

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of Fresh Gas Flow on the speed of inhalational induction with sevoflurane in children

Protocol summary

Study aim

Studying the speed of induction with inhalation anesthesia using sevoflurane with constant percentage but with different amounts of Fresh Gas Flow in children

Design

A randomized, phase 3, single blind, clinical trial with three intervention groups will be performed using the Power and Sample Size software and considering the alpha error of 5% and the study power of 90%, the calculated sample size for each group is 17. It will be the case that with an additional safety margin of about 15%, a total of 60 patients (20 in each group) will be studied. The rand function of Excel software was used for randomization.

Settings and conduct

60 children aged 6 months to 8 years and with ASA class I and II whom are candidates for elective orthopedic surgeries will be studied in 3 separate groups at Shohada Hospital in Tabriz. After obtaining informed consent from the parents, they will be randomly placed in three separate groups A, B, and C, which are defined based on the amount of FGF during inhalation induction. Calibrated will be done. Only the patient is blind to the medicine received.

Participants/Inclusion and exclusion criteria

Age between 6 month to 8 years old Candidate for elective orthopedic surgery Having an indication for inhalational induction of anesthesia

Intervention groups

Three groups named A, B and C will be arranged based on the amount of fresh gas flow, Consisting of group A = 2 L/min, group B = 4 L/min, group C = 6 L/min. In all three groups, a fixed output percentage of sevoflurane (8%) will be used for induction of anesthesia.

Main outcome variables

Duration of reaching to the Bispectral Index between 60 to 70 Duration till the loss of response to squeezing the trapezius muscle Duration until Laryngeal Mask Airway installation Existence of reaction to Laryngeal Mask

Airway installation Heart rate Blood pressure Oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220301054154N1**

Registration date: **2022-09-20, 1401/06/29**

Registration timing: **retrospective**

Last update: **2022-09-20, 1401/06/29**

Update count: **0**

Registration date

2022-09-20, 1401/06/29

Registrant information

Name

Elham sadat Tabatabaeenezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 4813

Email address

tabatabaeenezhadelham@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Fresh Gas Flow on the speed of inhalational induction with sevoflurane in children

Public title

The effect of Fresh Gas Flow on the speed of inhalational induction with sevoflurane in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 6 month to 8 years candidate for elective orthopedic surgery having an indication for inhalational induction of anesthesia

Exclusion criteria:

lack of parental consent emergent surgery not being NPO significant cardiovascular disease pulmonary disease neurologic disorder prediction of a difficult airway or IV line facial or airway anomalies history of malignant hyperthermia in the patient or their family acute respiratory infection in the past week history of GERD

Age

From **6 months** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Through a randomly generated computer-generated list, individuals will be assigned to three intervention groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research only the patient is unaware of the fresh gas flow.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National committee for ethics in biomedical research

(Tabriz university of medical sciences)

Street address

Faculty of medicine, Tabriz university of medical sciences, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-09-28, 1400/07/06

Ethics committee reference number

IR.TBZMED.REC.1400.557

Health conditions studied**1****Description of health condition studied**

The effect of Fresh Gas Flow on the speed of inhalational induction with sevoflurane

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes**1****Description**

duration of reaching to the Bispectral Index between 60 to 70

Timepoint

from the start point of induction untill reaching to the Bispectral Index between 60 to 70

Method of measurement

using the bispectral index monitor based on electroencephalogram waves during anesthesia, measuring time in seconds

2**Description**

duration till the loss of response to squeezing the trapezius muscle

Timepoint

from the start point of induction to complete loss of response to squeezing the trapezius muscle

Method of measurement

measuring time in seconds, by physical examination and observing patient's reaction

3**Description**

Duration until Laryngeal Mask Airway installation

Timepoint

from the start point of induction until Laryngeal Mask Airway installation

Method of measurement

measuring time in seconds

4

Description

Existence of reaction to Laryngeal Mask Airway installation

Timepoint

During Laryngeal Mask Airway insertion

Method of measurement

Observing the patient's reaction

5

Description

heart rate

Timepoint

Immediately before induction and one minute after induction and during operation of the Laryngeal Mask Airway

Method of measurement

Beat Per minute using a non-invasive heart rate monitor

6

Description

Blood pressure

Timepoint

Immediately before induction and one minute after induction and during operation of the Laryngeal Mask Airway

Method of measurement

In millimeters of mercury using a non-invasive method of measuring blood pressure by monitoring device.

7

Description

Oxygen saturation

Timepoint

Immediately before induction and one minute after induction and during operation of the Laryngeal Mask Airway

Method of measurement

in percent, by pulse oximeter device

Secondary outcomes

1

Description

Breath holding

Timepoint

From the beginning of induction to the end of anesthesia

Method of measurement

observation

2

Description

coughing

Timepoint

From the beginning of induction to the end of anesthesia

Method of measurement

observation

3

Description

bradycardia

Timepoint

From the beginning of induction to the end of anesthesia

Method of measurement

Beat Per minute using a non-invasive heart rate monitor

4

Description

low Blood pressure

Timepoint

From the beginning of induction to the end of anesthesia

Method of measurement

In millimeters of mercury using a non-invasive method of measuring blood pressure by device.

5

Description

laryngospasm

Timepoint

From the beginning of induction to the end of anesthesia

Method of measurement

observation

6

Description

vomiting

Timepoint

From the beginning of induction to the end of anesthesia

Method of measurement

observation

Intervention groups

1

Description

Intervention group: A with FGF of 2 L/min

Category

Treatment - Drugs

2

Description

Intervention group: B with FGF of 4 L/min

Category

Treatment - Devices

3

Description

Intervention group: C with FGF of 6 L/min

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada hospital

Full name of responsible person

Dr. Masoud Parish

Street address

Shohada Hospital, Golshahr street, El Goli Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5167846171

Phone

+98 41 3389 3336

Email

parishm@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

Street address

Research Vice-Chancellor, Third floor, the
headquarter building No 2, Tabriz University of
Medical Sciences, Golgasht street, Tabriz

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5165665931

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Email

research-vice@tbzmed.ac.ir

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

Masoud Parish

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shohada Hospital, Gholshahr Avenue, Yaghchian
street

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parishm@tbzmed.ac.ir

Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Masoud Parish

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

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Email

parishm@tbzmed.ac.ir

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

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academia and people in industry.

Under which criteria data/document could be used

There are no specific restrictions on the use of data or documentation.

From where data/document is obtainable

Dr .Masoud Parish Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran oudparish@yahoo.com Phone: +98 413 3341994

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

Applicants will have access to the data from the present study by sending an email to the responsible author for a maximum of one week.

Comments