Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effectiveness of intramuscular paravertebral injection of Oxygen –Ozone and epidural injection of Hyaluronidase on pain and function in patient with lumbosacral canal stenosis

Protocol summary

Study aim
Effectiveness of Epidural Hyaluronidase Injection and Comparison with Ozone Muscle Injection to Reduce Pain and Improve Function in Patients with Lumbosacral Spinal Stenosis

Design
Clinical trial with control group, with parallel groups, triple-blind, randomized through block randomization method

Settings and conduct
Patients are initially divided into two groups, and after obtaining written consent, the study begins. Treatment in one group involves injecting a mixture of Ozone-Oxygen in the paravertebral muscles. Injections are performed three times with interval of one week at the Physical Medicine and Rehabilitation Clinic in Haj Ismail Emtiaz Hospital. In the second group, treatment consists of injecting a single-dose epidural Hyalase _1500 unit under a Fluoroscopic-guided epidural injection. In this study, blinding in patients, health care providers and statistical consultant was done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Back pain and other symptoms of spinal canal stenosis in the last six months Age between 35_75 years Confirmation of spinal canal stenosis through MRI and EDX. Non-inclusion criteria: Diabetes Melitus; Rheumatologic and collagen vascular diseases; peripheral neuropathy and nerve injury; Brucellosis.

Intervention groups
Intervention group: Ozone treatment group. Injection of 18 ml of Ozone-Oxygen mixture (2% _98%) at a concentration of 20 µg / dl at six points (three cc each point) in the paravertebral muscles. Control group: Hyaluronidase treatment group. Injection of a Hyaluronidase_1500 unit unit and 4 cc Marcain by Epidural-guided fluoroscopy in Epidural space

Main outcome variables
Pain and Activity of Daily Living

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191004044980N1**
Registration date: **2019-11-25, 1398/09/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-25, 1398/09/04**
Update count: **0**

Registration date
2019-11-25, 1398/09/04

Registrant information
Name
Reyhane Parvin
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 5364 2641
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of intramuscular paravertebral injection of Oxygen –Ozone and epidural injection of Hyaluronidase on pain and function in patient with lumbosacral canal stenosis

Public title
The effect of Hyaluronidaz and Ozon on spinal canal stenosis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Back pain and other symptoms of spinal canal stenosis in the last six months Age between 35_75 years Confirmation of spinal canal stenosis through MRI and EDX
Exclusion criteria:
Diabetes Melitus Rheumatologic and collagen vascular diseases peripheral neuropathy and nerve injury Brucellosis BMI more than 41 History of trauma and spinal fracture Bleeding disorder Allergic reaction to Bovin protein Genetic disease such as Galactose intolerance or Lactase deficiency Patient with cardiac problem Inability to communicate and complete the questionnaire History of liver ,kidney and cardiopulmonary problem History of periarticular or intraarticular in the past 6 months Pregnant women People with cancer People taking Anticoagulant Favism

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Complete randomized block design with SPSS software is used for randomization and then sealed non-transparent envelopes are used to hide the random sequence.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participant:The participant is explained that if they are interested, they can join our research project. Two methods used to reduce patient pain in our study are explained to the patient. Benefits and possible complications of both methods are described to the patient and the patient is told to randomly fall into one of the intervention groups. If the patient is accepted to admit the study, by random allocation software, the patient falls into one of two groups Clinical Caregiver: We teach the caregiver how to complete the questionnaire. This person is not aware of the patient's intervention. Researcher: In this study we are not capable of blinding the researcher because the researcher performs both interventions himself and is aware of any intervention in each group. Outcome Assessor: Completed questionnaires are handed to a person who is unaware of interventions and requested to determine the extent of pain reduction and performance enhancement in each individual according to the questionnaire. Data analyzer: Questionnaires are finally given to the individual after completing and collecting all the information to evaluate the information. This person is unaware of any of the steps in the study and group division and intervention allocation.

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
Atlas buildin, Alley 4, Azadi Blvd, Atlas Square, Shiraz
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Shiraz
Province
Fars
Postal code
7145647855

Approval date
2018-10-15, 1397/07/23

Ethics committee reference number
IR.SUMS.MED.REC.1397.283

Health conditions studied

1

Description of health condition studied
Lumbosacral spinal stenosis

ICD-10 code
M48.06

ICD-10 code description
Spinal stenosis, lumbar region

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 Qestionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of 18 cc Ozone-Oxygen mixture (2% _98%) at a concentration of 20 µg / dl at six points (three cc in each point) in the paravertebral muscles at 2 cm from the lumbar spine 4 and 5 and the first sacral vertebrae are injected through the nidel thin gage 22 at an angle of about 90 degrees to the sagittal plate, for three sessions at a interval of one week.
Category
Rehabilitation

2

Description
Control group: a single unit of hyaluronidase-1500 unit and 4 cc marcain 0.5% is injected epidurally under fluoroscope-guided epidural injection. The injection is done only one time.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical Medicine and Rehabilitation Clinic of Shahid Rajaee Hospital in Shiraz
Full name of responsible person
Reyhane Parvin
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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
Street address
Atlas buildin, Alley 4, Azadi Blvd, Atlas Square, Shiraz
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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

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Reyhane Parvin

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All available data can be shared after making people unidentifiable

When the data will become available and for how long
Start access period one year after publishing the results

To whom data/document is available
Everyone can access to this information

Under which criteria data/document could be used
If the information in this study helps to improve the science process.

From where data/document is obtainable
reyhaneh.parvin@gmail.com 00989171324770

What processes are involved for a request to access data/document
After sending the desired message, all authors of the study will be consulted and all information will be sent within a maximum of three weeks if permitted.

Comments