Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Mahin Seyed Hejazi
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Associate Professor
Latest degree
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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