Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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 / cm^2. 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; Baqaei Pour Clinic; Shahid Sadoughi Hospital; Ibn Sina Blvd; Yazd

City

Yazd

Province

Yazd

Postal code

8915887856

Phone

+98 35 3183 3004

Fax

+98 35 3822 9009

Email

baghaei@ssu.ac.ir

Web page address

http://ssu.ac.ir/cms/index.php?id=3022

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

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3822 9105

Email

baghaei@ssu.ac.ir

Web page address

http://ssu.ac.ir

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

Street address

Baqaei Pour Clinic; Shahid Sadoughi Hospital; Ibn Sina Blvd; Yazd

City

Yazd

Province

Yazd

Postal code

8916884818

Phone

+98 35 3822 6575

Email

shahabi.867@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

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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