Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing of recovery in total intravenous anesthesia(TIVA) with inhalation anaesthetic (sevoflurane) in children between 2-10 years old

Protocol summary

Study aim
Comparing of recovery in total intravenous anesthesia(TIVA) with inhalation anaesthetic (sevoflurane) in children

Design
Clinical trial with intervention groups, with parallel groups, double-blinded, randomized

Settings and conduct
In this double-blind randomized clinical trial, 80 patients from Tabriz children hospital with American society of Anesthesiologists (ASA) status I and II, undergoing elective outpatient operation under an hour(from March 2019 to August 2019) will be enrolled. The patients will be randomized in one of the two groups of total intravenous(T) and sevoflurane anesthesia.

Participants/Inclusion and exclusion criteria
inclusion criteria: children between 2-10 years old, Indicative Outpatient Surgery, Admitted to the Children's Hospital, Parental informed consent for the study, ASA class I and II Exclusion criteria:Sensitivity to any of the drugs used in the study, Children with underlying illnesses such as diabetes; asthma; congenital heart disease and ...

Intervention groups
Intervention group1:" Total Intravenous Anesthesia.received midazolam (0/03-0/05 mg/kg), Fentanyl 1µg/kg as a premedication. Anesthesia induction will be with Lidocaine 1mg / kg and propofol 3-5 mg / kg , Then LMA will be inserted with the right size. . Anesthesia maintenance with total Intravenous Anesthesia will be by infusion of propofol 100-200 mcg / kg and remifentanil 0.1 mcg / kg, 50% N2O, 50% O2 "Intervention group2:" Inhalation anesthesia with sevoflurane. received midazolam (0/03-0/05 mg/kg), Fentanyl 1µg/kg as a premedication. Anesthesia induction will be with Sevoflurane 8% , 50% N2O, 50% O2 .LMA will be inserted with the right size. Anesthesia maintenance will be by Sevoflurane inhalation 2-3% , 50% N2O, 50% O2

Main outcome variables
duration of stay in recovery, Blood pressure, Heart rate, pain, nausea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190114042358N1**
Registration date: **2019-02-25, 1397/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-25, 1397/12/06**
Update count: **0**

Registration date
2019-02-25, 1397/12/06

Registrant information

Name
Daryoush Sheikhzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3526 2257

Email address
dr.d.sheik@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-08-21, 1398/05/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of recovery in total intravenous anesthesia(TIVA) with inhalation anaesthetic (sevoflurane) in children between 2-10 years old

Public title

Comparing of recovery in total intravenous anesthesia(TIVA) with inhalation anaesthetic (sevoflurane) in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

children between 2-10 years old Indicative Outpatient Surgery Admitted to the Children's Hospital Parental informed consent for the study ASA class I and II

Exclusion criteria:

Sensitivity to any of the drugs used in the study Children with underlying illnesses such as diabetes; asthma; congenital heart disease and ...

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Random method: Block, Random unit: individual, Random Tool: Random Block 4. for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, BAAB. For selecting each blocks, dice drooped and the block number will be selected. this procedure continued to completed the allocation and reached to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blinded study and Researcher and patients are kept unaware of intervention in each group and In order to allocation concealment, the type of intervention will be written on paper and placed in numbered, matte and packed envelopes.The envelopes will be opened in the order of participation of the participants and the type of group will be determined.

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

Tabriz University of Medical Science , Gholghasht street , Azadi street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2019-01-13, 1397/10/23

Ethics committee reference number

IR.TBZMED.REC.1397.834

Health conditions studied

1

Description of health condition studied

inhalation anesthesia

ICD-10 code

Y48.0

ICD-10 code description

Inhaled anaesthetics

2

Description of health condition studied

Intravenous Anesthesia

ICD-10 code

Y48.1

ICD-10 code description

Parenteral anaesthetics

Primary outcomes

1

Description

Duration of stay in recovery

Timepoint

After entering till release from recovery

Method of measurement

According to Alderet Score

2

Description

Blood pressure

Timepoint

Every 5 minutes till release from recovery

Method of measurement

Monitor

3

Description

Heart rate

Timepoint

Every 5 minutes till release from recovery

Method of measurement

ECG device

4

Description

Nausea

Timepoint

After entering till release from recovery

Method of measurement

Visual Analogue Scale

5

Description

pain

Timepoint

After entering till release from recovery

Method of measurement

wong - baker pain scale

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" Total Intravenous Anesthesia.received midazolam (0/03-0/05 mg/kg), Fentanyl 1µg/kg as a premedication. Anesthesia induction will be with Lidocaine 1mg / kg and propofol 3-5 mg / kg , Then LMA will be inserted with the right size. Anesthesia maintenance with total Intravenous Anesthesia is done by infusion of propofol 100-200 mcg / kg and remifentanil 0.1 mcg / kg, 50% N2O, 50% O2

Category

Treatment - Drugs

2

Description

"Intervention group2:" Inhalation anesthesia with sevoflurane. received midazolam (0/03-0/05 mg/kg), Fentanyl 1µg/kg as a premedication. . Anesthesia induction will be with Sevoflurane 8% , 50% N2O, 50% O2 .LMA will be inserted with the right size. Anesthesia maintenance will be with Sevoflurane inhalation 2-3% , 50% N2O, 50% O2

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children's Hospital

Full name of responsible person

Daryoush Sheikhzadeh

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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
Daryoush Sheikhzadeh
Position
Assistant 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
No - There is not 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
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
Title and more details about the data/document
A portion of the data that represents the final outcome
When the data will become available and for how long
Access will be 6 months after the results are printed.
To whom data/document is available
All Physicians and residents of the department of Anesthesia
Under which criteria data/document could be used
After obtaining permission from the deputy research of group
From where data/document is obtainable

Person responsible for scientific accountability of study

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

First approved by the Research Vice-President

Comments