

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of laryngotracheal anesthesia with McKenzie method for the ease of pediatric rigid bronchoscopy.

Protocol summary

Study aim

Checking the effects of laryngotracheal anesthesia on the ease of bronchoscopy in children.

Design

Clinical trial with intervention and control groups, with parallel groups, double-blind, randomized, sample of 64 patients. Randlist software was used for randomization.

Settings and conduct

All patients candidate for pediatric bronchoscopy and undergoing laryngotracheal anesthesia at Tabriz pediatric Hospital will be included in this study. Patients are randomly assigned to two intervention and control groups. In intervention group, lidocaine and in control group, normal saline will be used to compare the effects of McKenzie's laryngotracheal anesthesia on rigid bronchoscopy in children. In this study, the patient and anesthesiologist are blinded to study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All children under the age of seven, With ASA grade, class I&II, Candidate for rigid bronchoscopy, Exclusion criteria: Head and neck anomalies, Feverish patients, Children with airway anomalies, Children with underlying disease.

Intervention groups

Intervention group: In this group after induction and laryngoscopy, the blend of lidocaine 2% (Caspian Taamin pharmaceutical company) 0.3 milliliter per kilogram with oxygen in the laryngotracheal area will be flashed by the McKenzie method (A kind of anesthesia method). Control group: In this group, 0.3 milliliter per kilogram normal saline 0.9% (Saamen pharmaceutical company) with oxygen in the laryngotracheal region, will be flashed by McKenzie method (A kind of anesthesia method).

Main outcome variables

Ease of bronchoscopy, blood pressure, heart rate, oxygen saturation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100527004041N21**

Registration date: **2020-05-22, 1399/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-22, 1399/03/02**

Update count: **0**

Registration date

2020-05-22, 1399/03/02

Registrant information

Name

Mahin Seyedhejazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of laryngotracheal anesthesia with McKenzie method for the ease of pediatric rigid bronchoscopy.

Public title

The effect of laryngotracheal anesthesia for pediatric bronchoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All children under the age of seven With ASA grade, class I&II and Candidate for rigid bronchoscopy

Exclusion criteria:

Head and neck anomalies Feverish patients Children with airway anomalies Children with underlying disease

Age

From **1 day** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients wishing to participate in the study who meet the inclusion criteria will be selected through convenient sampling and then randomly assigned to two control and intervention groups using Randlist software and blocks of size two.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, the thesis owner student provides the drugs to the anesthesiologist and is the only person who is not blind to the study. The anesthesiologist, who is in charge of the patient's anesthesia management, injects the drug through coded syringes that have already been prepared by the thesis owner. So that anesthesiologist is unaware of the injected drug to patient during injection. The anesthesia nurse, who is responsible for collecting information and variables from the patient and is unaware of the type of prescribed drug, fills in the checklist during surgery and recovery. The patient is also unaware of the type of Injecting drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.TBZMED.REC.1399.045

Health conditions studied

1

Description of health condition studied

Pediatric bronchoscopy

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Ease of bronchoscopy

Timepoint

Before induction, after induction, after flashing the desired solution every 3 minutes to 3 times and then every 5 minutes.

Method of measurement

Based on the surgeon's consent, scoring as: Easy (0) - Medium (1) - Hard (2)

2

Description

Systolic and diastolic blood pressure

Timepoint

Before induction, after induction, after flashing the desired solution every 3 minutes to 3 times and then every 5 minutes.

Method of measurement

Mercury barometer

3

Description

Heart rate

Timepoint

Before induction, after induction, after flashing the desired solution every 3 minutes to 3 times and then every 5 minutes.

Method of measurement

Counting in each minutes

4

Description

Saturation of peripheral oxygen

Timepoint

Before induction, after induction, after flashing the desired solution every 3 minutes to 3 times and then every 5 minutes.

Method of measurement

Via the Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:In this group after induction and laryngoscopy, the blend of lidocaine 2%(Caspian Taamin pharmaceutical company)0.3milliliter per kilogram with oxygen in the laryngotracheal area will be flashed by the McKenzie method(A kind of anesthesia method).

Category

Treatment - Drugs

2

Description

Control group:In this group,0.3 milliliter per kilogram normal saline 0.9% (Saamen pharmaceutical company)with oxygen in the laryngotracheal region,will be flashed by McKenzie method(A kind of anesthesia method).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Tabriz Children Hospital

Full name of responsible person

Dr. Mahin Seyedhejazi

Street address

Tabriz pediatric hospital,sheshgelan street,Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Vice chancellor for research, Daneshgah street, Tabriz

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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

Dr. Mahin Seyedhejazi

Position

Anesthesiologist/Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Tabriz pediatric hospital,sheshgelan street,Tabriz
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Person responsible for scientific inquiries

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Position
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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 potential data can be shared after making peoples unrecognizable.

When the data will become available and for how long

Starting 6 months after publication .

To whom data/document is available

Documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data

From where data/document is obtainable

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

Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.

Comments