

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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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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
 Isfahan
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 1 µg/kg, and dexmedetomidine at a dose of 1 µg/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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Street address
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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Amir Shafa

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

Amir Shafa

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Department of Anesthesiology; Imam Hossein Hospital; Imam Khomeini street

City**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