

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Efficacy of steroid caudal epidural injection with or without ozone in lumbosacral canal stenosis under ultrasonography guidance

Protocol summary

Study aim

Determine the efficacy of epidural steroid injection with or without simultaneous injection of ozone gas in patients with lumbar stenosis under ultrasound guide

Design

Double blind, randomized clinical trial with a control group based on the hospital, two groups of 25 parallel interventions

Settings and conduct

This clinical trial was conducted on 50 patients suffering from lumbar stenosis referred to Shahid Modarres Medical Center in Tehran. Patients were randomized into two groups: TriamHexal injections with lidocaine and distilled water with and without ozone gas (O₂ + O₃) simultaneously injected with ultrasound guide.

Participants/Inclusion and exclusion criteria

Entry requirements: The duration of symptoms is more than 1 month and less than 1 year; Visual analog scale for pain More than 7; Age Between 50 and 70 years; Body Mass Index between 20 and 32; Signs of Neurogenic claudication; Having MRI confirming Lumbar Stenosis Exclusion criteria: Diabetes; Neuropathy; Spondylolesthesis; Extruded disk; Grade 4 knee osteoarthritis; Previous lumbar spine surgery; Scoliosis; Pregnancy; Clinical or laboratory evidence of infection; Coagulopathy; Symptoms of quada equina syndrome

Intervention groups

The first group was injected 80 mg triamcinolone hexavalent with 4 ml of marquine 0.5% and 6 cc distilled water. In the second group, in addition to the injections of the first group, 10 cc (10 µg / cc) ozone gas (O₂ + O₃) was injected.

Main outcome variables

Visual analog scale for pain; walking distance; Oswestry Disability Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090704002117N2**
Registration date: **2019-08-07, 1398/05/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-07, 1398/05/16**

Update count: **0**

Registration date

2019-08-07, 1398/05/16

Registrant information

Name

Seyed Mansoor Rayegani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

rayegani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-25, 1398/02/05

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of steroid caudal epidural injection with or without ozone in lumbosacral canal stenosis under ultrasonography guidance

Public title

Efficacy of steroid caudal epidural injection with or without ozone in lumbosacral canal stenosis under ultrasonography guidance

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. neurogenic claudication 2. Age of the patient between 50-70 years 3. Body mass index (BMI) Between 20-32 4. Duration of symptoms more than 1 month and less than 1 year 5. Visual Analog Scale <7-MRI Confirmation of lumbar canal stenosis

Exclusion criteria:

1-Diabetes mellitus 2-Neuropathy 3-Spondylolisthesis 4-Extruded disk 5-Knee-arthritis of grade 4 6-Scoliosis 7-pregnancy 8- previous lumbar spine surgery 9-Clinical or laboratory evidence of infection 10-Coagulopathy 11-Symptoms of cauda equina syndrome

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The computer generates random numbers between 0 and 1, if the number is less than 0.500, the person enters the Corticosteroid recipient group, and if the number is greater than 0.500, it enters the Corticosteroid and ozone recipient group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and outcome assessor were blind about the patients` group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

No. 1983969411, Shahid Beheshti University of

Medical Sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, velenjak

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2019-04-23, 1398/02/03

Ethics committee reference number

IR.SBMU.MSP.REC.1398.019

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

Lumbar canal stenosis

ICD-10 code

M99.53

ICD-10 code description

Intervertebral disc stenosis of neural canal of lumbar region

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

pain

Timepoint

Before intervention, 1 & 6 month after intervention

Method of measurement

Visual Analogue Scale

2**Description**

walking distance

Timepoint

Before intervention, 1 & 6 month after intervention

Method of measurement

Ask the patient

3**Description**

Oswestry disability index (ODI)

Timepoint

Before intervention, 1 & 6 month after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 80 mg triamcinolone hexavalent with 4 ml of marquine 0.5% and 6 cc distilled water with simultaneous injection of 10 cc of ozone gas (O2 + O3) at a concentration of 10 mcq / cc

Category

Treatment - Drugs

2

Description

Control group: Injection of 80 mg triamcinolone hexavalent with 4 ml of marquine 0.5% and 6 cc of distilled water

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Vahid Soltani

Street address

No. 1998734383, Shahid Modarres Hospital, Kaj square, Saadat Abad

City

Tehran

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Phone

+98 21 2236 3244

Email

drvahidsoltani1810@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Seyed Ahmad Raeissadat

Street address

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a_raeissadat@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vahid Soltani

Position

Resident in Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

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Vahid Soltani

Position

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available