

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparative study of nasal fiberoptic intubation VS. fiberoptic intubation through laryngeal mask airway for difficult airway management in children

Protocol summary

Study aim

Comparative study of nasal fiberoptic intubation Vs. fiberoptic intubation through laryngeal mask airway for difficult airway management in children

Design

This clinical trial study has a control group, with parallel groups, single blind on 40 patients, with stratified block randomization.

Settings and conduct

This study will be conducted at Mofid Children's Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 6 months to 6 years with ASA I class and ASA II candidate for elective surgery who have difficulty intubating with clinical criteria. Exclusion Criteria: congenital heart and respiratory diseases, productive cough, fever, wheezing or crackling in the lung hearing, cancellation of surgery after the patient enters the operating room and cancellation of parental cooperation

Intervention groups

first Intervention group: Two minutes after prescribing intravenous drugs, we insert the bronchoscope through the nose, and after seeing the vocal cords, we insert the tracheal tube, which we had already inserted into the bronchoscope, into the trachea with a bronchoscope guide. second Intervention group: Two minutes after intravenous drug administration, the patient will be implanted with LMA and then inserted a fiber optic bronchoscope through the laryngeal mask, and after seeing the vocal cords, we insert the tracheal tube that we had previously inserted into the bronchoscope.

Main outcome variables

The duration of intubation (from the time of initiation fiber optic intubation to the end of the time the tracheal tube enters to the trachea) is based on seconds. mean arterial pressure, heart rate and SPO2, before prescribing intravenous drugs, immediately before bronchoscopy

and immediately After intubation will be recorded

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160301026866N12**

Registration date: **2020-07-23, 1399/05/02**

Registration timing: **retrospective**

Last update: **2020-07-23, 1399/05/02**

Update count: **0**

Registration date

2020-07-23, 1399/05/02

Registrant information

Name

Amir Shafa

Name of organization / entity

Isfahan University of Medical Sciences, Imam hossein Hospital

Country

Iran (Islamic Republic of)

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+98 31 3627 2655

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of nasal fiberoptic intubation VS. fiberoptic intubation through laryngeal mask airway for difficult airway management in children

Public title

Comparison of nasal fiberoptic intubation Vs. fiberoptic intubation through laryngeal mask airway for difficult airway management in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 6 months to 6 years ASA I, ASAII Candidate for elective surgery Probability of difficult intubation

Exclusion criteria:

congenital heart and respiratory diseases Productive cough fever wheezing or crackle Cancellation of surgery after the patient enters the operating room

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the small number of samples, we will use the block randomization method, The first step is random sequence generation. The second step is allocation concealment and finally execute random allocation. There are 8 patients in each block (4 patients from the control group and 4 patients from the intervention group). No one will know how people are arranged.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients do not know how to be in groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahid Beheshti University of Medical Sciences, Ethics committees

Street address

Shahid Beheshti University of Medical sciences, Yaman Ave. Chamran Highway

City

Tehran

Province

Tehran

Postal code

1546815514

Approval date

2020-05-30, 1399/03/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.137

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

Fiber optic intubation in difficult airways

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mean Arterial Pressure

Timepoint

Before prescribing medication, before intubation, after intubation

Method of measurement

Anesthesia monitoring device

2**Description**

Heart Rate

Timepoint

Before prescribing medication, before intubation, after intubation

Method of measurement

Anesthesia monitoring device

3**Description**

Spo2

Timepoint

Before prescribing medication, before intubation, after intubation

Method of measurement

Anesthesia monitoring device

4

Description

Intubation time

Timepoint

After intubation

Method of measurement

chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two minutes after prescribing intravenous drugs, we insert the bronchoscope through the nose, and after seeing the vocal cords, we insert the tracheal tube, which we had already inserted into the bronchoscope, into the trachea with a bronchoscope guide.

Category

Treatment - Devices

2

Description

Intervention group: Two minutes after intravenous drug administration, the patient will be implanted with LMA and then inserted a fiber optic bronchoscope through the laryngeal mask, and after seeing the vocal cords, we insert the tracheal tube that we had previously inserted into the bronchoscope.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children Hospital

Full name of responsible person

Amir Shafa

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zargi

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Shafa

Position

Fellowship Residency

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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 data is shareable

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

It is unrestricted for research activities

From where data/document is obtainable

Amir Shafa: shafa_amir@yahoo.com

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

Request via email

Comments