

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Comparative Study of the Efficacy of Ozone Injection with Two Doses and Oxygen Injection on Pain and Physical Function of Patients with Radicular Low back pain: A Controlled Randomized Trial with A six-Month Follow -up

Protocol summary

Study aim

Evaluation of ozone injection in two different Doses compared to oxygen on pain and performance improvement in patients with low back pain (LBP)

Design

Phase 3 double-blind randomized clinical trial (RCT) with parallel groups of patients with clinical signs of radicular LBP, randomized to 54 patients using PASS 11 software from the Means menu below Menu one way ANOVA

Settings and conduct

If the patient eligible, he is included in the study. the research checklist and the results of the research will be evaluated for the patient and the information obtained from the record will be collected. Patients are selected from the clients of the Rasool Akram Hospital Sports Medicine Clinic in 1402(2023) . The patient will be evaluated before the first and after the intervention sessions (tenth intervention session), 3 and 6 months later. Patients will be randomly divided into three treatment groups. The first group contains 10 cc of drug with 40 µg / ml ozone in the O2O3 composition, the second group 10 cc of O2O3 composition with a concentration of 20 µg / ml and the third group 10 cc of pure O2 at each point (BL23 , 24.25 points acupuncture) and will receive on both sides.

Participants/Inclusion and exclusion criteria

Patients with diffuse LBP with at least pain intensity 4 according to VAS criteria At least 1 month of LBP Failure to respond to supportive therapy Age 30-60 years old Patients with BMI 20-35 MRI based on the presence of a disc herniation which location is associated with symptoms

Intervention groups

Group of patients receiving a dose of 40 micro grams per ml of ozone Group of patients receiving a dose of 20 micro grams per ml of ozone Group of patients receiving

pure oxygen or O2 group

Main outcome variables

back pain, functional tests, disability due to pain (ODI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211116053072N1**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

Hooman Angoorani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8827 1703

Email address

angoorani.h@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study of the Efficacy of Ozone Injection with Two Doses and Oxygen Injection on Pain and Physical Function of Patients with Radicular Low back pain: A Controlled Randomized Trial with A six-Month Follow -up

Public title

Study of the Efficacy of Ozone Injection on low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with diffuse low back pain with minimal pain intensity 4 according to VAS criteria At least 1 month of low back pain Failure to respond to supportive therapy (such as medication or physiotherapy) Age 30-60 years old Patients with body mass index 20-35 MRI based on the presence of a disc herniation whose location is associated with symptoms

Exclusion criteria:

Previous spinal surgery Bone lesions of the spine or spinal cord History of receiving ozone or topical injection of any other drug Pregnancy Spinal cord diseases Uncontrolled diabetes

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The list of random allocation of patients will be done individually and in treatment groups randomly using random blocks of 3 volume

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients, primary evaluators, interveners and collectors of results and analysts are blind to the study

Placebo

Used

Assignment

Parallel

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

4th STE, No 12 APT, Hossein Mardi Alley, Khark St, Habibollahi BLVD, Sattarkhan BLVD

City

Tehran

Province

Tehran

Postal code

1455813643

Approval date

2021-05-08, 1400/02/18

Ethics committee reference number

IR.IUMS.FMD.REC.1400.083

Health conditions studied**1****Description of health condition studied**

Radicular Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

2**Description of health condition studied**

DISC HERNIATION

ICD-10 code

M51.9

ICD-10 code description

Unspecified thoracic, thoracolumbar and lumbosacral intervertebral disc disorder

Primary outcomes**1****Description**

patient with low back pain on minimum scale 4 of VAS

Timepoint

before the study, 3 month and 6 month after the beginning

Method of measurement

VAS questionnaire

2

Description

functional progress in patient with low back pain

Timepoint

before the study, 3 month and 6 month after the beginning

Method of measurement

functional tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receiving a dose of 40 micrograms per milliliter of ozone or group O3 40mg

Category

Treatment - Drugs

2

Description

Intervention group: Patients receiving a dose of 20 micrograms per milliliter of ozone or group O3 20mg

Category

Treatment - Drugs

3

Description

Control group: Group of patients receiving pure oxygen or O2 group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Marzieh Urumieh

Street address

Niyayesh ST, Sattarkhan BLVD

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Fax

+98 21 6651 5000

Email

marziehorumieh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hossein Keyvani

Street address

Clinical Research Development Center, No. 4 Building, Rasool Akram hospital, Niyayesh Ave, Sattarkhan Blvd

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6655 4785

Fax

+98 21 6435 2353

Email

RCRDC.TEAM@GMAIL.COM

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

Marzieh Urumieh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

Street address

4th STE, No 12 APT, Hossein Mardi Alley, Khark St, Habibollahi BLVD, Sattarkhan BLVD

City

Tehran

Province

Tehran
Postal code
1455814115
Phone
+98 21 6655 4259
Email
marziehorumieh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Marzieh Urumieh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
4th STE, No 12 APT, Hossein Mardi Alley, Khark St,
Habibollahi BLVD, Sattarkhan BLVD
City
Tehran
Province
Tehran
Postal code
1455814115
Phone
+98 21 6655 4259
Email
marziehorumieh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Marzieh Urumieh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
4th STE, No 12 APT, Hossein Mardi Alley, Khark St,
Habibollahi BLVD, Sattarkhan BLVD
City
Tehran
Province
Tehran
Postal code
1455814115
Phone
+98 21 6655 4259
Email
marziehorumieh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available