Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 studty (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 was 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 was 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 Siences

Country

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+98 44 3346 9932

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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 Isofuran 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; Jahad 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
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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 updating data

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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