Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Randomized clinical trial ozone therapy on protruded lumbar disc herniation

Protocol summary

Study aim

1- Determine the change in pain intensity before and after ozone therapy 2- Determination of changes in the test of the lens before and after treatment with ozonotherapy 3- Comparison of two methods of treatment of cannosetics and ozone therapy in the treatment of lumbric disopathies

Design

Patients with acute low back pain created by lumbar disc herniation were randomly divided into two groups of control and recipients of muscle intramuscular injection of ozone

Settings and conduct

. All patients 2 weeks, 3 and 6 months after the end of treatment were evaluated clinically by VAS and the results of Chi - Square or Fisher exact test, Student t test will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criterias ; Acute low back pain with radiculopathy and the presence of a moderate to severe (5-10cm) Visual Analog Scale (VAS) on one leg and MRI indicating a protruded disc without degenerative disc.exclusion criteria ; Extruded discs, clinical signs of radiculopathy (reduction of tendon reflexes, muscle weakness, sensory impairment), horse tail syndrome, progressive neurological deficits, spinal cord stenosis. Spondylolisthesis, Previous Surgery; Diabetic Neuropathy , Body mass index greater than 30, lower back scoliosis more than 20 degrees; Lower limb length difference of more than 1.5 centimeters in simple radiography; pregnancy; and favism in which ozone therapy is contraindicated.Patients who have recently received ozone therapy.

Intervention groups

Injection of 250 micro grams of ozone in the disk space between the prosthetic disk Break the nucleotide proteoglycan so that the water is removed from the disk and the disk is collected and Oral administration of a non-steroidal anti-inflammatory drug Naproxen 500 mg every 12 hours and baculofen 10 mg muscle relaxant every 12 hours for 2 weeks.

Main outcome variables

paraverteal lumbar injection, which is associated with minimal invasion, seems to be in the elimination of pain, and It also reduces the inability and the use of analgesic drugs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170727035336N1**
Registration date: **2017-12-31, 1396/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-31, 1396/10/10**
Update count: **0**

Registration date

2017-12-31, 1396/10/10

Registrant information

Name

seyed reza javaheri

Name of organization / entity

tabriz medical science university

Country

Iran (Islamic Republic of)

Phone

+98 44 3384 8699

Email address

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Recruitment status

Recruitment complete

Funding source

tabriz medical science university

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial ozone therapy on protruded lumbar disc herniation

Public title

Randomized clinical trial ozone therapy on protruded lumbar disc herniation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute low back pain with radiculopathy and the presence of a moderate to severe (5-10cm) Visual Analog Scale (VAS) on one leg and MRI indicating a protruded disc without degenerative disc

Exclusion criteria:

Extruded discs, clinical signs of radiculopathy (reduction of tendon reflexes, muscle weakness, sensory impairment), horse tail syndrome, progressive neurological deficits, spinal cord stenosis. Spondylolisthesis, Previous Surgery; Diabetic Neuropathy , Body mass index greater than 30, lower back scoliosis more than 20 degrees; Lower limb length difference of more than 1.5 centimeters in simple radiography; pregnancy; and favism in which ozone therapy is contraindicated.Patients who have recently received ozone therapy.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Tabriz Medical Science University

Street address

Golgasht Avenue

City

Tabriz

Province

East Azarbaijan

Postal code

57158-74746

Approval date

2017-07-10, 1396/04/19

Ethics committee reference number

IR.TBZMED.REC.1396.286

Health conditions studied

1

Description of health condition studied

Diseases of the nervous system

ICD-10 code

G50,G51,G5

ICD-10 code description

Nerve, nerve root and plexus disorders

Primary outcomes

1

Description

Changes in pain intensity and basal test before and after treatment of ozonotherapy

Timepoint

2 weeks, 3 and 6 months after treatment

Method of measurement

Clinical evaluation will be performed by the VAS (Pain Observation Scale)

Secondary outcomes

1

Description

The amount of analgesic use

Timepoint

2 weeks, 3 and 6 months after treatment

Method of measurement

Based on the dose of analgesic

Intervention groups

1

Description

Injection of 250 micrograms of ozone in the disk space

between the prosthetic disk Break the nucleotide proteoglycan so that the water is removed from the disk and the disk is collected

Category

Treatment - Drugs

2

Description

Oral administration of a non-steroidal anti-inflammatory drug Naproxen 500 mg every 12 hours and bacullofen 10 mg muscle relaxant every 12 hours for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Firooz Salehpoor MD

Street address
Imam Reza Hospital, Golgasht Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person
Firooz Salehpoor MD

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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

Vice chancellor for research, Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Seyed Reza Javaheri MD

Position
Neurosurgery Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Neurosurgery

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available