

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of ozone-oxygen gas injection and high power laser in paravertebral muscles on pain and activity in patients with lumbar spinal stenosis

Protocol summary

Study aim

Comparison of the effect of ozone-oxygen gas injection with high power laser in paravertebral muscles on pain and activity in patients with lumbar spinal canal stenosis

Design

Clinical trial with three control and intervention groups 1 and 2, double-blind, randomized simple block method, number of patients 28 in each group and a total of 84 cases

Settings and conduct

Study place: Patients who are referred to the physical medicine and rehabilitation clinic of Shahid Sadoughi hospital in Yazd, who have presented with spinal canal stenosis; Type of blinding: Double blind; How to blind: In this way, after selecting the patients, they are told that in all groups, the treatment methods were without complications and can reduce pain. The treatment can be placebo (normal saline), ozone-oxygen or high power laser. The patient and the treating physician are not aware of the nature of the treatment. Each patient and the drug used for him is identified by the same number. For example, patient number 8 and drug number 8.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent to participate in the study; neurological pain in the last six months; age 35-75 years; absence of any disease around the spine; no response to drug for more than 3 months. Exclusion criteria: diabetes; history of spinal fractures; rheumatic diseases; allergic reactions to bovine proteins; pregnant women; history of previous spinal surgery; indication of emergency surgery

Intervention groups

Intervention group 1: Treated with medication, exercise and intramuscular ozone in paravertebral muscles. Intervention group 2: Treated with medication, exercise and high power laser. Control group: Treated with medication and exercise.

Main outcome variables

Neuroischemic pain; Physical activity; Satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190419043319N1**

Registration date: **2021-11-30, 1400/09/09**

Registration timing: **retrospective**

Last update: **2021-11-30, 1400/09/09**

Update count: **0**

Registration date

2021-11-30, 1400/09/09

Registrant information

Name

Samira Shahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 6575

Email address

shahabi.867@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-29, 1398/02/09

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-04-29, 1398/02/09

Actual recruitment end date

2019-09-23, 1398/07/01
Trial completion date
 2020-12-21, 1399/10/01

Scientific title
 Comparison of ozone-oxygen gas injection and high power laser in paravertebral muscles on pain and activity in patients with lumbar spinal stenosis

Public title
 The effect of ozone-oxygen gas on pain and activity in patients with lumbar spinal stenosis

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Informed consent to participate in the study Existence of neurological pain and lameness in the last six months Age between 35-75 years Absence of any spinal or musculoskeletal disease No response to drug treatment for more than 3 months
Exclusion criteria:
 Diabetes mellitus Body mass index more than 41 History of fracture of the spine History of bleeding disorders Rheumatic diseases Neuropathy Psychological diseases Brucellosis Genetic diseases such as galactose intolerance or lactase deficiency Congenital heart diseases Allergic reactions to bovine proteins Inability to communicate History of significant liver, kidney and heart disorders Injections in or around the affected joint in the last six months Pregnancy Cancer People who are taking anticoagulants People with Favism Vascular claudication History of previous spinal surgery Indication of emergency surgery Any ban on ozone treatment Any ban on acetaminophen People consuming codeine

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

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **84**
 Actual sample size reached: **84**

Randomization (investigator's opinion)
 Randomized

Randomization description
 After selecting the sample, they were randomly divided into three groups. In this study, individuals were assigned to three groups using permutation block method. In this method, A represents the person receiving the first intervention, B represents the person receiving the second intervention, and C represents the person receiving the placebo. Considering blocks of size 6, they were categorized into the desired permutations and patients were classified by random selection from the permutation envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description
 For the double blinding process, after selecting patients, they are told that in all groups, the treatment methods are uncomplicated and could reduce pain. The treatment can be placebo (normal saline), ozone-oxygen or high power laser. The patient and the treating physician are not aware of the nature of the treatment. Each patient and the drug used for him is identified by the same number. For example, patient number 8 and drug number 8.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Shahid Sadoughi University of Medical Sciences
Street address
 8915887856; Baqaei Pour Clinic; Shahid Sadoughi Hospital; Ibn Sina Blvd; Yazd
City
 yazd
Province
 Yazd
Postal code
 8915887856

Approval date
 2019-06-26, 1398/04/05

Ethics committee reference number
 IR.SSU.MEDICINE.REC.1398.107

Health conditions studied

1

Description of health condition studied
 lumbar spinal stenosis

ICD-10 code
 M48.06

ICD-10 code description
 Spinal stenosis, lumbar region

Primary outcomes

1

Description
 Pain

Timepoint
 Before treatment, immediately after treatment, and at

weeks 4 and 8 after treatment
Method of measurement
Somatic symptom scale questionnaire

2

Description
Physical activity

Timepoint
Before treatment, immediately after treatment, and at weeks 4 and 8 after treatment

Method of measurement
Somatic symptom scale questionnaire

3

Description
Satisfaction

Timepoint
Before treatment, immediately after treatment, and at weeks 4 and 8 after treatment

Method of measurement
Somatic symptom scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: intramuscular paravertebral injection of oxygen -ozone with 10 microgram/cc - 3 times at week for 5 weeks

Category
Treatment - Drugs

2

Description
Intervention group 2: high intensity laser 30 W; dose 100 J / cm². 5 15-minute sessions per week for 2 weeks

Category
Treatment - Devices

3

Description
Control group: Exercises included lower trunk rotation; knee to chest; pelvic tilt, which strengthens and stabilizes the muscles of the abdomen, back and pelvis. All treatment groups were instructed to exercise three times a day for 2 weeks.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghaeipour clinic

Full name of responsible person

Samira Shahabi Rabori

Street address

8915887856; Baqaiei Pour Clinic; Shahid Sadoughi Hospital; Ibn Sina Blvd; Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Masoud Mirzaei

Street address

Headquarters of Shahid Sadoughi University of Medical Sciences and Health Services; Dr. Shahid Bahonar Square; Yazd

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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

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Samira Shahabi Rabori
Position
Specialist Assistant in Physical Medicine and Rehabilitation
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
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