Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the effect of using three anesthesia methods with propofol, sevoflurane, and dexmedetomidine on respiratory complications in children aged 1 month to 3 years undergoing fiber optic bronchoscopy.

Protocol summary

Study aim
Determining and comparing the use of three anesthesia methods with propofol, sevoflurane, and dexmedetomidine on respiratory complications in children aged 1 month to 3 years undergoing fiber optic bronchoscopy

Design
A randomized, double-blinding clinical trial, with the parallel groups, Phase 2 on 120 patients

Settings and conduct
In this double-blind randomized clinical trial study, 120 eligible children referred to Imam Hossein Hospital in Isfahan will be included in the study and will be randomly divided into three groups. Patients are given propofol, sevoflurane, and dexmedetomidine, respectively. The intervention will be carried out in such a way that the patient, the researcher and the statistical analyst will not have any knowledge of the type of intervention. Then the hemodynamic parameters and complications of the patients will be evaluated and compared among the three groups.

Participants/Inclusion and exclusion criteria
The criteria for entering the study include children from 1 month to 3 years old, candidates for diagnostic fiberoptic bronchoscopy, with ASA equal to I or II, and consent to participate in the study. Exclusion criteria include comorbidity and bronchoscopy therapy.

Intervention groups
The first intervention group: patients in this group are under anesthesia with inhaled sevoflurane. The second intervention group: patients in this group underwent induction of anesthesia with 1 mg/kg propofol and then they were given propofol at a dose of 0.6 mg/kg/h as anesthesia maintenance. The third intervention group: patients in this group underwent induction of anesthesia with dexmedetomidine at a dose of 1µg/kg, and dexmedetomidine at a dose of 1µg/kg/h is used as anesthesia maintenance.

Main outcome variables
Blood pressure; Heart beat; Oxygen saturation percentage (SPO2); Respiratory complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N69**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **prospective**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**

Registration date
2023-06-18, 1402/03/28

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 0000 0000

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-21, 1402/04/30

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of using three anesthesia methods with propofol, sevoflurane, and dexmedetomidine on respiratory complications in children aged 1 month to 3 years undergoing fiber optic bronchoscopy.

Public title

The effect of using three anesthesia methods with propofol, sevoflurane, and dexmedetomidine on respiratory complications in children aged 1 month to 3 years undergoing fiber optic bronchoscopy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children from 1 month to 3 years Candidate for diagnostic fiber optic bronchoscopy ASA equal to I or II Consent to participate in the study

Exclusion criteria:

Having comorbidity (Such as heart disease, metabolic disease, history of seizures, high ICP, porphyria, thyroid disease) Therapeutic bronchoscopy (presence of foreign body, etc.)

Age

From **1 month** old to **3 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 120 eligible children are randomly selected. For this, the letter A is written on 40 sheets, the letter B is written on 40 sheets, the letter C is written on 40 sheets, and each of them is placed in an envelope. Each Parents of patients is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to achieve the triple-blind study, three drugs, propofol, sevoflurane, and dexmedetomidine will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A, B, and C. And is given daily to the anesthesiologist (researcher). Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfehan

Postal code

8179964167

Approval date

2023-04-15, 1402/01/26

Ethics committee reference number

IR.MUI.MED.REC.1402.043

Health conditions studied

1

Description of health condition studied

Fiber optic bronchoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood pressure

Timepoint

upon entering the operating room, and every 5 minutes during bronchoscopy and every 15 minutes during recovery until the end of recovery

Method of measurement

Monitoring device

2

Description

Heart beat

Timepoint

upon entering the operating room, and every 5 minutes during bronchoscopy and every 15 minutes during recovery until the end of recovery

Method of measurement

Monitoring device

3

Description

Oxygen saturation (SpO2)

Timepoint

upon entering the operating room, and every 5 minutes during bronchoscopy and every 15 minutes during recovery until the end of recovery

Method of measurement

Monitoring device

4

Description

Respiratory complications

Timepoint

During bronchoscopy

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: patients in this group are under anesthesia with inhaled sevoflurane. In this way, they are first induced with 2 MAC and after deepening the anesthesia, they receive 3.3% sevoflurane(equivalent to 1 MAC) as an anesthesia maintenance. When the patient's sedation score reaches 3, the bronchoscopist starts the procedure.

Category

Treatment - Drugs

2

Description

Second intervention group: patients in this group underwent induction of anesthesia with 1 mg/kg propofol and then they were given propofol at a dose of 0.6 mg/kg/h as anesthesia maintenance. When the patient's sedation score reaches 3, the bronchoscopist starts the procedure.

Category

Treatment - Drugs

3

Description

Third intervention group: patients in this group underwent induction of anesthesia with dexmedetomidine at a dose of 1µg/kg, and dexmedetomidine at a dose of 1µg/kg/h is used as anesthesia maintenance. When the patient's sedation score reaches 3, the bronchoscopist starts the procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital in Isfahan

Full name of responsible person

Amir Shafa

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Imam Khomeini street

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Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
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Position
Associate Professor
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available