

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)

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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

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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 proccses 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

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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

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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