

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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Urmia University of Medical Sciences, Resalat street, Jihad 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

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Kashani Ave., Shahi Motahhari hospital., Urmia., Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Subspecialist
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Person responsible for updating data

Contact

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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