Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of ilio-inguinal block iliohypogastric by Landmark method with different doses of ropivacaine on intra and postoperative analgesia in children with inguinal hernia.

Protocol summary

Study aim

Evaluation of the effect of ilio-inguinal block iliohypogastric by Landmark method with different doses of ropivacaine on analgesia during and after surgery in children with inguinal hernia.

Design

Double-blind clinical trial with three parallel groups, randomized by simple randomization method. Sample size in each group 21, total 63 patients.

Settings and conduct

Children 1 to 7 years old who are candidates for unilateral inguinal hernia surgery are admitted to Bahrami Hospital. Conscious consent is obtained from the patient's parents. Patients are randomly assigned to group 1,2 or 3. After induction of anesthesia and vital signs recording , ilioinguinal iliohypogastric block is performed in group 1 with a dose of 0.1, in group 2 with a dose of 0.2, in group 3 with a dose of 0.3 ml / kg ropivacaine 0.2% by Landmark single injection method. Immediately after the surgical incision, the patient's vital signs are re-recorded. After the operation, the severity of the patient's pain is assessed in recovery, and the type and dose of analgesia prescribed are recorded in the recovery and surgery ward. The study is double-blind. The patient and the anesthesiologist and the data analyzer do not know which group the patient is in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 1 to 7 years old with no history of disease and ASA1,2 classification, candidate for unilateral inguinal hernia surgery Conditions of non-entry: dissatisfaction of the patient's parents or legal guardian, allergy to local anesthetics, use of any analgesic.

Intervention groups

The patients are allocated in three groups: 1. Ilioinguinal iliohypogastric block with 0.1 ml/kg ropivacaine 0.2% 2. Ilioinguinal iliohypogastric block with 0.2 ml/kg ropivacaine 0.2% 3. Ilioinguinal iliohypogastric block with 0.3 ml/kg ropivacaine 0.2%

Main outcome variables

Mean arterial pressure; Heart rate; Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201126049500N1**
Registration date: **2022-01-03, 1400/10/13**
Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**
Update count: **0**

Registration date

2022-01-03, 1400/10/13

Registrant information

Name

Bita Malekianzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2285 1471

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

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

Evaluation of the effect of ilio-inguinal block iliohypogastric by Landmark method with different doses of ropivacaine on intra and postoperative analgesia in children with inguinal hernia.

Public title

The effect of ilio-inguinal block of iliohypogastric on analgesia in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 1-7 years old Candidate for unilateral inguinal hernia repair ASA class 1,2 In Bahrami Children hospital

Exclusion criteria:

Dissatisfaction of Parents or legal guardian of the patient Allergy to local anesthetic drugs Peripheral nerve block contraindication Intermittent or continuous consumption of any type of analgesics

Age

From **1 year** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be identified by the Randomization (Restricted Randomization) block method with 6 blocks and using a random number table of Random Allocation Software. Random allocation software will be used to generate random sequences by blocking method. 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 the 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

The study is double-blind. The patient does not know which group he is in. The researcher is an anesthesiologist who performs the nerve block and knows which group the patient is in. The person who monitors the patient and evaluates the outcome is an anesthesia nurse who does not know the patient group. the data analyzer also does not know the patient group. The group number is recorded in the patient information sheet and the type of intervention of each group is not recorded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Children's Medical Center, Tehran University of Medical Sciences

Street address

Tehran, Ghods Town, Iran Sima St., between Flamak and Zarafshan, Headquarters of the Ministry of Health, Treatment and Medical Education

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2021-08-21, 1400/05/30

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.100

Health conditions studied

1

Description of health condition studied

Intraoperative and postoperative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Intraoperative and postoperative in recovery

Method of measurement

Intraoperative: 20% increase in heart rate or mean arterial pressure. Postoperative: flacc pain score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Children 1 to 7 years old undergoing unilateral inguinal hernia surgery, ilio-inguinal iliohypogastric block with a dose of 0.1cc / kg ropivacaine 0.2%
Category
Treatment - Drugs

2

Description
Intervention group: Children 1-7 years old undergoing unilateral inguinal hernia surgery, ilioinguinal iliohypogastric block with 0.2 cc/kg ropivacaine 0.2%
Category
Treatment - Drugs

3

Description
Intervention group: Children 1-7 years old undergoing unilateral inguinal hernia surgery, ilioinguinal iliohypogastric block with 0.3 cc/kg ropivacaine 0.2%
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami Children's Hospital
Full name of responsible person
Bita Malekianzadeh
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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
Bita Malekianzadeh
Position
assistant professor
Latest degree
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Person responsible for updating data

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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