Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of caudal epidural method with S1 transforaminal block in patients undergoing lumbar discectomy with symptoms of post-surgery failure syndrome.

Protocol summary

Study aim

Comparison of caudal epidural method with S1 transforaminal block in patients undergoing lumbar discectomy with symptoms of post-surgery failure syndrome.

Design

This study will be conducted as a randomized clinical trial (blocks of four), double-blind (statistical consultant and patient), without control group, with parallel groups and with 2-3 phase with the participation of 52 patients after discectomy.

Settings and conduct

This randomized clinical trial study will be conducted with the participation of 52 patients referred to Imam Hossein Hospital (Shahid Beheshti University of Medical Sciences) with lower limb radicular symptoms after discectomy surgery. Patients will be randomly divided into two groups, caudal block and transforaminal block, and the pain intensity after the intervention will be compared between the two groups. The patients and the statistical consultant will be blinded during the study and the study will be conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria

The criteria for entering the study are patients who underwent lumbar discectomy and have lower radicular pain symptoms and consent to participate in the research plan, and the exclusion criteria also include: use of anticoagulant drugs, systemic infection, history of severe heart diseases and lumbar infection .

Intervention groups

This study is a randomized clinical trial without a control group, which will be conducted with the participation of 52 patients after lumbar discectomy surgery. Patients will be divided into two treatment methods, caudal block and transforaminal block, and the intensity of pain will be compared in them after the intervention.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N31**
Registration date: **2023-03-17, 1401/12/26**
Registration timing: **prospective**

Last update: **2023-03-17, 1401/12/26**
Update count: **0**

Registration date

2023-03-17, 1401/12/26

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-08-05, 1402/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of caudal epidural method with S1 transforaminal block in patients undergoing lumbar discectomy with symptoms of post-surgery failure syndrome.

Public title
Comparison of caudal epidural method with S1 transforaminal block in patients undergoing lumbar discectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who underwent lumbar discectomy and have lower radicular pain symptoms. Consent to participate in the research project

Exclusion criteria:
Taking anticoagulant drugs Systemic infection History of severe heart disease Lumbar infection

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block random division method (blocks of 4) is used. One of the colleagues of the study, who was not blinded, names the caudal block method with the letter A and the transforaminal block method with the letter B. Then, the researcher distributes packages A and B among the referring patients in order to participate in the study using a block random division method (of 4). Then, among the created blocks, so many blocks are randomly selected to reach the required sample size. To make a random sequence, we give numbers from 1 to 13 to the possible blocks (13 blocks). According to the sample size, any number of 4 blocks will be used. Block numbers will be selected from the table of random numbers and the sequence of blocks in each group will be determined based on these numbers. Finally, with the help of 13 blocks of four, random allocation will be done.

Blinding (investigator's opinion)
Double blinded

Blinding description
The first researcher will divide the patients into study groups using blocks of four and complete the relevant checklists and hand them over to the statistical consultant. The statistical consultant will be blinded to which groups the patients fall into. Also, patients will be unaware of the type of drug injected; Therefore, the patients will also be blind during the study; Therefore, this study will be conducted in a double-blind manner.

Placebo
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
Shahid Beheshti University of Medical Sciences

City
Tehran

Province
East Azarbaijan

Postal code
5165665631

Approval date
2023-03-04, 1401/12/13

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.875

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
G89.29

ICD-10 code description
Other chronic pain

Primary outcomes

1

Description
Pain

Timepoint
Before the intervention, one month and three months after the intervention

Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The patient is placed in the prone position and a pillow is placed under the abdomen to increase access to the lumbar position. After prep and drape, the target sacral surface for the block is identified under ultrasound guidance after hitting the trajectory. The surgeon enters the area with a #22 spinal needle and one cc of lidocaine will be injected. After reaching the inferomedial pedicle, four cc of triamcinolone drug and 4 cc of normal saline will be injected. Pain intensity will be measured before the intervention and one month and three months after the intervention using the VAS tool.

Category

Treatment - Drugs

2

Description

Intervention group2: The patient is placed in the prone position and a pillow is placed under the abdomen to increase access to the lumbar position. After prep and drape, the target sacral surface for the block is identified under ultrasound guidance after hitting the trajectory. The surgeon enters the area with a #22 spinal needle and one cc of lidocaine will be injected. After reaching the inferomedial pedicle, four cc of triamcinolone drug, 2 cc of ropivacaine drug and 2 cc of normal serum will be injected. Pain intensity will be measured before the intervention and one month and three months after the intervention using the VAS tool.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hosein Hospital

Full name of responsible person
Artadokht Khoshooee

Street address
Imam Hossein Hospital, Shahid Madani Street, Imam Hossein Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Behzad Abtahi

Street address
Shahid Shahriari Square, Evin, Tehran

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Abtahi@hotmail.com

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
Tabriz University of Medical Sciences

Full name of responsible person
Mehdi Khanbabayi Gol

Position
MSc in Nursing Education

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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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