Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 osteoartheritis; 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
Oswetry 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
Province
Tehran
Postal code
1998734383
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
No. 1998734383, Shahid Modarres Hospital, Kaj square, Saadat Abad
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 3244
Email
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
Street address
No. 1998734383, Shahid Modarres Hospital, Kaj square, Saadat Abad
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 3244
Email
drvahidsoltani1810@gmail.com

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

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

City
Tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2236 3244

Fax
+98 21 2236 3244

Email
a_raeissadat@sbmu.ac.ir

Person responsible for updating data

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

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

City
Tehran

Province
Tehran

Postal code
1998734383

Phone
+98 21 2236 3244

Email
drvahidsoltani1810@gmail.com

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