

# 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 be 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 be chosen randomly and will be divided into two groups of case and control. Each patient will be auscultated by a pediatric anesthesia specialist. If diagnosed with abnormal auscultation, the patient enters the study, regardless of the intensity of abnormality and will be compared with him/herself before and after suction. The patients, the person responsible for 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 with 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 into 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; SPO<sub>2</sub>; Expiratory CO<sub>2</sub>; 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3385 2252

##### Email address

seidhejazie@tbzmed.ac.ir

##### 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 University 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

**Street address**

Tabriz children hospital, Sheshgelan St

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5136735886

**Phone**

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seidhejazie@tbzmed.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hasan Soleymanpour

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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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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahin Seyed Hejazi

**Position**

Head of pediatric anesthesia ward/pediatric anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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Tabriz University of Medical Sciences

**Full name of responsible person**

Mahin Seyed Hejazi

**Position**

Head of pediatric anesthesia ward/pediatric anesthesiologist

**Latest degree**

Specialist

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**Fax****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**