

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of induction with incremental versus fixed high concentration of sevoflurane in children

Protocol summary

Study aim

Comparison of induction with incremental versus fixed high concentration of sevoflurane in children.

Design

Double-blind clinical trial, randomized, control group, with parallel groups

Settings and conduct

This study will be conducted in the operating room of Tabriz Children's Hospital. Data carers and data analyst will be blinded. Patients will be randomly divided into two groups and intervention will be performed as follows. The anesthetic system will be filled in with a 30% oxygen mixture and 70% N₂O after closing the pop-off and end of the system. Then with mask filled with anesthetic gases, an inhalation with a mask begins. After two minutes of Sevoflurane, 8% is added to the anesthetic gases.

Participants/Inclusion and exclusion criteria

Entry requirements: ASA Class I and II Conditions of Exit
Study: Dissatisfied to participate in the study

Intervention groups

Intervention group: Anesthesia induction with 30% oxygen mixture and 70% N₂O will be performed and after two minutes, sevoflurane 8% will be added to the anesthetic gases. control group: The anesthetic induction will begin with oxygen and N₂O, as in the first group, and after 2 minutes, 1% sevoflurane will be added and 1% after each 2-3 breaths of sevoflurane will be added.

Main outcome variables

Duration of induction of anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N3**

Registration date: **2019-05-15, 1398/02/25**

Registration timing: **prospective**

Last update: **2019-05-15, 1398/02/25**

Update count: **0**

Registration date

2019-05-15, 1398/02/25

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of induction with incremental versus fixed high concentration of sevoflurane in children

Public title

Induction of general anesthesia in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I-II classes

Exclusion criteria:
Dissatisfied to participate in the study

Age
From **2 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups using the random numbers table.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher and the individual statistical analyst will not be aware of the type of group intervention during the intervention, and will only receive the information completed by the researcher's assistance outside the operating room.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Childrens Hospital, Sheshgelan Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Approval date
2019-03-11, 1397/12/20

Ethics committee reference number
IR.TBZMED.REC.1397.1093

Health conditions studied

1

Description of health condition studied

Depth of anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of induction of anesthesia

Timepoint

Every five minutes

Method of measurement

Researcher made checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Anesthesia induction is started with oxygen and N2O, and after two minutes, Sevoflurane is added at a concentration of 8% until the eye-lash Reflex is removed. After the disappearance of the eyelid reflex, the concentration of anesthetic gas will be changed to 50% oxygen and 50% N2O and 3% Sevoflurane and continue to increase the anesthetic depth of the anesthetic gas for the insertion of the intravenous catheter at the same concentration.

Category

Prevention

2

Description

Control group: Anesthesia induction is started with oxygen and N2O, and after 2 minutes, 1% of Sevoflurane is added and after 1 to 2 breaths, Sevoflurane is added until the eye-lash refractory. After elimination of the eyelid reflex Concentrate anesthetic gas to 50% oxygen and 50% N2O 3% Sevoflurane and continue to increase the depth of anesthesia for insertion of an IV catheter into anesthetic gases at the same concentration.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Childrens Hospital

Full name of responsible person

Mahin SEyed Hejazi

Street address

Sheshgelan Ave, Childrens Hospital

City

Tabriz

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5981764863

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Fax**Email**

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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Ajouyban@hotmail.com

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

Mahin Seyed Hejazi

Position

Associate Professor

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mahin Seyed Hejazi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available