

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the postoperative analgesia between the caudal and ilioinguinal/ iliohypogastric blocks in pediatric inguinal hernia repair surgery

Protocol summary

Study aim

Comparison of the postoperative analgesia between the caudal and ilioinguinal/ iliohypogastric blocks in inguinal hernia repair surgery

Design

A double-blind, randomized clinical trial study with parallel groups and phases 3 on 60 patients. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct

This study will be conducted on children under inguinal hernia repair surgery in Urmia Shahid Motahhari hospital. In this double-blind study, the patient and the researcher will evaluate the outcomes and will be blinded to the allocation of patients into two blocks.

Participants/Inclusion and exclusion criteria

In this study, 60 children undergoing inguinal hernia repair surgery will be included. Inclusion criteria will be patients with physical status equal to or greater than two according to the criteria of the American Anesthesia Association (II>ASA), aged between 6 months and 5 years, and no having a spinal deformity. patients with coagulation problems such as hemophilia, DIC, severe infections such as septicemia, meningitis, and brain tumors with increased intracranial pressure will be excluded.

Intervention groups

Both groups will be under general anesthesia with midazolam 0.05 mg/kg, fentanyl 1 microgram/kg, lidocaine 1 mg/kg, and propofol 3 mg/kg. Then, in one group, the caudal block will be performed using a 22-gauge needle from the sacral hiatus space with 1 ml/kg of bupivacaine 0.2% and 5 micrograms/kg of epinephrine at the lateral decubitus position. In the other group, ilioinguinal/iliohypogastric block will be performed with 0.1 cc/kg of bupivacaine 0.2% and epinephrine 5 micrograms/kg before surgery.

Main outcome variables

Pain score, prescription of an analgesic drug, and time of the first request for an analgesic drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516033992N11**

Registration date: **2022-07-06, 1401/04/15**

Registration timing: **prospective**

Last update: **2022-07-06, 1401/04/15**

Update count: **0**

Registration date

2022-07-06, 1401/04/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3222 2010

Email address

karami.t@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the postoperative analgesia between the caudal and ilioinguinal/ iliohypogastric blocks in pediatric inguinal hernia repair surgery

Public title
Comparison of the postoperative analgesia between the caudal and ilioinguinal/ iliohypogastric blocks

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with physical status equal to or greater than two according to the criteria of the American Anesthesia Association (II>ASA) Aged between 6 months and 5 years Not having a spinal deformity
Exclusion criteria:
Coagulation problems such as hemophilia, DIC Severe infections such as septicemia, meningitis Brain tumors with increased intracranial pressure Allergy to local anesthetics Chemotherapy with drugs such as cisplatin Hypovolemia Skin or subcutaneous lesions like infection, angioma at the puncture site

Age
From **6 months** old to **5 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first, the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated to one of two block methods based on generated numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be conducted as a double-blind clinical trial. The patient and the researcher who will be evaluating the outcomes will be blind to the allocation of patients into two blocks. Blocks will be performed by an anesthesiologist (other than the outcome assessor) and the name of blocks will be encoded with the letters A and B.

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
Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734

Approval date
2022-05-25, 1401/03/04

Ethics committee reference number
IR.UMSU.REC.1401.073

Health conditions studied

1

Description of health condition studied
Postoperative pain

ICD-10 code
MG31.2

ICD-10 code description
Acute postoperative pain, not elsewhere classified

Primary outcomes

1

Description
Pain score

Timepoint
in recovery, 6, 12 and 24 hours after surgery

Method of measurement
Face, Legs, Activity, Cry, Consolability (FLACC) pain scale

2

Description
Prescribing an analgesic

Timepoint
after surgery

Method of measurement
yes/no

3

Description

The time of the first request for an analgesic

Timepoint

after surgery

Method of measurement

Minute

Secondary outcomes

1

Description

Heart rate

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Monitoring

2

Description

Systolic blood pressure

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Monitoring

3

Description

Diastolic blood pressure

Timepoint

In recovery, 6, 12 and 24 hours after surgery

Method of measurement

Monitoring

4

Description

Nausea and vomiting

Timepoint

After surgery

Method of measurement

yes/no

Intervention groups

1

Description

Intervention group: group 1: Patients will be under general anesthesia with midazolam 0.05 mg/kg, fentanyl 1 microgram/kg, lidocaine 1 mg/kg, and propofol 3 mg/kg. Then, the caudal block will be performed using a 22-gauge needle from the sacral hiatus space with 1 ml/kg bupivacaine 0.2% and epinephrine 5 micrograms/kg at the lateral decubitus position before surgery.

Category

Treatment - Other

2

Description

Intervention group: group 2: Patients will be under general anesthesia with midazolam 0.05 mg/kg, fentanyl 1 microgram/kg, lidocaine 1 mg/kg, and propofol 3 mg/kg. Then, an ilioinguinal/iliohypogastric block will be performed with 0.1 cc/kg of bupivacaine 0.2% and epinephrine 5 micrograms/kg before surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Urmia Shahid Motahhari hospital

Full name of responsible person

Dr. Tohid Karami

Street address

Kashani Ave., Shahid Motahhari hospital., Urmia., Iran.

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Email

karami.t@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

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Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.

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gholizadeh.s@umsu.as.ir

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

Yes

Title of funding source

Oroumia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Tohid Karami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Motahhari hospital., Kashani Ave, Urmia, Iran.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Tohid Karami

Position

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Latest degree

Subspecialist

Other areas of specialty/work

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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Tohid Karami

Position

Assistant professor

Latest degree

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Other areas of specialty/work

Anesthesiology

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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

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data will not be published individually and the results will be available as the published articles.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

Not applicable

From where data/document is obtainable

Email address of the corresponding author:
karami.t@umsu.ac.ir

What processes are involved for a request to access data/document

Email address of the corresponding author:
karami.t@umsu.ac.ir

Comments