

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

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

Protocol summary

Study aim

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

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. Excel software rand function is used for randomization.

Settings and conduct

80 patients with LBP (in 3 groups of 20) will be studied in this double-blind randomized clinical trial (researcher and patient) in 4 groups (control, triamcinolone, dextrometomidine and magnesium. Pain score based on VAS, ODI, It will be recorded in 5 times (before the intervention, second week, first month, third and sixth after the intervention) and statistical analysis will be performed by SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion criteria Chronic low back pain with a history of more than six months with or without diffusion to the lower extremities, moderate to high pain (pain score greater than 3), age 40 to 70 years, and 1 ASA Physical Status. Exclusion criteria included severe spinal deformity, spinal tumors, spinal fractures, vertebral listesis more than grade 2, local or systemic infection, use of anticoagulants, drug use, history of allergic reactions to drugs, history of mental illness Severe, pregnancy and lactation, Severe disorders or sudden onset of neurological complications such as urinary incontinence, BMI above 35, Patient dissatisfaction, Diabetes,

Intervention groups

Intervention group 1: Patients undergoing epidural injection of caudal Intervention group 2: Patients undergoing epidural injection of caudal plus triamcinolone injection Intervention group 3: Patients undergoing epidural injection of caudal plus dextrometomidine injection Intervention group 4: Patients undergoing epidural injection of caudal plus magnesium

injection

Main outcome variables

Visual analogue scale, The Oswestry Disability Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111102007984N32**

Registration date: **2022-09-02, 1401/06/11**

Registration timing: **retrospective**

Last update: **2022-09-02, 1401/06/11**

Update count: **0**

Registration date

2022-09-02, 1401/06/11

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

farnadimani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-03, 1398/12/13

Expected recruitment end date

2021-03-03, 1399/12/13

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 and Magnesium sulfate in caudal neuroplasty in chronic low back pain

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic low back pain more than six months +/- radiculopathy Moderate to severe pain score (> 3, based on the Visual Analog Scale) Being at the age of 40-70 years Inadequate response to conservative and physiotherapy treatments after three months American Anesthesiologists Classification (ASA) I-II Disc protrusion in MRI

Exclusion criteria:

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

AgeFrom **40 years** old to **70 years** old**Gender**

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, the Restricted randomization method (block randomization) will be used. Blocking is usually used to balance the number of samples assigned to each of the study groups. All blocks are equal and we will have 8 blocks (including 2 participants in each group) in this experiment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The senior resident who performs all assessments, data collection, and follow-up of the patient will be unaware of how randomly grouped patients are. The pain specialist who performs the intervention will be blind to the grouping or materials used. The patient will also be unaware of the intervention she/he is receiving

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

Rasoul Akram Hospital, Maziar Mansouri St, Sattar Khan St.

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-01-08, 1398/10/18

Ethics committee reference number

IR.IUMS.REC.1398.1335

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**

visual analog scale

Timepoint

At the beginning of the study (before the intervention) and 14, 30, 90 and 180 days after the intervention

Method of measurement

Visual Analogue Scale

2

Description

Oswestry Disability Index

Timepoint

At the beginning of the study (before the intervention) and 14, 30, 90 and 180 days after the intervention

Method of measurement

Oswestry Low Back Pain Disability Questionnaire

Secondary outcomes

1

Description

The amount of painkiller used

Timepoint

At the beginning of the study (before the intervention) and 14, 30, 90 and 180 days after the intervention

Method of measurement

Preset form for recording the amount of painkiller used

Intervention groups

1

Description

Control group: which undergoes epidural epidural injection using 2-3 ml of Xylocaine (without preservative and without epinephrine) by a 17-gauge spinal injection needle.

Category

Treatment - Drugs

2

Description

First Intervention group: Intervention group: In addition to epidural injection of caudal (as in the control group), the injection solution containing 10 ml of ropivacaine 0.2%, 10 ml of hypertonic sodium 5% and 1500 units of hyalase with 80 mg of triamcinolone is injected via epidural caudal injection.

Category

Treatment - Drugs

3

Description

Second intervention group: In addition to epidural injection of caudal (as in the control group) received an injection solution similar to the first intervention group, with the difference that instead of triamcinolone, dexmedetomidine is added 0.5 micrograms per kilogram.

Category

Treatment - Drugs

4

Description

Third intervention group: In addition to epidural injection of caudal (like the control group) received an injection solution similar to the first intervention group, with the

difference that instead of triamcinolone, magnesium sulfate 50 mg is added.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram hospital

Full name of responsible person

Farnad Imani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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