Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Effectiveness of percutaneus epidural neuroplasty(RACZ procidures) with and without epidural OZONE injection in patients with chronic low back pain

Protocol summary

Study aim

Investigating the effect of epidural neuroplasty with and without ozone in chronic low back pain. Determining and comparing the average pain intensity and disability of the patients before the intervention and 24 hours and one and three months after the intervention in two groups.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 38 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Patients with chronic back pain who are candidates for RACZ procedure are assigned to one of two groups A or B based on 1:1 random allocation after obtaining informed consent. The intensity of pain and the degree of disability before the procedure and 24 hours, one month and three months after the procedure are checked and recorded using questionnaires. Patients and those who complete and analyze the questionnaires are not aware of the study groups.

Participants/Inclusion and exclusion criteria

The research population is chronic low back pain patients. Inclusion criteria include age between 25 and 80 years, radicular back pain for at least three months that has not responded to non-invasive treatments including drugs and physical therapy and pain score based on VNS (verbal numerical scale) more than 4. The exclusion criteria include acute trauma patients and spine fractures, malignancies, rheumatic diseases, pregnancy, mental illnesses, peripheral neuropathies, hyperthyroidism and favism, coagulopathy, chronic systemic infection, urinary and fecal incontinence, local infection of the sacrum and The patient's lack of satisfaction at any stage of the research.

Intervention groups

Intervention group or group A (neuroplasty with ozone injection in the epidural space) and control group or group B (neuroplasty without ozone injection in the epidural space).

Main outcome variables

Pain score,, percentage of disability,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150724023315N3**
Registration date: **2023-02-24, 1401/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-24, 1401/12/05**
Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Mahmoud Ganjifard

Name of organization / entity

Birjand University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date
2023-06-21, 1402/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of percutaneus epidural neuroplasty(RACZ procidures) with and without epidural OZONE injection in patients with chronic low back pain

Public title
The effect of ozone on low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1- Radicular back pain for at least three months that has not responded to non-invasive treatments including medicine and physical therapy. 2- The pain score based on VNS (verbal numerical scale) should be more than 4
Exclusion criteria:
Patients with acute trauma and spinal fractures, malignancies rheumatic diseases pregnancy mental illnesses peripheral neuropathies hyperthyroidism coagulopathy chronic systemic infection urinary and fecal incontinence local infection of the sacrum area patient dissatisfaction favism
Age
From **25 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done using the randomized permutation block with Excel software. The blocks are provided to the attending physician and when each patient enters, a block envelope is randomly selected and based on the sticker removed, the patient will be assigned to the relevant treatment group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, those who register the results of the intervention and statistical analysis are not aware of what intervention was done for each patient and each group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Neuroscience Research Institute, Tehran University of Medical Sciences
Street address
Keshavarz Boulevard
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tehran
Province
Tehran
Postal code
1417653761
Approval date
2023-01-28, 1401/11/08
Ethics committee reference number
IR.TUMS.NI.REC.1401.085

Health conditions studied

1

Description of health condition studied
chronic low back pain
ICD-10 code
g55.1
ICD-10 code description
Nerve root and plexus compressions in intervertebral disc disorders

Primary outcomes

1

Description
Pain intensity of patients based on verbal numeric scale (VNS)
Timepoint
before the intervention, twenty-four hours, one month and three months after the intervention
Method of measurement
Pain intensity assessment questionnaire

2

Description
The percentage of disability due to back pain based on the OSWESTRY disability index questionnaire
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement

OSWESTRY disability index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(neuroplasty using the RACZ method plus ozone): The neuroplasty procedure of patients is performed in the operating room under aseptic conditions. The patient is placed in the prone position and standard monitoring (including blood pressure, ECG and pulse oximetry) and venous access are established and intravenous sedation with midazolam and fentanyl is prescribed. After the scraping, the doctor disinfects the area (waist, sacrum, and buttocks) with betadine, wearing a sterile gown, gloves, hat, and mask, and covers the patient's body with a sterile gown from the upper thoracic region to the knees. After the administration of prophylactic antibiotic (one gram of intravenous cefazolin), a 15G or 16G size epidural needle is inserted through the sacral hiatus under fluoroscopy guidance and 10 cc of contrast is injected to determine the location of the adhesion and defect. The RACZ catheter is inserted through the epidural needle and guided to the adhesion site or the area determined according to the patient's symptoms or MRI, and removal of the adhesion is done with mechanical maneuvers. In the next step, 1500 units of hyaluronidase dissolved in 10 cc of normal saline are injected, followed by 10 cc of 0.25% ropivacaine solution and 40 mg of methylprednisolone. in this group, 10 cc of ozone 25 micrograms per cc are injected. Finally, after 15 to 20 minutes, 5% hypertonic saline solution is injected in both groups for 15 minutes. At the end, the catheter is removed and the health of the catheter is checked. The patient is checked for sensory and motor deficits and is discharged home with education.

Category

Treatment - Drugs

2

Description

Control group(neuroplasty using the RACZ method): The neuroplasty procedure of patients is performed in the operating room under aseptic conditions. The patient is placed in the prone position and standard monitoring (including blood pressure, ECG and pulse oximetry) and venous access are established and intravenous sedation with midazolam and fentanyl is prescribed. After the scraping, the doctor disinfects the area (waist, sacrum, and buttocks) with betadine, wearing a sterile gown, gloves, hat, and mask, and covers the patient's body with a sterile gown from the upper thoracic region to the knees. After the administration of prophylactic antibiotic (one gram of intravenous cefazolin), a 15G or 16G size epidural needle is inserted through the sacral hiatus under fluoroscopy guidance and 10 cc of contrast is injected to determine the location of the adhesion and defect. The RACZ catheter is inserted through the epidural needle and guided to the adhesion site or the area determined according to the patient's symptoms or MRI, and removal of the adhesion is done with mechanical maneuvers. In the next step, 1500 units of hyaluronidase dissolved in 10 cc of normal saline are injected, followed by 10 cc of 0.25% ropivacaine solution and 40 mg of methylprednisolone.Finally, after 15 to 20 minutes, 5% hypertonic saline solution is injected in both groups for 15 minutes. At the end, the catheter is removed and the health of the catheter is checked. The patient is checked for sensory and motor deficits and is discharged home with education.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran University of Medical Sciences

Full name of responsible person
Mahmoud Ganjifard

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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
Tehran University of Medical Sciences
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Mahmoud Ganjifard
Position
assistant of fellowship
Latest degree
Specialist
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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