Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of analgesic quality in two methods of bilateral illioinguinal block and caudal block with rupivacaine 0.2% in patients aged 3 to 8 years undergoing bilateral inguinal hernia surgery under general anesthesia in the Childern's Medical Center Hospital, 2021-22

Protocol summary

Study aim

Determining and comparing the quality of analgesia in two methods of bilateral ilioinvaginal block and caudal with rupivacaine 0.2% in patients aged 3 to 8 years undergoing bilateral inguinal hernia surgery under general anesthesia

Design

Clinical trial, with parallel groups, double-blind, On 66 patients (33 patients in each group). Random number table will be used for randomization.

Settings and conduct

The blocks will be performed in the general operating room in Childrens' medical Center Hospital. In the first group, after induction, the patient underwent ultrasound inguinal block with rupivacaine 0.2% (0.1 ml /kg) and in the second group, patients will be subjected to caudal block (1 ml/kg) with rupivacaine 0.2%. A person who records the severity of pain and the patient herself is not aware of the type of block.

Participants/Inclusion and exclusion criteria

Inclusion criteria is children 3 to 8 years old candidate for bilateral inguinal hernia repair without a history of disease, ASA class 1 & 2. Exclusion criteria is allergy to local anesthetics, non-Persian speaking patients, sacral infection, coagulation disorders, history of seizures, weight more than 20 kg and patients who are being treated with a variety of painkillers and psychiatric medications for any reason.

Intervention groups

The first group underwent bilateral ilioinguinal block under ultrasound guide/ The second group under caudal block

Main outcome variables

After induction of anesthesia, heart rate and mean arterial pressure are measured and recorded. In PACU , the patient's pain intensity is assessed using the Children's Hospital of Eastern Ontario Pain Scale criterion (CHEOPS) and the patient's restlessness and delirium are assessed using The Pediatric Anesthesia Emergence Delirium (PAED) criterion. Also, the length of stay in recovery and other vital signs in recovery will be recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047530N3**
Registration date: **2023-08-25, 1402/06/03**
Registration timing: **retrospective**

Last update: **2023-08-25, 1402/06/03**
Update count: **0**

Registration date

2023-08-25, 1402/06/03

Registrant information

Name

Nima Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of analgesic quality in two methods of bilateral illioinguinal block and caudal block with rupivacaine 0.2% in patients aged 3 to 8 years undergoing bilateral inguinal hernia surgery under general anesthesia in the Childern's Medical Center Hospital, 2021-22

Public title

Comparative study of analgesic quality in two methods of bilateral ilioinguinal block and caudal block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All children from 3 to 8 years old Candidate for bilateral inguinal hernia surgery Under general anesthesia ASA class 1 and 2

Exclusion criteria:

Allergy to local anesthetics Non-Persian speaking patients Sacral infection Coagulation disorders History of seizures Weight more than 20 kg Patients who are being treated with a variety of painkillers and psychiatric medications for any reason

Age

From **3 years** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample will be identified by the randomization (restricted randomization) block method with 6 blocks and using a random number table of Random Allocation Software. The randomization tool is the random sequence generation software version 2.0, it will be available from the following address:(http://random.allocation software, version 2.0). Allocation concealment will be used to execute random sequences on participants. Each random sequence generated will be recorded on a card and the cards will be sealed in opaque envelopes. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface, and finally the letter envelopes are glued and placed in a box respectively. Registration of participants, based on the order of entry of eligible participants into study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

A person who records the severity of pain and the patient does not know the type of block. The double blindness of the study will be done this way.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Etichs Committee of Tehran University Of Medical Sciences

Street address

Qods St, Keshavarz Blv

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2021-03-30, 1400/01/10

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.018

Health conditions studied

1

Description of health condition studied

Bilateral inguinal hernia surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score based on CHEOPS criteria

Timepoint

After the patient enters the recovery ward, the pain score is recorded.

