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, Jahad 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
Hart 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.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 7077
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
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
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.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 7077
Email
karami.t@umsu.ac.ir

Person responsible for scientific 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.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 7077
Email
karami.t@umsu.ac.ir

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
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Motahhari hospital., Kashani Ave., Urmia., Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 7077
Email
karami.t@umsu.ac.ir

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