Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 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 dexmedetomodine 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 6months later, and, MRI before and 6months 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) Sequestrated disc, 3) Sever spinal deformity, tumors, and fracture, 4) infection, 5) Drug reaction, 6) Sever psychological disorders,7) Pregnancy and lactation, 8) Severe or sudden neurological deficit, 9) Patient's refusal

Intervention groups
En Ist 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)
Phone
+98 21 6651 5758
Email address
farnadimani@yahoo.com

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) Sequestrated disc (fragmented),3) Decreased disc height more than 60%,4) Sever 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) Sever 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

Street address
Iran University of Medical Sciences, Hemmat Expressway corner

City
Tehran

Province
Tehran

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 moth after intervention. Blood sugar ,before injection,2 th day and 2th week after injectionHbA1C, before injection,3 and 6 month after injection MRI, before injection and 6 month 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

Street address
Anesthesiology and pain department of Hzrat-Rasoul Medical Complex Niayesh street, sattar-Khan Avenue.

City
Tehran

Province
Tehran

Postal code
۱۴۴۵۶۱۳۱۳۱

Phone
+98 21 6651 5758

Fax
+98 21 6651 5758

Email
farnadimani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyed Kazem Malakoti

Street address
Iran University of Medical Sciences, Hemmat highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 8670 2503

Email
research@iums.ac.ir

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

Street address
Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

City
Tehran

Province
Tehran

Postal code
1445613131

Phone

+98 21 6651 5758

Email

farnadimani@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Farnad Imani

Position

professor of anesthesiology,Interventional pain fellowship

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5758

Email

farnadimani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

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

Street address

Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5758

Email

zmjalali56@gmail.com

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