Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

۱۴۴۹۶۱۴۵۳۵

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

Street address
Firoozgar Hospital, Behafarin Avenue, 1617763141, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1617763141

Phone

+98 21 8214 1612

Email

forogh.b@iums.ac.ir

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

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

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