

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of paraspinal ozone-oxygen therapy vs. pure oxygen injection, on chronic discogenic low back pain patients' function and pain

Protocol summary

Study aim

The purpose of this study is that in the future, paraspinal ozone injection treatment can be used as a minimally invasive and non-surgical treatment to improve the symptoms of patients with chronic low back pain.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 20 patients. The rand function of Excel software was used for randomization.

Settings and conduct

20 patients clinically with the diagnosis of chronic discogenic low back pain , after ruling out other causes, , referred to the Physical Medicine and Rehabilitation Department of Firouzgar Hospital and met the inclusion criteria, will be included in the study. As primary data, the amount of pain and activity disorder of the patient will be collected from the patients through a questionnaire. Then, paraspinal ozone or oxygen injection intervention is performed and relevant follow-ups are performed. Gas mixture will prepared by another person, and with identical appearances in the case and control groups, blinding of the patient and the researcher will be considered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with complaints of back pain that lasted for more than 3 months, disorder in at least one of the lumbosacral discs that is evident in the MRI. Exclusion criteria: Ozone therapy contraindications, neurological defects and canal stenosis at more than two levels.

Intervention groups

For the patients in the case group, paraspinal injection of the combination of ozone-oxygen gas with a certain dose is prescribed along with exercise training, and for the patients in the control group, paraspinal injection of pure medical oxygen gas is prescribed along with exercise training.

Main outcome variables

functional impairment of the patient according to the Oswestry Disability Index; Intensity of the patient's pain (using the Visual Analogue Scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190306042945N5**

Registration date: **2024-08-29, 1403/06/08**

Registration timing: **prospective**

Last update: **2024-08-29, 1403/06/08**

Update count: **0**

Registration date

2024-08-29, 1403/06/08

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

2024-09-22, 1403/07/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty	assignment of each code to the case or control group will be done randomly by someone other than the researcher and based on the random function of Excel software (even number = case and odd = control). For allocation concealment, based on the relevant code, the registration of patients in two control and sample groups will be done away from the reach of the researcher, and until after the end of the treatment and the analysis, the patient and the therapist will not know the type of treatment (ozone+oxygen or pure oxygen).
Trial completion date	Blinding (investigator's opinion)
empty	Double blinded
Scientific title	Blinding description
Evaluation of paraspinal ozone-oxygen therapy vs. pure oxygen injection, on chronic discogenic low back pain patients' function and pain	Regarding the double-blindness of this study, it should be noted that all patients receive apparently similar treatment (the appearance and details of the intervention are completely identical for the sample group and the control group) and despite the patient's knowledge of participating in the trial study, being in the control group or the sample group will not be known.
Public title	Placebo
Comparison of paraspinal ozone vs. oxygen injection, on low back pain	Not used
Purpose	Assignment
Treatment	Parallel
Inclusion/Exclusion criteria	Other design features
Inclusion criteria:	Secondary Ids
Patients with BMI less than 35 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 Disorder in at least one of the lumbar spinal discs (L2-S1) that is evident in MRI The patient's willingness to participate in the research project	empty
Exclusion criteria:	Ethics committees
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.) The patient's back pain can be justified by any reason other than lumbar disc disorders Exacerbation of back pain in the patient with neurological defects such as weakness, loss of deep reflexes Occurrence of urinary and stool control disorders and numbness of the perineum 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) Use of medication or other treatment for back pain during the study Non-referral to record the desired scales during the follow-up period Presence of multilevel disc involvement and lumbar spinal canal stenosis in more than two levels	1
Age	Ethics committee
From 45 years old to 60 years old	Name of ethics committee
Gender	Ethics committee of Iran University of Medical Sciences
Male	Street address
Phase	Iran University of Medical Sciences, Iran University of Medical Sciences, Central Headquarters Building, Research and Technology Vice-Chancellor, next to Milad tower, Hemmat Highway
2-3	City
Groups that have been masked	Tehran
- Participant - Care provider - Investigator - Outcome assessor - Data analyser	Province
Sample size	Tehran
Target sample size: 20	Postal code
Randomization (investigator's opinion)	۱۴۳۹۶۱۴۵۳۵
Randomized	Approval date
Randomization description	2024-07-08, 1403/04/18
After assigning a special code to each subject, the	Ethics committee reference number
	IR.IUMS.REC.1403.313
	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, during the last intervention session, after one month and three months after completing three intervention sessions

Method of measurement

Completion of the Visual Analogue Scale by the patient

2

Description

Functional impairment of the patient based on the Oswestry Disability Index

Timepoint

before, during the last intervention session, after one month and three months after completing three intervention sessions

Method of measurement

Completion of the Oswestry Disability Index questionnaire by the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three sessions of paraspinal intramuscular injection of ozone with a dose of 20ug/ml and a volume of 5cc in each point, total four points, two points on each side at a distance of 2cm from the spinous process of the involved level based on MRI and with an interval of one week between each injection.

Category

Treatment - Drugs

2

Description

Control group: Three sessions of paraspinal intramuscular injection of oxygen gas with a volume of 5cc in each point, total four points, two points on each side at a distance of 2cm from the spinous process of the involved level based on MRI and with an interval of one week between each injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Bijan Forogh

Street address

Beh Afarin St., Karim Khan St., Valiasr Square

City

Tehran

Province

Tehran

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1593747811

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bijanfr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Tehran

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Tehran

Province

Tehran

Postal code

1449614535

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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

Bijan Forogh

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Firoozgar Hospital, Behafarin Avenue, 1617763141,
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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor

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Person responsible for updating data

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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

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 Forogh 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