Method of measurement

Children's Hospital of Eastern Ontario Pain Scale

2

Description
PAED Delirium Score
Timepoint
After the patient enters the recovery ward, it is recorded.
Method of measurement
It is obtained based on The Pediatric Anesthesia Emergence Delirium criteria.

Secondary outcomes

1

Description
Recovery time
Timepoint
It is recorded and calculated between the time the patient enters the recovery ward and the patient leaves it.
Method of measurement
It is recorded and calculated between the time the patient enters the recovery ward and the patient leaves it.

2

Description
Need for additional drugs (fentanyl)
Timepoint
Additional dose of fentanyl prescribed after surgical incision or in the recovery ward
Method of measurement
Additional dose of fentanyl prescribed after surgical incision or in the recovery ward in micrograms per kilogram

Intervention groups

1

Description
Intervention group 1: Patient under bilateral ilioinguinal block with rupivacaine 0.2%(manufactured by MOLTENI farmaceutici) under ultrasound guide. After determining the sedation score according to Ramsay criteria, patients are directed to the operating room. After installing standard monitoring equipment and obtaining a peripheral vein, 2 mg/kg sodium thiopental and 1 µg/kg fentanyl m is prescribed. Induction of anesthesia will be done by mapleson and under spontaneous inhalation. sevoflurane 8% and 100% oxgygen will be used in induction. After endotracheal tube insertion, maintenance of anesthesia will be provided by 100% oxygen and isoflurane 2.5%. After induction of anesthesia, heart rate and mean arterial pressure will be measured and recorded.In performing ilio-inguinal block, the child is in the supine position and after prep and drape a short 24G needle will be used. Rupivacaine 0.2% at a dose of 0.1 ml / kg will be used for drug injection. In case of increased heart rate or systolic blood pressure after incision by more than 20% of basal values, fentanyl will be repeated and recorded at a dose of 1 µg /kg. After surgery, the patient's pain intensity will be assessed using the CHEOPS criteria and the delirium score will be assessed by PAED score. In post anesthesia care unit, patients with CHEOPS pain score greater than 10 will be prescribed 1 of fentanyl µg /kg.Rupivacaine is from the Bioindustria L.i.m.s.p.a brand.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients under caudal block with rupivacaine 0.2%. After determining the sedation score according to Ramsay criteria, patients are directed to the operating room. After installing standard monitoring equipment and obtaining a peripheral vein, 2 mg/kg sodium thiopental and 1 µg/kg fentanyl m is prescribed. Induction of anesthesia will be done by mapleson and under spontaneous inhalation. sevoflurane 8% and 100% oxgygen will be used in induction. After endotracheal tube insertion, maintenance of anesthesia will be provided by 100% oxygen and isoflurane 2.5%. After induction of anesthesia, heart rate and mean arterial pressure will be measured and recorded./In performing ilio-inguinal block, the child is in the supine position and after prep and drape a short 24G needle will be used. Rupivacaine 0.2% at a dose of 0.1 ml. In the second group, the child is in a lateral position,The hip will flex and the lower leg will flex. After prep and drape, a short 24G needle was used Rupivacaine 0.2% at a dose of 1 ml / kg will be used.In case of increased heart rate or systolic blood pressure after incision by more than 20% of basal values, fentanyl will be repeated and recorded at a dose of 1 µg /kg. After surgery, the patient's pain intensity will be assessed using the CHEOPS criteria and the delirium score will be assessed by PAED score. In post anesthesia care unit, patients with CHEOPS pain score greater than 10 will be prescribed 1 of fentanyl µg /kg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Center Hospital
Full name of responsible person
Nima Nazari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Nima Nazari
Position
assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The documents will be published in general and in the form of articles.

When the data will become available and for how long

The data will be provided after the publication of the article.

To whom data/document is available

Researchers at academic institutions can generally access study data.

Under which criteria data/document could be used

Researchers are allowed to use the data only by citing the source and referring to the present study.

From where data/document is obtainable

Dr. Nima Nazari/ E-mail: Nima.nazari1366@gmail.com

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

After requesting the person in charge via email, the data will be provided to the researchers.

Comments