Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of anesthesia maintenance with Isoflurane or Sevoflurane with Laryngeal mask during minor surgery in newborns and infants

Protocol summary

Study aim
Evaluation of hemodynamic changes between isoflurane and sevoflurane anesthesia groups in infants under one year of age

Design
A clinical trial with intervention and control groups, with parallel groups, double-blind, randomized, a sample of 68 patients, creating random numbers using a calculator.

Settings and conduct
All infants who are candidates for limited surgery at Tabriz Children's Hospital will be included in this study. Patients are randomly assigned to intervention and control groups. In this study, the patient (who is an infant) and the anesthesia nurse and one of the anesthesiologists are blinded to the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Infants under one year of age are candidates for elective surgery in less than one hour. Exclusion criteria: Requires endotracheal intubation for surgery; Underlying cardiovascular disease.

Intervention groups
Intervention group: 34 infants are placed under anesthesia with 1.5% isoflurane in a mixture of 50% oxygen and 50% N2O, and hemodynamic changes are carefully monitored. Control group: 34 infants are anesthetized with 2.5% sevoflurane in a mixture of 50% O2 and 50% N2O, and hemodynamic changes are carefully monitored.

Main outcome variables
Systolic and diastolic blood pressure, Heart rate, Saturation of peripheral oxygen, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100527004041N23**
Registration date: **2021-07-25, 1400/05/03**
Registration timing: **prospective**

Last update: **2021-07-25, 1400/05/03**
Update count: **0**

Registration date
2021-07-25, 1400/05/03

Registrant information

Name
Mahin Seyedhejazi

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-04-21, 1401/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of anesthesia maintenance with Isoflurane or Sevoflurane with Laryngeal mask during minor surgery in newborns and infants

Public title
Comparison of maintenance anesthesia with isoflurane or

sevoflurane in neonates and infants during surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Infants under one year of age candidates for elective surgery less than one hour

Exclusion criteria:

Requires endotracheal intubation for surgery Underlying cardiovascular disease

Age

From **1 day** old to **1 year** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a random number table that includes numbers from 1 to 68. With each refers until the 68th patient, we create a number using the random selection system of the calculator (each number has a chance to happen only once). According to the created number, each patient is in one of the two intervention groups: 1 anesthesia with isoflurane (34 people) and the control group with anesthesia with sevoflurane (34 people). If the random number is odd, the patient places in the intervention group. If the number is even, the patient is allocated into the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, 2 anesthesiologists will participate. Anesthesiologist No. 1, who will induce anesthesia in both groups, and be aware of the allocation of each patient (codes and type of anesthesia), will leave the operation room. The anesthesiologist No. 2 and the anesthesia nurse, responsible for collecting information and variables, are unaware of the type of prescription medications. They will fill the checklists during the surgery and in the recovery section. Patients (infants) and their parents are also unaware of the allocation. But the baby's parents are fully aware of the used medications in the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.TBZMED.REC.1400.239

Health conditions studied

1

Description of health condition studied

Comparison of hemodynamic changes after anesthesia with sevoflurane and isoflurane.

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

Method of measurement

Mercury barometer

2

Description

Heart rate

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

Method of measurement

Counting in each minutes

3

Description

Saturation of peripheral oxygen

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

Method of measurement

Via the Pulse Oximeter

4

Description

nausea and vomiting

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 34 infants are placed under anesthesia with 1.5% isoflurane in a mixture of 50% oxygen and 50% N2O, and hemodynamic changes are carefully monitored.

Category

Diagnosis

2

Description

Control group: 34 infants are anesthetized with 2.5% sevoflurane in a mixture of 50% O2 and 50% N2O, and hemodynamic changes are carefully monitored.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Tabriz Children Hospital

Full name of responsible person

Dr. Mahin Seyedhejazi

Street address

Tabriz pediatric hospital,sheshgelan street,Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mahin Seyedhejazi

Position

Anesthesiologist/Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data can be shared after making peoples unrecognizable.
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
Documents will be available for people working in academic institutions and also people working in businesses.
Under which criteria data/document could be used
There will be no specific limitations to the utilization of the data
From where data/document is obtainable
Dr .Mahin Seyedhejazi, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran ,Phone+98 413 3341994, Fax+98 41 33341994 , seidhejazie@tbzmed.ac.ir
What processes are involved for a request to access data/document
Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.
Comments