

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of the effects of Triamcinolone and Dexmedetomidine in caudal neuroplasty in chronic low back pain.

Protocol summary

Study aim

Comparative study of triamcinolone and dexmedetomidine in caudal neuroplasty in chronic low back pain

Design

Fifty patients will be randomly assigned into two groups of 25. Intervention group receives Dexmedetomidine, and control group receiving triamcinolone for caudal neuroplasty.

Settings and conduct

The aim of this study is comparison of triamcinolone and Dexmedetomidine for caudal neuroplasty. Fifty patients with lumbar radiculopathy were randomly divided into two groups. In the first group, triamcinolone (80 mg), and in the 2nd group, magnesium (50 mg) were injected into the caudal space. In the 2nd day, the same drug was injected into the catheter by half a day via catheter. The evaluation criteria included physical examinations, pain scale, Disability Index, analgesic consumption before, 2 weeks, and 1, 3, and 6 months later, blood glucose before procedure, 2nd day, and two weeks later, HgA1C before, 3, and 6 months later, and, MRI before and 6 months later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Chronic low back pain, 2) Moderate to severe pain score, 3) Age 40-70 years, 4) Inadequate response to conservative, 5) Disc protrusion Exclusion criteria: 1) Severe canal stenosis, 2) Sequestered disc, 3) Severe spinal deformity, tumors, and fracture, 4) infection, 5) Drug reaction, 6) Severe psychological disorders, 7) Pregnancy and lactation, 8) Severe or sudden neurological deficit, 9) Patient's refusal

Intervention groups

En 1st group received triamcinilone and ropivacaine 2nd group received Dexmedetomidine and ropivacaine

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111102007984N28**

Registration date: **2018-12-17, 1397/09/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-17, 1397/09/26**

Update count: **0**

Registration date

2018-12-17, 1397/09/26

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effects of Triamcinolone and Dexmedetomidine in caudal neuroplasty in chronic low back pain.

Public title

A comparison of the effects of Triamcinolone and Dexmedetomidine in caudal neuroplasty in chronic low back pain.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1) Chronic low back pain more than six months +/- radiculopathy, 2) Moderate to severe pain score (> 3, based on the Visual Analog Scale), 3) Age 40-70 years, 4) Inadequate response to conservative and physiotherapy treatments after three months, 5) ASA classification I-II, 6) Disc protrusion (at MRI)

Exclusion criteria:

1) Severe canal stenosis (more than two thirds in axial MRI view), 2) Sequestered disc (fragmented), 3) Decreased disc height more than 60%, 4) Severe spinal deformity, 5) Spinal tumors, 6) Vertebral fracture, 7) Spondylolisthesis > Grade II, 8) Local or systemic infection, 9) Taking anticoagulants, 10) Drug abuse, 11) History of drug reaction, 12) Severe psychological disorders, 13) Pregnancy and lactation, 14) Severe or sudden neurological deficit such as urinary or fecal incontinence, 15) Body Mass Index (BMI) > 35, 16) Patient's refusal, 17) Diabetes mellitus, 18) MRI contraindications (cardiac pacemaker, defibrillator, aortic aneurysm clips), 19) Impossible prone positioning

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

En By using the randomized table, they were divided into two equal groups (n=25). The first group (TR) received triamcinolone plus ropivacaine, and the second group (MR) received Dexmedetomidine plus ropivacaine. for caudal neuroplasty.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both drugs are injectable and the injection site of the drug in the patient's body is in same area. Therefore, patients are not aware of the type of drug. Also, the outcome evaluator is unaware of how random allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

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Iran University of Medical Sciences, Hemmat Expressway corner

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-07-25, 1397/05/03

Ethics committee reference number

IR.IUMS.REC.1397.298

Health conditions studied**1****Description of health condition studied**

low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

low back pain

Timepoint

Before injection, two weeks, 1, 3 and 6 month after intervention

Method of measurement

pain score measured with visual analogue scale in Questionnaire

Secondary outcomes**1****Description**

Oswestry Disability Index questionnaire (ODI) and

straight leg raising test (SLR), Reverse straight leg raising test (RSLR), Bonnet, FABER, Gaenslen, Tiptoe and Heel walking, analgesic consumption, blood sugar, HbA1C, MRI

Timepoint

Before injection, two weeks, 1, 3 and 6 months after intervention. Blood sugar, before injection, 2th day and 2th week after injection HbA1C, before injection, 3 and 6 months after injection MRI, before injection and 6 months after injection

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: In intervention group 10ml Ropivacaine 0.2%, 50mg Dexmedetomidine (Excir, Iran) and was injected in the caudal epidural space by a catheter under fluoroscopy.

Category

Treatment - Drugs

2

Description

In control group 10ml 0.2% Ropivacaine (Molteni, Italy), 80 mg Triamcinolone (Caspian, IRAN) was injected in the caudal epidural space by a catheter under fluoroscopy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Medical Center

Full name of responsible person

Farnad Imani

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Anesthesiology and pain department of Hadrat-Rasoul Medical Complex Niayesh street, Sattar-Khan Avenue.

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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

Interventional pain fellowship, professor of anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

zahra Mirblook jalali

Position

Head of Pain Research Center, Iran University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Psychology

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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

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

Title and more details about the data/document

Part of the clinical information of the patient is shared

When the data will become available and for how long

6 months 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 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 will be referred to the research center during the administrative process and the data will be received by the committee of the research center of the center with a commitment and acceptance.

Comments