Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of caudal block, intravenous and suppository acetaminophen preemptive analgesia in pediatric inguinal herniotomy

Protocol summary

Study aim
Election the best analgesic method after inguinal hernia repair surgery in children

Design
Interventional study with a control group of parallel, randomized, double-blind Phase 2-3 using the table of random numbers that were performed on 159 patients

Settings and conduct
This double-blind study is performed on 159 children who are candidates for inguinal hernia repair surgery referred to Akbar Hospital in Mashhad. Patients and the analyzers will be blinded. patients will be divided into 3 groups based on analgesia methods.In the intervention groups, one group is given intravenous acetaminophen and the second is given acetaminophen suppository and the control group is subjected to caudal block and the evaluation of analgesia is performed according to the behavioral-FLACC criteria.

Participants/Inclusion and exclusion criteria
Children aged 6 months to 3 years are candidates for inguinal hernia repair surgery, no history of bupivacaine allergy, no local infection in the spine, no pilonidal cyst, no deformity or lesion in the spine, no history of allergies To acetaminophen, no history of liver problems, no history of heart disease

Intervention groups
Candidate children for inguinal hernia repair surgery who underwent general anesthesia by induction with 1 microgram / kg fentanyl, 3 to 5 mg / kg 1% propofol and 0.5 mg / kg atracurium, intubated, in the first intervention group after induction and before surgery, intravenous acetaminophen 12.5 mg / kg and in the second intervention group 15 mg / kg acetaminophen suppository and in the control group 0.25% bupivacaine block dose at a dose of 1 ml / kg is used, after surgery and extubation, the patient is transferred to recovery and the patient's pain is measured according to the behaivorial-FLACC criterion.

Main outcome variables
The amount of analgesia after surgery in recovery according to the behaivorial-FLACC criteria

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120911010811N2**
Registration date: **2022-01-13, 1400/10/23**
Registration timing: **prospective**

Last update: **2022-01-13, 1400/10/23**
Update count: **0**

Registration date
2022-01-13, 1400/10/23

Registrant information

Name
Alireza Sabzevari

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of caudal block, intravenous and suppository acetaminophen preemptive analgesia in pediatric inguinal herniotomy

Public title

Comparison of pediatric intravenous acetaminophen and acetaminophen suppository in hernia surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for inguinal hernia repair surgery Parents' consent based on children's participation in the study Participants are children from 6 months to 3 years

Exclusion criteria:

History of bupivacaine allergy Existence of local infection in the spine Presence of pilonidal cyst History of acetaminophen allergy History of liver problems History of heart disease

Age

From **6 months** old to **3 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at ''www.randomization.com'' website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are not aware of the intervention and the type of treatment received . Also, outcome assessors are unaware of how patients are grouped.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committe of Mashhad university of Medical Sciences

Street address

Ghoreyshi Building, Daneshgah street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-11-30, 1400/09/09

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.613

Health conditions studied

1

Description of health condition studied

Patients with inguinal hernia who are candidates for surgery

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

The amount of analgesia

Timepoint

After inguinal hernia surgery in recovery

Method of measurement

Based on the behaivorial-FLACC criteria

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Children who are candidates for inguinal hernia repair surgery, general anesthesia is performed with 1 mg / kg fentanyl, 3 to 5 mg / kg 1% propofol and 0.5 mg / kg atracurium, the patient is intubated After induction and before surgery, they are placed in a caudal block with 0.25% bupivacaine at a dose of 1 ml / kg. At the end of surgery and extubation, the patient is transferred to recovery and the patient's pain is measured according to the behaivorial-FLACC criterion.

Category
Treatment - Drugs

2

Description
Intervention group: Children who are candidates for inguinal hernia repair surgery: General anesthesia is performed with 1 mg / kg fentanyl, 3 to 5 mg / kg 1% propofol, and 0.5 mg / kg atracurium. The patient is intubated, after induction and before surgery, intravenous acetaminophen is prescribed at 12.5 mg / kg, after the end of surgery and extubation, transferred to recovery and the patient's pain is measured according to the behaivorial-FLACC criterion.
Category
Treatment - Drugs

3

Description
Intervention group: Children who are candidates for inguinal hernia repair surgery: General anesthesia is performed with 1 mg / kg fentanyl, 3 to 5 mg / kg 1% propofol, and 0.5 mg / kg atracurium. The patient is intubated, after induction and before surgery, acetaminophen suppositories are given at a dose of 15 mg / kg, after the end of surgery and extubation, transferred to recovery and the patient's pain is measured according to the behaivorial-FLACC criterion.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Hospital Allergy Clinic
Full name of responsible person
Alireza Sabzevari
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Alireza Sabzevari
Position
Associate professor
Latest degree
Subspecialist
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)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available