Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessing the effect of adding magnesium sulfate to Boupivacain 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

Country
Iran (Islamic Republic of)

Phone
+98 44 3346 9931

Email address
nasiriali7@gmail.com

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

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

Public title

Assessing the effect of adding magnesium sulfate to Boupivacain 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 / 5,000Translation resultsIn 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 (ABABABABAB) 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 ABABABABAB, 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

Street address

West Azarbaijan University of Medical Sciences, Resalat Blvd, Urmia

City

Urmia

Province

West Azarbaijan

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
Street address
Kashani St. - Shahid Motahari educational and therapeutic center
City
Urmia
Province
West Azarbaijan
Postal code
57146154637
Phone
+98 44 3223 7080
Fax
+98 44 3197 7149
Email
Nasiriali7@gmail.com
Web page address
https://umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia, Resalat Blvd., Emergency Room, West Azarbaijan University of Medical Sciences and Healthcare Services, Research and Technology Vice-Chancellor
City
Urmia
Province
West Azarbaijan
Postal code
57146154637
Phone
+98 44 3223 1930
Email
sabergholizadeh@yahoo.com
Web page address
http://umsu.ac.ir
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

Street address
Emam khomini university hospital-Eeshad AVE-Modarres Blvd-urmia-iran

City
Urmia

Province
West Azarbaijan

Postal code
5715781351

Phone
009844334557286

Email
Nasiriali7@gmail.com

Web page address
https://umsu.ac.ir

Person responsible for scientific 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

Street address
Emam khomini university hospital-Eeshad AVE-Modarres Blvd-urmia-iran

City
Urmia

Province
West Azarbaijan

Postal code
5715781351

Phone
+98 44 3345 7286

Email
Nasiriali7@gmail.com

Web page address
https://umsu.ac.ir

Person responsible for updating data

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

Street address
Emam khomini university hospital-Eeshad AVE-Modarres Blvd-urmia-iran

City
Urmia

Province
West Azarbaijan

Postal code
5715781351

Phone
+98 44 3345 7286

Email
Nasiriali7@gmail.com

Web page address
https://umsu.ac.ir

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