

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of emergence agitation frequency in pediatrics candidate for elective hernioraphy under general anesthesia with Sevoflurane and Isoflurane

Protocol summary

Study aim

Comparison of emergence agitation frequency in pediatrics candidate for elective hernioraphy under general anesthesia with Sevoflurane and Isoflurane

Design

In this double-blind clinical trial parallel study (phase 3), children 2 to 6 years old candidate for elective hernioraphy were included. Patients were randomly divided into two groups using a table of random numbers. Maintenance of anesthesia was in a group with 1.2 MAC of Sevoflurane (n=25) and in the other group with 1.2 MAC of Isoflurane (n = 25) with nitrous oxide and oxygen in both groups.

Settings and conduct

This double-blind clinical trial study aimed to comparison of emergence agitation frequency in pediatrics who candidate for elective hernioraphy under general anesthesia with Sevoflurane and Isoflurane. pediatrics candidate for elective hernioraphy in Urmia Shahid Motahhari hospital were enrolled. the patient, the researcher and the person who assessed the outcomes were blind.

Participants/Inclusion and exclusion criteria

Children aged 2 to 6 years who were candidates for hernioraphy surgery under general anesthesia were included in this study. Children with a history of mental and behavioral disorders since birth, emergency surgeries, having a active disease in the respiratory system, a history of sleep apnea, a history of febrile seizures, developmental disorders and heart disorders were excluded from the study.

Intervention groups

Maintenance of anesthesia was in a group with 1.2 MAC of Sevoflurane (n=25) and in the other group with 1.2 MAC of Isoflurane (n = 25) with nitrous oxide and oxygen in both groups.

Main outcome variables

emergence agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170515033986N2**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **retrospective**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

Registration date

2020-11-23, 1399/09/03

Registrant information

Name

Nazli Karami

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-02-19, 1397/11/30
Trial completion date
2019-02-19, 1397/11/30

Scientific title
Comparison of emergence agitation frequency in pediatrics candidate for elective hernioraphy under general anesthesia with Sevoflurane and Isoflurane

Public title
The effect of Sevoflurane and Isoflurane on emergence agitation of children under hernioraphy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children 2 to 6 years Pediatrics candidate for inguinal hernioraphy under general anesthesia
Exclusion criteria:
History of mental and behavioral disorders since birth
Having an active disease in the respiratory system
History of sleep apnea Developmental disorders and cardiac disorders
History of febrile seizures

Age
From **2 years** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly divided into two groups using a table of random numbers. firstly a number was randomly selected from the table and moving from top to bottom in the table continued. the numbers between 01 to 25 were assigned to the Sevoflurane group and the numbers between 26 to 50 were assigned to the Isoflurane group. according to the determined sample size (50 patient), as regards the number of last patient was 50 so that the numbers greater than 50 were ignored.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient, the researcher and a person who assessed the outcomes were blind to the belonging of the patient to the Isoflurane or Sevoflurane group.in the operating room the anesthetics of Sevoflurane and Isoflurane were covered with a cloth during surgery so that the type of prescribed anesthetic could not be detected during the surgery.Therefore, the researcher did not know about the type of anesthetic prescribed to the patient. The person who assessed the outcomes was an anesthesia

technician other than researcher that did not know the type of prescribed anesthetics for each patient.

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; Jihad Blvd; Urmia; Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734

Approval date
2018-09-05, 1397/06/14

Ethics committee reference number
IR.UMSU.REC.1397.200

Health conditions studied

1

Description of health condition studied
Emergence agitation
ICD-10 code
R45.1
ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
Emergence agitation
Timepoint
10 minutes, 20 minutes and 30 minutes after surgery
Method of measurement
Pediatric Anesthesia Emergence Delirium (PAED) Scale.

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: group 1: Maintenance anesthesia with 1.2 MAC of Sevoflurane and nitrous oxide and oxygen.

Category

Treatment - Other

2

Description

Intervention group: group 2: Maintenance anesthesia with 1.2 MAC of Isoflurane and nitrous oxide and oxygen.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Shahid Motahhari Hospital

Full name of responsible person

Dr. Nazli Karami

Street address

Shahid Motahhari hospital; Kashani street; Urmia; Iran.

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karami.n@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences; Resalat street; Jihad Blvd; Urmia; Iran.

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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

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. Nazli Karami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

report the results as published article

When the data will become available and for how long

after publishing of article

To whom data/document is available

Researchers

Under which criteria data/document could be used

as published article

From where data/document is obtainable

corresponding author

What processes are involved for a request to access data/document

If necessary through e-mail addresses of corresponding author in the published article can have access to the data.

Comments