Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Hossein Keyvani
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Clinical Research Development Center, No. 4 Building, Rasool Akram hospital, Niyayesh Ave, Sattarkhan Blvd
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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
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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