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, dextromitonidine 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 dextomitonidine 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

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Iran (Islamic Republic of)

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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 +/- radiculopathyModerate 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 monthsAmerican Anesthesiologists Classification (ASA) I-IIDisc protrusion in MRI
Exclusion criteria:
Severe canal stenosis (more than two thirds in axial MRI view) Sequestrated disc (fragmented) Decreased disc height more than 60% Sever spinal deformity Spinal tumors Vertebral fracture Spondylolisthesis Grade>2 Local or systemic infection Taking anticoagulants Drug abuse History of drug reaction Sever 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
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator

Sample size
Target 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.
City
Tehran
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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 rupivacaine 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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Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av, Tehran, Iran.
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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

Iran University of Medical Sciences

Full name of responsible person

Farnad Imani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurosurgery

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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