Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the outcomes of inhaled anesthesia in children undergoing inguinal hernia repair surgery under general anesthesia

Protocol summary

Study aim
Comparison of the outcomes of inhaled anesthesia in children undergoing inguinal hernia repair surgery under general anesthesia

Design
A Single-blind, randomized- controlled clinical trial study with parallel groups and phases 3 on 70 patients. Randomization will be done based on block randomization using Random allocation software.

Settings and conduct
In this study, children undergoing inguinal hernia repair surgery in Urmia Motahari Hospital will be included. This study will be a single blind study and the patient will be blind about allocation in the intervention or control group.

Participants/Inclusion and exclusion criteria
In this study, 70 children of 2 to 6 years who are candidates for inguinal hernia repair surgery under general anesthesia will be included. Emergency surgeries, Surgeries longer than an hour, children with an active disease in the respiratory system, A history of sleep apnea, fever-induced seizures, developmental disorders and cardiac disorders will be excluded.

Intervention groups
In the intervention group, inhalation anesthesia will be induced with 8% sevoflurane and oxygen and nitrous oxide before peripheral intravenous insertion. In the control group, peripheral intravenous insertion will be performed without induction of inhalation anesthesia and when the patient is awake. In both groups, anesthesia induction will be performed after peripheral intravenous insertion with propofol 3-5 mg / kg and lidocaine 1 mg / kg and then airway management will be done with laryngeal mask airway (LMA) according to the weight of the child.

Main outcome variables
Frequency and severity of agitation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033992N9**
Registration date: **2022-02-20, 1400/12/01**
Registration timing: **prospective**

Last update: **2022-02-20, 1400/12/01**
Update count: **0**

Registration date
2022-02-20, 1400/12/01

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3222 2010
Email address
karami.t@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2022-06-21, 1401/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the outcomes of inhaled anesthesia in

children undergoing inguinal hernia repair surgery under general anesthesia

Public title
Inhaled anesthesia in children undergoing inguinal hernia repair surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children 2 to 6 years Children undergoing inguinal hernia repair surgery
Exclusion criteria:
Emergency surgeries Surgeries longer than an hour The presence of active disease in the respiratory system A history of sleep apnea Fever-induced seizures Developmental Disorders Cardiac disorders
Age
From **2 years** old to **6 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into intervention and control groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated in intervention or control groups based on generated numbers.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be conducted as single blind clinical trial study. The patient will be blind that inhalation anesthesia will be induced before peripheral venous route insertion or not.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2021-11-10, 1400/08/19
Ethics committee reference number
IR.UMSU.REC.1400.346

Health conditions studied

1

Description of health condition studied
Inguinal hernia repair
ICD-10 code
K40
ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Agitation
Timepoint
Every 10 minutes to 30 minutes after surgery
Method of measurement
Confusion or disturbance in the patient's awareness to the place and time

2

Description
Agitation severity
Timepoint
Every 10 minutes to 30 minutes after surgery
Method of measurement
Scores based on Pediatric Anesthesia Emergence Delirium(PAED) Scale

Secondary outcomes

1

Description
Nausea and vomiting
Timepoint
Every 10 minutes to 30 minutes after surgery
Method of measurement
clinical examination

2

Description
Time to wake up
Timepoint
Duration until waking up
Method of measurement
Minutes

Intervention groups

1

Description
Intervention group: inhalation anesthesia will be induced with 8% sevoflurane and oxygen and nitrous oxide before peripheral intravenous insertion. In addition routine anesthesia induction will be performed after peripheral intravenous insertion with propofol 3-5 mg / kg and lidocaine 1 mg / kg and then airway management will be done with laryngeal mask airway (LMA) according to the weight of the child.
Category
Treatment - Other

2

Description
Control group: peripheral intravenous insertion will be performed without induction of inhalation anesthesia and when the patient is awake. In addition routine anesthesia induction will be performed after peripheral intravenous insertion with propofol 3-5 mg / kg and lidocaine 1 mg / kg and then airway management will be done with laryngeal mask airway (LMA) according to the weight of the child.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Shahid Motahhari hospital
Full name of responsible person
Dr. Tohid Karami
Street address
Kashani Ave.,Shahid Motahhari hospital., Urmia., Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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gholizadeh.s@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Tohid Karami
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Kashani Ave., Shahi Motahhari hospital., Urmia., Iran.
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of patient information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data will not be published individually and the results will be available as published article.
When the data will become available and for how long
After publishing the article
To whom data/document is available
Researchers
Under which criteria data/document could be used
Not applicable
From where data/document is obtainable
Email address of corresponding author
What processes are involved for a request to access data/document
Email address: karami.t@umsu.ac.ir
Comments