

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the of effects Magnesium Sulfate and triamcinolone as Adjuvants with Ropivacaine for caudal block in Low Back Pain

Protocol summary

Study aim

comparison of pain score following caudal block with ropivacaine and triamcinolone and magnesium sulfate as adjuvant in patients with low back pain.

Design

Randomized double blind clinical trial with control group, phase 3 on 40 patients. Rand function of Excel was used for randomization.

Settings and conduct

patients with low back pain who refer to pain clinic of Imam Hussain Hospital will be divided in two groups recruiting software blocked randomization. Detection of caudal canal will be confirmed using injection of 2 ml of radio opaque contrast solution. Following negative aspiration of CSF or blood, 10 ml of ropivacaine 0.1% in conjunction with 40 triamcinolone or 200 milligram magnesium sulfate will be injected. The patient will be monitored 30 minutes postoperatively for hemodynamic stability and presence of adverse effects. Demographic data and MRI findings will be recorded. Pain scores based on numeric rating scale and Modified Oswestry Disability Questionnaire preoperatively and 1 and 3 month postoperatively will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion: Patients with low back pain at least 3 month before, no response to physiotherapy least 6 month and NRS ≥ 4 and age between 30-60 yrs/o Exclusion: epidural steroid injection during last 3 month, coagulopathy, pregnancy, breast feeding, sensitivity to contrast medium, psychiatric disease, hemodynamic and respiratory unstability, previous back surgery, local anesthetic sensitivity, local infection, patient's refusal.

Intervention groups

Patients with low back pain

Main outcome variables

comparison of triamcinolone and magnesium sulfate as adjuvant with ropivacaine 0.1% for caudal block on pain score in patients with low back pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230502058054N1**

Registration date: **2023-07-18, 1402/04/27**

Registration timing: **prospective**

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

Registration date

2023-07-18, 1402/04/27

Registrant information

Name

Payman Dadkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7758 3043

Email address

pdadkhah@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the of effects Magnesium Sulfate and triamcinolone as Adjuvants with Ropivacaine for caudal block in Low Back Pain Public title Comparison the of effects Magnesium Sulfate and triamcinolone as Adjuvants with Ropivacaine for caudal block in Low Back Pain Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: All patients with low back pain who have had canal stenosis, multiple disc herniation or multiple degenerative joint disease(based on MRI report), with at least 3 months pain and non responsive to conservative treatments such as physiotherapy with pain score of at least 4 between 30-60 years old. Exclusion criteria: Patients with :1-epidural steroid injection during last 3 months, without previous MRI report.2- coagulation disorders 3- pregnant 4- women with milk feeding 5- sensitivity to radiology contrast medications 5- patients with psychological disease 6- unstable hydrodynamic status. 7- previous back surgery 8- contraindication for local anesthetic drugs.9- infection 10- Allergy to medications(local anesthetic, steroid or magnesium) 11- unwillingness of patients to study 12- patients who do not sign inform consent. Age From 30 years old to 60 years old Gender Both Phase 3 Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor • Data analyser Sample size Target sample size: 40 Randomization (investigator's opinion) Randomized Randomization description Web based randomization: This service permits patient randomization into one of two or more treatment arms at any time without incurring the need for personnel continuously present at the central site at all times. The only prerequisite is the availability of a computer workstation equipped with an internet link and a standard browser for the world wide web. Blinding (investigator's opinion) Double blinded Blinding description In this study participants, care provider, investigator, outcome assessor and data analyst are all blinded to patients groups. Placebo Not used	Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Shahid Beheshti University of medical Sciences Street address Tehran- Velenjac-Shahid Shahriari square-Shahid Arabi St-Shahid Beheshti University of Medical Sciences City Tehran Province Tehran Postal code 1985717443 Approval date 2023-05-03, 1402/02/13 Ethics committee reference number IR.SBMU.RETECH.REC.1402.070 Health conditions studied 1 Description of health condition studied Patients with low back pain who have spinal canal stenosis or several disc bulging or protrusion or degeneration changes in MRI ICD-10 code M54.4 ICD-10 code description low back with sciatica Primary outcomes 1 Description Comparison of magnesium sulfate and triamcinolone as adjuvant with ropivacaine for caudal block on pain score in patients with low back pain Timepoint Preblock and 1 and 3 month after block Method of measurement numeric rating scale Secondary outcomes
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1

Description

modified Oswestry disability questionnaire score

Timepoint

Preblock and 1 and 3 month after block

Method of measurement

Questionnaire score

Intervention groups

1

Description

Intervention group: Magnesium Sulfate

Category

Treatment - Drugs

2

Description

Intervention group: Triamcinolone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein pain clinic

Full name of responsible person

Alireza Jaffari

Street address

Imam Hussein Square, Shahid Madani st

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 3000

Email

alirezajaffari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Afshin Zarghi

Street address

Velenjac, Shahid Shahriari square, Shahid Araabi st,
Shahid Beheshti University of Medical Sciences, 5th
Floor

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Email

info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Payman Dadkhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Hussein Hospital, Shahid Madani Ave., Tehran,

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7758 3043

Fax

Email

pdadkhah@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

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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

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Payman Dadkhah

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work