Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the prevalence of respiratory complications in two methods of anesthesia with endotracheal intubation and without endotracheal intubation in children under two years old candidate for endoscopy

Protocol summary

Study aim
Comparison of anesthesia with intubation and non intubation technique in children under two years of age, candidates for endoscopy, referred to Mofid hospital

Design
Randomized clinical trail with control group. Randomization with blocking method. Sample size of 120 patients (60 in each group).

Settings and conduct
All patients under two years old referred to the endoscopic ward of Mofid children's hospital. There is no blinding in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: ASA Class I,II patients; under 2 years ;admitted or outpatient. Non-inclusion criteria: Emergent patients; ASA Class III and higher.

Intervention groups
Intervention group 1: sedated without tracheal intubation
Intervention group 2: anesthetized with tracheal intubation

Main outcome variables
laryngospam; cough; bronchospasm; patient movement; seizure; apnea; nausea; vomiting; salivation; bleeding; gastric perforation; esophageal perforation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200518047491N1**
Registration date: **2020-08-26, 1399/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-26, 1399/06/05**
Update count: **0**

Registration date
2020-08-26, 1399/06/05

Registrant information

Name
nastaransadat mahdavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2225 0680

Email address
nasimahdavi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-10-22, 1399/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the prevalence of respiratory complications in two methods of anesthesia with endotracheal intubation and without endotracheal intubation in children under two years old candidate for endoscopy

Public title
The prevalence of respiratory complications in two

methods of anesthesia with endotracheal intubation and without endotracheal intubation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being in ASA Class I & II Admitted outpatient or inpatient

Exclusion criteria:

Emergent patients ASA Class III and higher

Age

From **1 day** old to **2 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the balance in the two groups, the block randomization method is used, which is a limited randomization method. The first step is to create a random sequence. In the second step, the blocks we created are concealed and then in the execution stage, the blocks are assigned. The number of the blocks is 8 (4 blocks for each group)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Mofid Children's Hospital; Shariati Street

City

Tehran

Province

Tehran

Postal code

15468-15514

Approval date

2020-06-23, 1399/04/03

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.257

Health conditions studied

1

Description of health condition studied

Children under two years of age who present with gastrointestinal symptoms and are candidates for endoscopy under the diagnosis of a pediatric gastroenterologist

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

O2 saturation

Timepoint

Duration of endoscopy until the end of recovery and discharge from the endoscopy unit

Method of measurement

questionnaire

2

Description

Respiratory rate

Timepoint

Duration of endoscopy until the end of recovery and discharge from the endoscopy unit

Method of measurement

questionnaire

3

Description

Heart rate

Timepoint

Duration of endoscopy until the end of recovery and discharge from the endoscopy unit

Method of measurement

questionnaire

4

Description

Blood pressure

Timepoint

Duration of endoscopy until the end of recovery and discharge from the endoscopy unit

Method of measurement

questionnaire

5

Description

ECG changes

Timepoint

Duration of endoscopy until the end of recovery and discharge from the endoscopy unit

Method of measurement

questionnaire

6

Description
Duration of anesthesia
Timepoint
time from starting the anesthesia to patient awakening
Method of measurement
questionnaire

7

Description
Duration of endoscopy
Timepoint
From the beginning of the endoscopy to the exit of the endoscope from the patient's mouth
Method of measurement
questionnaire

8

Description
laryngospasm complication during anesthesia
Timepoint
From the beginning of anesthesia to the end of anesthesia
Method of measurement
questionnaire

9

Description
bronchospasm complication during anesthesia
Timepoint
From the beginning of anesthesia to the end of anesthesia
Method of measurement
questionnaire

10

Description
patient movement during anesthesia
Timepoint
From the beginning of anesthesia to the end of anesthesia
Method of measurement
questionnaire

11

Description
bucking and coughing during anesthesia
Timepoint
From the beginning of anesthesia to the end of anesthesia
Method of measurement
questionnaire

12

Description
nausea and vomiting
Timepoint
From the start of anesthesia to discharge from recovery
Method of measurement
questionnaire

13

Description
seizure
Timepoint
From the start of anesthesia to discharge from recovery
Method of measurement
questionnaire

14

Description
apnea
Timepoint
From the start of anesthesia to discharge from recovery
Method of measurement
questionnaire

15

Description
salivation
Timepoint
From the start of anesthesia to discharge from recovery
Method of measurement
questionnaire

16

Description
bleeding after endoscopy
Timepoint
From the start of endoscopy to discharge from recovery
Method of measurement
questionnaire

17

Description
gastric / esophageal perforation after endoscopy
Timepoint
From the start of endoscopy to discharge from recovery
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: sedation without tracheal intubation, after confirming adequate fasting (6 hours for foods and milk, 4 hours for breast milk, 2 hours for clear liquids) if they are over 6 months old, Midazolam is given at the dose of 0.05 mg per kilogram of body weight. Then Ketamine is

injected at the dose of 1 mg per kilogram. Sedation is continued with repeated doses of Propofol at 0.3 to 1 mg per kilogram during endoscopy. Depending on the anesthesiologist's diagnosis and to increase the depth of anesthesia and sedation, patients receive Fentanyl at the dose of 1 microgram per kilogram of body weight.

Category

Treatment - Devices

2

Description

Intervention group: sedation with tracheal intubation , after confirming adequate fasting (6 hours for foods and milk, 4 hours for breast milk, 2 hours for clear liquids) if they are over 6 months old, Midazolam is given at the dose of 0.05 mg per kilogram of body weight. Then Ketamine is injected at the dose of 1 mg per kilograms. After injecting Propofol with the dose of 1.5-2 mg per kilogram and ensuring adequate apnea and relaxation, intubation is performed with a suitable size tube. Sedation is continued with repeated doses of Propofol at 0.3 to 1 mg per kilogram during endoscopy. Depending on the anesthesiologist's diagnosis and to increase the depth of anesthesia and sedation, patients receive Fentanyl at the dose of 1 microgram per kilogram of body weight.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's hospital

Full name of responsible person

Nastaransadat Mahdavi

Street address

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Phone

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Email

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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 Zarghi

Street address

Velenjak street; Shahid Chamran Highway

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1983963113

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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

90

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

Nastaransadat Mahdavi

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
associate professor
Latest degree
Subspecialist
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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
Files will be provided to researchers after sending an email
When the data will become available and for how long
one year after publication
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
In order to use scientific and practical results of the study Mentioning references and other ethical and professional principles
From where data/document is obtainable
nastaransadat mahdavi nasimahdavi@gmail.com 00982122250680
What processes are involved for a request to access data/document
send mail Wait for a week to check email Wait a month for the requested data to be sent
Comments