Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of bilateral ilioinguinal block and rectal acetaminophen on postoperative pain in children undergoing bilateral inguinal hernia surgery

Protocol summary

Study aim
Determining the effect of bilateral ilioinguinal block and rectal acetaminophen on postoperative pain in patients undergoing bilateral inguinal hernia surgery

Design
This double-blind clinical trial, without control group, was randomized with parallel groups. This phase 3 study will be performed on 60 patients who are candidates for surgery.

Settings and conduct
The patient and the person collecting the information do not know the patient grouping. The nurse who records the patient's data during the operation and in the recovery is not at the patient's bedside at the beginning of the operation and does not know what procedure has been performed for the patient's analgesia.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients candidate for inguinal hernia surgery; being at the age of 1 to 6 years; class 1 and 2 anesthesia; with the consent to participate in the project; no history of sensitivity to local anesthetics. Non-inclusion criteria: seizure disorders; patients with mental disorders; gastrointestinal disorders; liver disease; history of seizures; weight more than 20 kg.

Intervention groups
In the intervention group of ilioinguinal block, after induction, the patient underwent ilioinguinal block with rupivacaine 0.2% underwent ultrasound and in the intervention group acetaminophen, rectal paracetamol at a dose of 40 mg / kg will be administered via nelaton. In performing ilioinguinal block, the child is placed in the supine position and after filling and dropping, a short 24G needle is used.

Main outcome variables
Postoperative pain using CHEOPS pain scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220526054992N1**
Registration date: **2022-07-01, 1401/04/10**
Registration timing: **prospective**

Last update: **2022-07-01, 1401/04/10**
Update count: **0**

Registration date
2022-07-01, 1401/04/10

Registrant information

Name
Sajjad Sattari forough

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-06, 1401/04/15

Expected recruitment end date
2022-08-22, 1401/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of bilateral ilioinguinal block and rectal acetaminophen on postoperative pain in children undergoing bilateral inguinal hernia surgery

Public title
The effect of bilateral ilioinguinal anesthesia and acetaminophen on postoperative pain in children undergoing hernia surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients candidate for inguinal hernia surgery Being at the age of 1 to 6 years Class 1 and 2 anesthesia With the consent to participate in the project No history of sensitivity to local anesthetics

Exclusion criteria:
Emergency surgery History of seizures History of allergy to local anesthetics patients with mental disorders gastrointestinal disorders liver disease history of seizures weight more than 20 kg.

Age
From **1 year** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups by 6-block method. Randomization is individual. Random numbers randomization tool.In this method, three allocations to the intervention group and three allocations to the control group are considered.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient and the person collecting the information do not know the patient grouping. The anesthesia nurse, who records the patient's vital signs during the operation and in the recovery, is not at the patient's bedside at the time of the operation and does not know what procedure has been performed to relieve the patient's pain.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Pediatric Medical Center-Tehran University of Medical Sciences

Street address
Central headquarters of Tehran University of Medical Sciences, Ghods street, Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2021-04-15, 1400/01/26

Ethics committee reference number
IR.TUMS.CHMC.REC.1400.032

Health conditions studied

1

Description of health condition studied
Bilateral inguinal hernia surgery

ICD-10 code
K40

ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Pain severity after surgery

Timepoint
Immediately after surgery, 10 minutes and 15 minutes after surgery

Method of measurement
CHEOPS pain score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Patients who undergo bilateral ilioinguinal block before surgery.

Category
Treatment - Surgery

2

Description

Intervention group2: Patients receiving rectal acetaminophen before surgery.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Children's Medical Center

Full name of responsible person
Bita Malekian Zadeh

Street address
No 62, Dr. Mohammad Gharib St., Keshavarz Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ali Akbar Fotuhi

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Vice Chancellor for Research and Technology; sixth floor; Central University Organization; Qods St.; Keshavarz Boulevard, ,

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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
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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
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
Title and more details about the data/document
Not all data can be shared.The results of the analysis based on the main aim of the study and the demographic information of the patients can be shared.
When the data will become available and for how long
2 months after article publication.
To whom data/document is available
Doctors, nurses, clinical researchers
Under which criteria data/document could be used
All analysis are possible on the data.
From where data/document is obtainable
Dr Mirsajjad Sattari forogh
What processes are involved for a request to access data/document
The request will be sent within about 7 days.
Comments