Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Ilioinguinal / Iliohypogastric Block and Caudal Block for Postoperative Analgesia in 3-7 years old Children Undergoing herniorrhaphy surgery

Protocol summary

Study aim
Comparison of Ilioinguinal / Iliohypogastric Block and Caudal Block for Postoperative Analgesia in 3-7 years old Children Undergoing herniorrhaphy surgery

Design
Clinical trial, parallel groups, double-blind, randomized, phase 3 on 72 patients. In order to randomize, the block randomization method will be used.

Settings and conduct
In this research, all children aged 3-7 years with inguinal hernia referred to Hazrat Ali Asghar Hospital in Tehran will be included in the study. Patients based on blocks 8 will be randomly divided into 2 groups. The sample size for each study group will 30 people. Parents of the children (patients), surgeon and data analyst will be blinded. The surgeon and the children's parents will be aware that they will be randomly assigned to one of two treatment groups, but they will not know which treatment will be given in which group. The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the information based on groups 1 and 2 and will not know the type of treatment provided in the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children aged 3-7 years, Suffering from Inguinal hernia, A person with normal health, A person with mild systemic disease, Normal CBC/PT/PTT/INR tests. Exclusion criteria: Sensitivity to the drugs used in this study, Seizure history, Injection site infection, Spine problems, Congenital neurological diseases, Neurological disorders and any type of neuropathy, Body mass index greater than 30, Coagulation disorders.

Intervention groups
Intervention group 1 includes children with inguinal hernia who receive the caudal block intervention of the child in the lateral decubitus position. Intervention group 2 includes children with inguinal hernia who receive ilioinguinal and iliohypogastric block intervention in supine position.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230518058225N3**
Registration date: **2024-06-02, 1403/03/13**
Registration timing: **retrospective**

Last update: **2024-06-02, 1403/03/13**
Update count: **0**

Registration date
2024-06-02, 1403/03/13

Registrant information

Name
Anahita Sadri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8670 2543

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sadri.anahita@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Ilioinguinal / Iliohypogastric Block and Caudal Block for Postoperative Analgesia in 3-7 years old Children Undergoing herniorrhaphy surgery

Public title

Comparison of Ilioinguinal / Iliohypogastric Block and Caudal Block for Postoperative Analgesia Undergoing herniorrhaphy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 3-7 years Suffering from Inguinal hernia A person with normal health A person with mild systemic disease Normal CBC/PT/PTT/INR tests

Exclusion criteria:

Sensitivity to the drugs used in this study Seizure history Injection site infection Spine problems Congenital neurological diseases Neurological disorders and any type of neuropathy Body mass index greater than 30 Coagulation disorders

Age

From **3 years** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into 2 groups. Block randomization method will be used for randomization. The randomization tool will be a table of random numbers. For this purpose, 8 blocks will be formed and in each block 4 people from the intervention group and 4 people will be placed in the control group. A total of 9 blocks will be considered to reach the sample size. In order to hide the random allocation, opaque envelopes sealed with a random sequence will be used. In this method, each of the generated random sequences will be recorded on a card and the cards respectively will be placed in the envelopes. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of participants, based on the order of entry of qualified participants into the study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be blinded to the type of block. The surgeon parents of the children (patients) will be unaware and blinded of the type of block. Children's parents will be aware that they will be randomly assigned to one of the two treatment groups, but will not know which block will be provided in that group. Patients will be assigned to one of two groups using a random number table. The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the data based on groups 1 and 2 and will not know the type of treatment provided in the groups and will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-01-14, 1401/10/24

Ethics committee reference number

IR.IUMS.FMD.REC.1401.507

Health conditions studied

1

Description of health condition studied

hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

pain

Timepoint

Immediately after surgery and 1, 3, 6, 12, and 24 hours after surgery

Method of measurement

The amount of pain immediately after surgery and 1, 3, and 6 hours after surgery is checked by the FLACC pain scale by the doctor, and at 12 and 24 hours by the Wonk Baker questionnaire from the patient's parents.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: To perform the caudal block, the child will be placed in the lateral decubitus position. We will gather his legs in the abdomen and after prep and drape in sterile conditions, we will find the sacral hiatus and under ultrasound guidance, we will insert the needle and the injection will be done. The anesthetic agent will be ropivacaine 0.02% (manufacturer: Varian Pharmed) and its dosage will be 1 cc per kilogram of the patient's body weight.

Category

Treatment - Other

2

Description

Intervention group 2: In ilioinguinal and Iliohypogastric block, at the first, the patient will be in the supine position and after the prep and drape, the line connecting from the ASIS to the navel is divided into 4 equal parts, where the injection site will be ¼ external. Under ultrasound guidance, the local anesthetic ropivacaine 0.02% (manufacturer: Varian Pharmed) will be used at a rate of 1 cc per kilogram of the patient's body weight.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital

Full name of responsible person

Sepide Bayat

Street address

Modares highway (north), Shahid Vahid Dastgardi street

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Sepide Bayat

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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