Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of targeted spinal nerve root blockade with caudal vs transforaminal approach in lumbar radiculopathy

Protocol summary

Study aim
The comparison of targeted spinal nerve root blockade with caudal vs tansforaminal approach in lumbar radiculopathy

Design
This randomized, double blinded, clinical trial at phase 2 is done on 50 patients. The sample size based on the formula n = (2 (z1-α / 2 + z1-b) ²δ² / d² ، is 50 patients which randomly divided into two equal groups.

Settings and conduct
This study is done in patients in operation room, under aseptic condition, local anesthesia, monitoring, on prone position, by fluoroscopic guidance. Patients is divided into Transforaminal (T), and Caudal (C) groups. In T group, blunt curved tip Racz needle G21 is introduced for each involved levels, under transverse process and pedicle conjunction by tunnel view, and after confirmation of correct position of the tip of needle, injectate for each level (Triamcinolone 20mg, and Ropivacaine %0.1, 5ml) is injected. In C group, Caudal Racz needle G17 is introduced, and Racz catheter is conducted up to involved levels, and injectate for each level (as same as T group) is injected. After procedure, patients are transferred to recovery and is discharged in case of hemodynamic stability.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Radicular moderate to sever low back pain, Lack of response to conservative therapy. Exclusion criteria: severe spinal deformity, infection, anticoagulants, drug abuse, history of allergic reaction to the studied drugs, history of severe psychological disorders, pregnancy and lactation, severe or sudden onset of neurological complications such as urinary or fecal incontinence, BMI>35 , patient refusal, history of lumbar spine surgery, peripheral neuropathy

Intervention groups
Transforaminal (T), and Caudal (C) groups

Main outcome variables
Visual Analogue Scale , Oswestry Disability Index , analgesia consumption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111102007984N31**
Registration date: **2022-01-14, 1400/10/24**
Registration timing: **prospective**

Last update: **2022-01-14, 1400/10/24**
Update count: **0**

Registration date
2022-01-14, 1400/10/24

Registrant information

Name
Farnad Imani

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of targeted spinal nerve root blockade with caudal vs transforaminal approach in lumbar radiculopathy

Public title
Comparison of the effect of lumbar spinal nerve root block by transforminal and codal method on nerve involved in low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Radicular unilateral or bilateral low back pain more than six months Maximum two levels involved Age 40 to 70 years Lack of response to conservative therapy after three months ASA I-II Moderate to sever pain (VAS > 3)

Exclusion criteria:
Severe spinal deformity Spinal tumors Spine fracture Vertebral listlsis more than G II Local or systemic infection Taking anticoagulants Drug abuse History of allergic reaction to the studied drugs History of severe psychological disorders Pregnancy and lactation Severe or sudden onset of neurological complications such as urinary or fecal incontinence BMI>35 Patient refusal MRI contraindication such as pacemakers, defibrillators, aortic aneurysm clips Respiratory incompetence cause prone position intolerance Smoking or alcohol consumption History of lumbar spine surgery Peripheral neuropathy such as diabetes

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences, Tehran, Iran

Street address
Rasool Akram Hospital, Niayesh St, Satarkhan Av.

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Tehran

Province
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Postal code
14665-354

Approval date
2021-01-11, 1399/10/22

Ethics committee reference number
IR.IUMS.FMD.REC.1399.563

Health conditions studied

1

Description of health condition studied
Lumbar spinal nerve root block, Transforminal, Kudal, Lumbar radiculopathy

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Visual Analogue Scale

Timepoint
Before, two weeks and one month, and three months after the procedure

Method of measurement
based on questionnaire

Secondary outcomes

1

Description
Oswestry Disability Index
Timepoint
One, and three months after the procedure
Method of measurement
Based on the questionnaire

2

Description
The amount of analgesia consumption
Timepoint
One, and three months after the procedure
Method of measurement
Record and take notes

Intervention groups

1

Description
Intervention group: Intervention group: In Transforaminal group, blunt curved tip Racz needle G21 is introduced for each involved levels, under transverse process and pedicle conjunction by tunnel view, and after confirmation of correct position of the tip of needle transuraminal block injection solution is administered slowly. The solution for injection in the triamcinolone group (T) contains 20 mg of triamcinolone (triamcinolone acetonide, elixir, Iran) and 0.2% rupivacaine 5 ml (rupivacaine multeni, Italy). In case of involvement of more than one spinal nerve root, the same amount is prescribed for the next levels (up to two levels, one or two sides). In the caudal group (C), the injection is the same as for the transformaminal group for each level.
Category
Treatment - Drugs

2

Description
Control group: In the caudal group, the Racz epidural needle No. 17G enters the caudal space, and the Racz catheter enters the caudal space, and is guided to each level involved, and the drug is injected into the affected surface.Injected drugs include 20 mg of triamcinolone (triamcinolone acetonide, elixir, Iran) and 5 ml of 0.5% ropivacaine (rupivacaine multeni, Italy).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Hospital, Building no. 2, 4th floor, Pain Research Center
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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
Iran 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
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Full name of responsible person
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Position
Prof of Anesthesiology

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Some part of the clinical information of the patients will be shared

When the data will become available and for how long
One year after the end of the project

To whom data/document is available
Faculty Members of Medical Sciences Universities

Under which criteria data/document could be used
For further studies

From where data/document is obtainable
Deputy of Research & Technology, and Pain Research Center, Iran University of Medical Sciences

What processes are involved for a request to access data/document
First, at the request of the university, she/he will be informed at the request of the university's deputy of the research department, and then she/he will be referred to the pain research center during the administrative process and the data will be received by the committee

of the pain research center of the center with a commitment and acceptance.

Comments