

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the incidence of rigid bronchoscopy complications with three anesthesia methods of spontaneous ventilation, controlled ventilation using Atracurium and controlled ventilation using Rocuronium in children with foreign body aspiration

Protocol summary

Study aim

Comparison of the incidence of rigid bronchoscopy complications with three anesthesia methods of spontaneous ventilation, controlled ventilation using Atracurium and controlled ventilation using Rocuronium in children with foreign body aspiration

Design

A parallel-group, double-blind, randomized (permutation blocks), phase 3 clinical trial on 63 children with foreign body aspiration, using the website www.sealedenvelope.com for randomization.

Settings and conduct

This study is conducted in Ali Asghar Children's Hospital. Children with foreign body aspiration are randomly assigned to 3 groups. The first group is removed by the method of maintaining spontaneous breathing, the second group by the method of controlled breathing with Atracurium, and the third group by the method of controlled breathing with Aocuronium. In this study, children do not know the type of treatment method.

Participants/Inclusion and exclusion criteria

Parents' consent to participate in the study after bronchoscopy, Age range 1 to 6 years, Children with foreign body aspiration , if the foreign body is not in the upper part of the main airway and in the larynx or hypopharynx, They should be in ASA class 1 and 2

Intervention groups

After induction of inhalation anesthesia with Sevoflurane in all three groups, in group P, Propofol infusion is started at a dose of 80-100 mcg/kg/min, and the relaxant drug is not injected, and after 3 minutes, hard bronchoscopy is started. to be In group R, 0.3 mg/kg of rocuronium is injected and bronchoscopy is started after 3 minutes, In group A, 0.3 mg/kg of Atracurium is injected, and after 3 minutes, bronchoscopy is started. Propofol infusion is not performed in group R and A.

Main outcome variables

Laryngospasm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230506058100N1**

Registration date: **2023-06-14, 1402/03/24**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-14, 1402/03/24**

Update count: **0**

Registration date

2023-06-14, 1402/03/24

Registrant information

Name

Tahereh Chavoshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

chavoshi.t@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the incidence of rigid bronchoscopy complications with three anesthesia methods of spontaneous ventilation, controlled ventilation using Atracurium and controlled ventilation using Rocuronium in children with foreign body aspiration

Public title
The incidence of rigid bronchoscopy complications in children with foreign body aspiration

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Parents' consent to participate in the study after bronchoscopy Age range 1 to 6 years Children with foreign body aspiration , if the foreign body is not in the upper part of the main airway and in the larynx or hypopharynx They should be in ASA class 1 and 2
Exclusion criteria:
Emergency cases Children with asthma and irritable airways Airway anomaly Drug allergy to any of the drugs used Neurological disorders and seizures kidney disease Cardiovascular disease Neuromuscular disorder Metabolic disorder

Age
From **1 year** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **63**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization method with block size 4 is used. The website <https://www.sealedenvelope.com> is used to generate random sequences. Each of the randomly generated sequences contains a unique code for concealment. The randomized list is provided to one of the operating room personnel and he tells the researcher which group each patient should be placed in. Then the patients are assigned to 3 groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Patient blinding: Patients are unaware of the treatment process due to their condition and they are unconscious. Care giver blinding: in 3 groups, Propofol will be drawn into a syringe and connected to the infusion pump, but it will be injected only in the Propofol group. Propofol is

distilled water, and in Rocuronium and Atracurium groups, the dose of the corresponding drug is the same, so it is not possible for the assistant data recorder and the person performing the bronchoscopy to distinguish the Propofol group from the other two groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences; Next to the Milad Tower; Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2023-04-17, 1402/01/28
Ethics committee reference number
IR.IUMS.FMD.REC.1402.026

Health conditions studied

1

Description of health condition studied
Foreign body aspiration
ICD-10 code
T17.9
ICD-10 code description
Foreign body in respiratory tract, part unspecified

Primary outcomes

1

Description
Laryngospasm
Timepoint
beginning of bronchoscopy to end of anesthesia and the patient waking up
Method of measurement
Decreased oxygen saturation following epiglottis closure

Secondary outcomes

empty

Intervention groups

1

Description

Group P or Propofol : After induction of inhalation anesthesia with Sevoflurane, Propofol infusion is started at a dose of 80-100 mcg/kg/min, and the relaxant drug will not be injected, and after 3 minutes, rigid bronchoscopy is started. In this group, assisted breathing is given by controlling the ambobag and chest movements, and after the procedure, the drugs are removed.

Category

Treatment - Surgery

2

Description

Group R or Rocuronium: after induction of inhalation anesthesia with Sevoflurane, Rocuronium is injected at a dose of 0.3 mg/kg and bronchoscopy is started after 3 minutes, Propofol infusion is not performed in this group, and the oxygen line is connected through an interface next to the bronchoscope (T segment), and controlled breathing is given with an ambobag through the Mepleson D system. If the procedure is prolonged, and need to repeat the relaxant Rocuronium is prescribed at a dose of 0.2 mg /kg and 0.3 mg /kg. After the procedure, breathing with a face mask and oxygen and low dose Sevoflurane (1%) continues until the patient's breathing returns, and then Sevoflurane is stopped and reversed with Atropine 0.02 mg /kg and Neostigmine 0.05 mg/kg.

Category

Treatment - Surgery

3

Description

Group A or Atracurium: after induction of inhalation anesthesia with Sevoflurane, Atracurium is injected at a dose of 0.3 mg/kg and after 3 minutes' bronchoscopy is started. Propofol infusion is not performed in this group, and the oxygen line is connected through an interface next to the bronchoscope (T segment), and controlled breathing is given with an ambobag through the Mepleson D system. If the procedure is prolonged need to repeat the relaxant drug, Atracurium is prescribed at a dose of 0.2 and 0.3 mg /kg. After the procedure, breathing with a face mask and oxygen and low dose Sevoflurane (1%) continues until the patient's breathing returns, and then Sevoflurane is stopped and reversed with Atropine 0.02 mg /kg and neostigmine 0.05 mg/kg is done.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliasghar Children's Hospital

Full name of responsible person

Tahereh Chavoshi

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No.193, Zafar St, Modares Highway,

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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?

No

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Tahereh Chavoshi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Phone

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable