Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of post intubation endotracheal suction before surgery on respiratory parameters in children with airway secretion

Protocol summary

Study aim
Post intubation airway secretion suction effects on respiratory parameter in children

Design
Controlled randomized clinical trial, with parallel groups, double-blinded, randomized

Settings and conduct
This study will carried out as a clinical trial and among the referring children to Tabriz Children's hospital (June 2018 to March 2019) who are surgery candidates and have pulmonary crackles, 100 cases will chosen randomly and will divide into two groups of case and control. Each patient will be auscultated by a pediatric anesthesia specialist. If diagnosed with abnormal auscultation , patient enters the study , regardless of the intensity of abnormality and will be compared with him/her self before and after suction. The patients, the person responsible of recording vital signs and analyzer of data are not informed about whether the airways have been suctioned or not.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1- Patients who are between 1 month to 6 years old and in need of intubation for surgery witch have coarse crackle in auscultation caused by secretion 2- urgent Patients with common cold exclusion criteria patients with persistent pulmonary hypertension (PPH), fever, and airway malformation

Intervention groups
patients will be divided in two groups for study: patients who had tracheal suction before surgery patients without tracheal suction before surgery in first group post intubation suction will be performed open and deeply,2 or 3 times till all secretions are eliminated and abnormal sounds are gone.Patients will be ventilated after every suction.in second group anesthesia will continue without pulmonary secretions suction.

Main outcome variables
Respiratory rate; Heart rate; SPO2; Expiratory CO2; Blood pressure and pressure of the airway before surgery, 5 minutes after suction ,every 15 minutes after intubation and during recovery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100527004041N14**
Registration date: **2018-06-26, 1397/04/05**
Registration timing: **retrospective**

Last update: **2018-06-26, 1397/04/05**
Update count: **0**

Registration date
2018-06-26, 1397/04/05

Registrant information

Name
Mahin Seyedhejazi

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
deputy of research and technology

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2019-03-19, 1397/12/28

Actual recruitment start date
2017-07-23, 1396/05/01

Actual recruitment end date
2018-01-21, 1396/11/01
Trial completion date
empty

Scientific title
Effect of post intubation endotracheal suction before surgery on respiratory parameters in children with airway secretion

Public title
Effect of post intubation endotracheal suction on respiratory parameters in children with airway secretion
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are between 1 month to 6 years old Patients need to intubate for surgery Patients have coarse crackle in auscultation caused by secretion. Urgent Patients with common cold
Exclusion criteria:
patients with persistent pulmonary hypertension(PPH) fever children with airway malformation
Age
From **1 month** old to **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
the surgery candidate children in "The children medical research and training hospital, Tabriz" will randomly be chosen using random number table and random permuted blocks divided in two 50 members groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Each patient will be auscultated by a pediatric anesthesia specialist. If diagnosed with abnormal auscultation , patient enters the study , regardless of the intensity of abnormality and will be compared with him/her self before and after suction.The data will be gathered by a pediatric anesthesia specialist with help of experienced nurses. Patients, the person who responsible of recording vital signs and analyzer of data are not informed about whether the airways have been suctioned or not.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
university /regional research ethics committee Tabriz university medical of sciences
Street address
Tabriz Unversity of Medical Sciences, Golgasht St
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2018-05-28, 1397/03/07
Ethics committee reference number
IR.TBZMED.REC.1397.204

Health conditions studied

1

Description of health condition studied
Patients with abnormal pulmonary auscultation
ICD-10 code
J20
ICD-10 code description
Acute bronchitis

Primary outcomes

1

Description
short time side effects
Timepoint
discharge from recovery
Method of measurement
observational

2

Description
Respiratory rate
Timepoint
Before surgery-during recovery
Method of measurement
Vital signs monitoring device

3

Description

Heart rate

Timepoint

Before surgery, 5 minutes after suction ,every 15 minutes after intubation and during recovery.

Method of measurement

Vital signs monitoring device

4

Description

SPO2(Blood Oxygen Saturation)

Timepoint

Before surgery, 5 minutes after suction ,every 15 minutes after intubation and during recovery

Method of measurement

pulse oximeter

5

Description

Expiratory CO2

Timepoint

every 15 minutes after intubation

Method of measurement

Vital signs monitoring device

6

Description

Blood pressure

Timepoint

before surgery, 5 minutes after suction ,every 15 minutes after intubation and during recovery.

Method of measurement

Vital signs monitoring device

7

Description

pressure of the airway

Timepoint

every 15 minutes after intubation

Method of measurement

Anesthesia manometer

Secondary outcomes

empty

Intervention groups

1

Description

Cases:Patients who had tracheal suction before surgery patients without tracheal suction before surgery in first group post intubation suction will be performed open and deeply,2 or 3 times till all secretions are eliminated and abnormal sounds are gone.Patients will be ventilated after every suction.

Category

Prevention

2

Description

Control group:in control group anesthesia will continue without pulmonary secretions suction

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz children hospital

Full name of responsible person

Mahin Seyed Hejazi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mahin Seyed Hejazi
Position
Head of pediatric anesthesia department
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Head of pediatric anesthesia ward/pediatric anesthesiologist
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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
we are going to publish all in a paper
When the data will become available and for how long
in the end of study
To whom data/document is available
every one who read the paper
Under which criteria data/document could be used
If the data is needed to be used for further analysis, only the study designer has access to the codes and patients information. If the data is going to be used in another study, a proposal (in which the goals of study are established) should be registered and ethics code must

be received.

From where data/document is obtainable

from the paper

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

no need for special process

Comments