

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### **A comparison between effectiveness of intramuscular ozone gas injection in paravertebral muscles with subcutaneous ozone gas injection in patients with lumbosacral spinal canal stenosis - a randomized clinical trail**

#### **Protocol summary**

##### **Study aim**

A comparison between effectiveness of intramuscular ozone gas injection in paravertebral muscles with subcutaneous ozone gas injection in patients with lumbosacral spinal canal stenosis

##### **Design**

The research is a randomize double blind clinical trial

##### **Settings and conduct**

The patients who had lumbosacral canal stenosis were selected from physical medicine and rehabilitation clinics of Shiraz University of Medical Sciences then patients were divided into two groups and after obtaining written consent the study was begun .In the group A ozone gas was injected into paravertebral muscles and in the group B, ozone gas was injected subcutaneous, and finally, their effect in reducing patients' pain, improving function and quality of life were measured.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: completion and signing of the consent form Presence of pain and other clinical symptoms of lumbar sacral stenosis in the last six months that did not respond to conservative treatments Age between 75-35 years and absence of any disease around the spine Non-inclusion criteria: Favism; infection involving lumbar spinal (brucella) Diabetes mellitus Rhumatological disorder(lupuse, gout) BMI more than 41Pregnancy Malignancy Liver disease sensitivity reaction to test drug Malnutrition Peripheral neuropathy Bleeding disorder Galactosemia Radiculopathy Inability to communicate and complete questionnaires

##### **Intervention groups**

Group A: subcutaneous injection of 2 cc of 25 ml/ug ozone gas in the area of back pain at an angle of 45-degree to the sagittal plate whit 25 needle. Group B: injection of 2 cc of 25 ml/ug ozone gas at the paravertebral muscles at an angle of 90-degree to the

sagittal plate 2cm bilateral from the lumbar spinous processes. whit 22 needle

##### **Main outcome variables**

Pain level, patient performance and daily routines quality of life

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20230701058636N1**

Registration date: **2023-10-11, 1402/07/19**

Registration timing: **prospective**

Last update: **2023-10-11, 1402/07/19**

Update count: **0**

##### **Registration date**

2023-10-11, 1402/07/19

##### **Registrant information**

##### **Name**

Ghazaleh Rezaeianpour

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 919 773 1017

##### **Email address**

ghazalrzpdr@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2023-10-23, 1402/08/01

**Expected recruitment end date**

2024-03-20, 1403/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison between effectiveness of intramuscular ozone gas injection in paravertebral muscles with subcutaneous ozone gas injection in patients with lumbosacral spinal canal stenosis - a randomized clinical trial

**Public title**

A comparison between effectiveness of intramuscular ozone gas injection in paravertebral muscles with subcutaneous ozone gas injection in patients with lumbosacral spinal canal stenosis - a randomized clinical trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Completion and signing of the consent form  
Presence of pain and other clinical symptoms of lumbar sacral stenosis in the last six months that did not respond to conservative treatments.  
Age between 75-35 years old  
Absence of any disease around the spine

**Exclusion criteria:**

Favism  
Infection involving lumbar spinal (brucella)  
Diabetes mellitus, Rheumatological disorder (lupuse, gout)  
BMI more than 41  
Pregnancy  
Malignancy  
Liver disease  
Sensitivity reaction to test drug  
Malnutrition  
Peripheral neuropathy  
Bleeding disorder  
Galactosemia  
Radiculopathy  
Inability to communicate and complete questionnaires

**Age**

From **35 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Blocked randomization method is used to randomize the study. The list is sorted by the computer with the same size block and the clinic secretary divides the patients based on the list

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Considering that the patient is unaware of the technique of performing the project and does not see the type of needle and the same drug is injected for him and the general conditions of the procedure are the same for both groups and only the technique of doing it is different: the patient, the questioner, the statistical analyst. are blind Only the performing doctor knows what kind of procedure he has performed. (The patient is blind).  
Clinical Caregiver: We teach the person who cares and examines how to complete the questionnaire. This person has no knowledge of the type of patient intervention. In this study, we do not have the researcher and the researcher, because the researcher gives both his studies and informs about the type of intervention in each group.  
Message evaluator: Questionnaires are completed to a person who is not informed about the interventions and determines the amount of pain reduction and performance increase in each person according to the questionnaire. Analysts: Finally, after completing and collecting all the information, the questionnaires are given to the person to check the information, that this person is not involved in any of the steps and how the intervention is divided.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Science

**Street address**

Central Building of Shiraz University of Medical Sciences, Zand Ave, Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Approval date**

2023-09-27, 1402/07/05

**Ethics committee reference number**

IR.SUMS.MED.REC.1402.271

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

Lumbosacral spinal stenosis

**ICD-10 code**

M48.06

**ICD-10 code description**

Lumbosacral spinal stenosis

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

Pain score according to Visual Analog Scale

**Timepoint**

At baseline (before intervention), 2, 4 and 8 weeks after injection

**Method of measurement**

Visual Analog Scale

**2****Description**

Patient Performance Score in Oswestry Disability Scale

**Timepoint**

At baseline (before intervention), 2, 4 and 8 weeks after injection

**Method of measurement**

Oswestry Low Back Pain Questionnaire

**3****Description**

Patient Performance Score in QUEBEC Back Pain Disability

**Timepoint**

At baseline (before intervention), 2, 4 and 8 weeks after injection

**Method of measurement**

QUEBEC Back Pain Disability Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group : including subcutaneous injection of 2 cc of 25 ml/ug ozone gas in the area of back pain at an angle of 45-degree to the sagittal plate whit 25-gage needle, for three sessions at a interval of one week.

**Category**

Rehabilitation

**2****Description**

Control group: - including injection of 2 cc of 25 ml/ug ozone gas at the paravertebral muscles at an angle of about 90-degree to the sagittal plate 2cm bilateral from the lumbar spinous procses whit 22-gage needle , for three sessions at a interval of one week.

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Physical Medicine and Rehabilitation Clinic of Shahid Rajaei Hospital in Shiraz

**Full name of responsible person**

Ghazaleh rezaeianpour

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Younes Qasemi

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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**

Shiraz 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

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
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Ghazaleh Rezaeianpour  
**Position**  
Medical Student  
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A Level or less  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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