

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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 transforaminal 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 $n = (2(z_{1-\alpha} / 2 + z_{1-\beta})^2 \delta^2 / d^2)$, 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

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 transforaminal and caudal 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 severe pain (VAS > 3)

Exclusion criteria:

Severe spinal deformity Spinal tumors Spine fracture Vertebral listhesis 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

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Rasool Akram Hospital, Niayesh St, Satarkhan Av.

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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, Transforaminal, 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 acetone, elixir, Iran) and 0.2% ropivacaine 5 ml (ropivacaine 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 acetone, elixir, Iran) and 5 ml of 0.5% ropivacaine (ropivacaine 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

Full name of responsible person

Dr. Farnad Imani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran University of Medical Sciences

Full name of responsible person

Farnad Imani

Position

Prof of Anesthesiology

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Farnad Imani

Position

Chairman, Pain Research Center

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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