Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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

Design
This clinical trial study has a control group, with parallel groups , single blind on 40 pationts,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 ASAI class and ASAII candidate for elective surgery who have difficulty intubating with clinical criteria.Exclusion Criteria: congenital heart and respiratory diseases, productive cough, fever, wheezing or cracking 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

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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 childeren

Public title
Comparision of nasal fiberoptic intubation Vs. fiberoptic intubation through laryngeal mask airway for difficult airway management in childeren
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 comittes
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
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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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Shahid Beheshti University of Medical sciences,Yaman Ave, Chamran High way
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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
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
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Person responsible for updating data

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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