exclusion criteria: Ozone therapy contraindications, neurological defects.

##### Intervention groups

For patients presenting with low back pain, elastosonography of the paraspinal muscles is first performed. Then, a paraspinal injection of ozone gas with a certain dose is administered at the target site

##### Main outcome variables

Intensity of the patient's pain (using the Visual Analogue Scale) Muscular tissue changes (based on elastosonography report)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190306042945N7**

Registration date: **2025-08-28, 1404/06/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-08-28, 1404/06/06**

Update count: **0**

##### Registration date

2025-08-28, 1404/06/06

##### Registrant information

###### Name

Bijan Forogh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8214 1612

###### Email address

forogh.b@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-08-25, 1404/06/03

##### Expected recruitment end date

2026-03-06, 1404/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the changes in the elastography of the para-spinal lumbar muscles on chronic low back pain patients after ozone injection

##### Public title

Elastographic changes in para-spinal ozone therapy

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

The patient's willingness to participate in the research project Complaint of low back pain (local or radicular) that has lasted for more than 3 months Pain intensity based on VAS should be higher than 4 Patients with BMI less than 35

#### **Exclusion criteria:**

History of any lumbar spine surgery Receiving interventional treatments for back pain during the last six months The presence of ozone therapy contraindications (G6PD, sickle cell anemia, uncontrolled thyroid disorder, pregnancy, breastfeeding, uncontrolled hypoglycemia, etc.) Drug and alcohol addiction Patients with major depression or significant psychiatric and mental diseases (such as needle phobia, etc.) History of tumor or local infection of the lumbar region History of malignant diseases (multiple myeloma, bone metastases, leukemia and lymphoma) Non-referral to record the desired scales during the follow-up period Occurrence of urinary and stool control disorders and numbness of the perineum

### **Age**

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

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **29**

### **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 Iran University of Medical Sciences

##### **Street address**

Iran University of Medical Sciences, Iran University of Medical Sciences, Central Headquarters Building,

Research and Technology Vice-Chancellor, next to Milad tower, Hemmat Highway

### **City**

Tehran

### **Province**

Tehran

### **Postal code**

۱۴۳۹۶۱۴۵۳۵

### **Approval date**

2024-05-15, 1403/02/26

### **Ethics committee reference number**

IR.IUMS.FMD.REC.1403.128

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Chronic low back pain

#### **ICD-10 code**

M54.5

#### **ICD-10 code description**

Low back pain

## **Primary outcomes**

### **1**

#### **Description**

Patient's pain intensity with Visual Analogue Scale

#### **Timepoint**

Before injection, one week after injection, two weeks after injection, one month after injection

#### **Method of measurement**

Completion of the Visual Analogue Scale by the patient

### **2**

#### **Description**

Muscle tissue changes (based on elastosonography report)

#### **Timepoint**

Before injection, one week after injection, two weeks after injection, one month after injection

#### **Method of measurement**

Recording ultrasound elastography values using an ultrasound device

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Pain-area elastography of the lower back to identify the injection point, then one session of para-spinal intramuscular ozone injection at a concentration of 20 µg/ml and a volume of 5 cc, given 2 cm from the spinous process of the involved level,

followed by elastography follow-ups at one week, two weeks, and one month after the injection.

**Category**

Diagnosis

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person**

Bijan Forogh

**Street address**

Sattar Khan Street, Maziar Mansouri Street, Rasool Akram Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6651 5001

**Email**

research@iums.ac.ir

**Web page address**

http://hrmc.iums.ac.ir/

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Falak

**Street address**

Iran University of Medical Sciences, Iran University of Medical Sciences, Central Headquarters Building, Research and Technology Vice-Chancellor, next to Milad tower, Hemmat Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8862 2703

**Email**

falak.r@iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Faramarz Mahmoodi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Firoozgar Hospital, Behafarin Avenue, 1617763141, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 3331 9653

**Email**

mahmoodi.faramarz@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Bijan Forogh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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+98 21 8214 1612

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Faramarz Mahmoodi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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Tehran, Iran

**City**

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**Postal code**

1617763141

**Phone**

+98 21 3331 9653

**Email**

mahmoodi.faramarz@yahoo.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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individual ID data.

**When the data will become available and for how long**

The access period starts 6 months after the results are published

**To whom data/document is available**

It will be available only to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

If needed, for use in future researches, please send a written request via email.

**From where data/document is obtainable**

Main researcher: Dr. Bijan Forough Email:  
forogh.b@iums.ac.ir

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

After sending the request to the e-mail, the information will be accessible within a period of about one week.

**Comments**