

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

laryngospasm; 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)

###### Phone

+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**

Mofid children's hospital; Shariati street

**City**

Tehran

**Province**

Tehran

**Postal code**

15468-15514

**Phone**

+98 21 2222 7021

**Email**

nasimahdavi@gmail.com

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 23871

**Email**

info@sbmu.ac.ir

**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

**Street address**

Mofid children's hospital; Shariati street

**City**

Tehran

**Province**

Tehran

**Postal code**

15468-15514

**Phone**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nastaransadat Mahdavi

**Position**

associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data****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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**Province**

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**Postal code**

15468-15514

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+98 21 2222 7021

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nasimahdavi@gmail.com

**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**