

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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)

Phone

+98 71 5364 2641

Email address

reyhaneh.parvin@gmail.com

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

City

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 Questionnaire

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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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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