

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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 behavioral-FLACC criterion.

##### Main outcome variables

The amount of analgesia after surgery in recovery according to the behavioral-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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1802 2677

##### Email address

sabzevaria@mums.ac.ir

##### 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 committee 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 behavioral-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 behavioral-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 behavioral-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 behavioral-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

**Street address**

Akbar Hospital, television square

**City**

Mashhad

**Province**

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**Postal code**

9176999311

**Phone**

+98 51 3871 3803

**Email**

sabzevaria@mums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghoreishy), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

**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

**Street address**

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## Person responsible for scientific inquiries

### Contact

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Mashhad University of Medical Sciences

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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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