

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Assessing the effect of adding magnesium sulfate to Bupivacaine for caudal anesthesia on postoperative pain in pediatric inguinal hernia repair surgery

Protocol summary

Study aim

Determining the effect of adding magnesium sulfate to bupivacaine in caudal anesthesia on pain after children's inguinal hernia repair surgery.

Design

Interventional study, double-blind, randomized, therapeutic, with parallel groups, 50 patients will be randomly divided into two equal groups, bupivacaine group and bupivacaine + magnesium sulfate group.

Settings and conduct

The two groups will be matched in terms of age. Patients of both groups will be under general anesthesia with the same drug by an anesthesiologist with the same technique. Patients under caudal block in the lateral decubitus position will be anesthetized from the sacral hiatus space; in the bupivacaine group, 0.5 cc bupivacaine will be added to 5 cc of normal saline or distilled water, and in the bupivacaine group, magnesium sulfate, 5 cc 20% magnesium sulfate will be added to 5cc of 0.5% bupivacaine

Participants/Inclusion and exclusion criteria

Inclusion criteria for children undergoing inguinal hernia repair surgery, American Anesthesiology Association (ASA) physical status, children 2 months to 7 years, absence of contraindications for caudal blocks. Exclusion criteria: patients with mental disorders, patients with coagulation disorders, history of allergic reactions to local anesthetics, history of underlying diseases

Intervention groups

Bupivacaine group and Bupivacaine + magnesium sulfate group

Main outcome variables

Pain measurement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056613N1**

Registration date: **2023-01-08, 1401/10/18**

Registration timing: **prospective**

Last update: **2023-01-08, 1401/10/18**

Update count: **0**

Registration date

2023-01-08, 1401/10/18

Registrant information

Name

aliakbar nasiri

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-09-20, 1402/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of adding magnesium sulfate to

Bupivacain for caudal anesthesia on postoperative pain in pediatric inguinal hernia repair surgery

Public title

Assessing the effect of adding magnesium sulfate to Bupivacain for caudal anesthesia on postoperative pain in pediatric inguinal hernia repair surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children undergoing inguinal hernia repair surgery
American Society of Anesthesiologist (ASA) physical status Children 2 months to 7 years
Absence of contraindications for pit blocks

Exclusion criteria:

Patients with mental disorders
patients with coagulation disorders
History of allergic reactions to local anesthetics
History of underlying diseases

Age

From **2 months** old to **7 years** old

Gender

Male

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **1**

200 / 5,000
Translation results
In the bupivacaine group, 5cc of 0.5% bupivacaine will be added to 5cc of normal saline or distilled water, and in the bupivacaine magnesium sulfate group, 5cc of 20% magnesium sulfate will be added to 5cc of 0.5% bupivacaine.

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by the random permutation block design method of two treatments with blocks of ten. First, 10 blocks of the composition (ABABABAB) will be listed and a code will be assigned to each, then according to the sample size equal to 50, 5 blocks will be selected in this order that the letter A for The bupivacaine group and letter B will be considered for the bupivacaine + magnesium sulfate group. Patients will be randomly assigned to two groups A and B using Random Allocation computer software. By selecting the simple randomization method in the randomization method section and entering the total sample size determined in this software, numbers will be given to the patients and the patients will be entered into two groups based on the numbers given by the computer. Randomization will be done based on the permuted block randomization method. Each block will have 10 capacities. Based on the example of ABABABAB, in each block, people are evenly assigned to two groups. 5 blocks will be built. After that, in each block, people are randomly assigned to bupivacaine group (A) (25 people) or bupivacaine +

magnesium sulfate (B) group (25 people). In this study, randomization will be simple, in a box, numbers from 1 to 50 will be written on sheets of paper and placed inside the box in an unspecified manner. One sheet will be removed for each disease, if the number is even. It will be placed in the first group, and if it is an odd number, it will be in the second group.

Blinding (investigator's opinion)

Double blinded

Blinding description

All the codes are secret and while the examiner will be one person and they will not be informed about the grouping of people, the method and process of conducting the study will be explained to the parents before prescribing the medicine. The study will be double-blind, the parents of the patients and the clinical evaluator will be unaware of the placement of the patients in the study groups, in other words, both the parents will be unaware of the group they have been placed in, and the clinical evaluator will not know the group of the patients. Finally, after collecting the data of each group separately, they will be compared by the clinical assessor - who does not know about the patient group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

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West Azarbaijan University of Medical Sciences, Resalat Blvd, Urmia

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Postal code

5714783734

Approval date

2022-04-19, 1401/01/30

Ethics committee reference number

IR.UMSU.REC.1401.013

Health conditions studied

1

Description of health condition studied

inguinal hernia

ICD-10 code

K40.0

ICD-10 code description

Bilateral inguinal hernia, with obstruction, without gangrene

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

intensity of pain

Timepoint

Times 1, 6, 12 and 24 hours after surgery

Method of measurement

Frankel pain measurement scale

Secondary outcomes

empty

Intervention groups**1****Description**

Children under caudal block, 5 cc of bupivacaine 0.5% will be added to 5 cc of normal saline or distilled water.

Category

Treatment - Drugs

2**Description**

Intervention group: Bupivacaine + magnesium sulfate group - children are placed under caudal block and once 5cc of magnesium sulfate 20% will be added to 5cc of bupivacaine 0.5% from Shahid Ghazi Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Motahari Teaching Hospital Urmia

Full name of responsible person

Ali Akbar Nasiri

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Kashani St. - Shahid Motahari educational and therapeutic center

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

دانشگاه علوم پزشکی ارومیه

Proportion provided by this source

100

Public or private sector

Private

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**

Oroumia University of Medical Sciences

Full name of responsible person

Ali Akbar Nasir

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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