

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the efficacy of Etomidate and Propofol in sedation induction in children undergoing upper gastrointestinal endoscopy

Protocol summary

Study aim

Comparison the efficacy of Etomidate and Propofol in sedation induction in children undergoing upper gastrointestinal endoscopy.

Design

A clinical trial with two intervention groups, with parallel groups, double-blind, randomized, phase 2 will be performed on 90 children undergoing endoscopy of the gastrointestinal tract. The simple random method will be used for randomization.

Settings and conduct

The study will done in the endoscopy department of Mofid Children's Hospital affiliated to Shahid Behehsti University of Medical Science in Tehran. This study will be conducted double-blinded: the patients (children) and the evaluator (analyzer) won't aware of the course of the intervention. Intervention will be done under the same conditions in both groups. After diluting, 1 mg/kg Propofol and 0.1 mg/kg Etomidate will be same as color, smell and volume.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 1 to 15 years old candidates for upper gastrointestinal tract endoscopy in class I, II according to American Association of Anesthesia. Non-inclusion criteria: A history of drug allergy to Propofol or Etomidate, kidney and liver disease, adrenal disease, severe pneumonia, ICU admission, history of postoperative nausea and vomiting, G6PD deficiency.

Intervention groups

The intervention group 1 receive Propofol (1%) 1 mg/kg (4 ml/kg) which is injected intravenous slowly, and the intervention group 2 receive Etomidate (0.2%) 0.1 mg/kg (2 ml/kg) which is diluted with 2 ml/kg injectable sterile water, and injected intravenous slowly.

Main outcome variables

The time and frequency of laryngospasm; The time and frequency of apnea; The time of waking up from sedation; Nausea after sedation; Vomiting after sedation; Restlessness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200515047452N1**

Registration date: **2020-08-23, 1399/06/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-23, 1399/06/02**

Update count: **0**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Tahereh Chavoshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2227 9871

Email address

t.chavoshi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of Etomidate and Propofol in sedation induction in children undergoing upper gastrointestinal endoscopy	
Public title	The efficacy of Etomidate and Propofol in sedation induction of children undergoing gastrointestinal endoscopy
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Children at the age of 1 to 15 years old Candidate for upper gastrointestinal tract endoscopic procedure Class I & II Exclusion criteria: History of drug allergy to Propofol or Etomidate Kidney disease Liver disease Adrenal disease Severe pneumonia ICU hospitalization History of Postoperative nausea and vomiting G6PD deficiency
Age	From 1 year old to 15 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser
Sample size	Target sample size: 90
Randomization (investigator's opinion)	Randomized
Randomization description	Simple randomization is assigned to a number from one to 90, respectively, to those who were eligible for the study. Then, without prior awareness, even numbers are allocated in the intervention group and odd numbers in the control group.
Blinding (investigator's opinion)	Double blinded
Blinding description	This study was conducted double-blinded: the patients (children) and the evaluator (analyzer) were not aware of the course of the intervention. Intervention under the same conditions as P and E the intervention groups. after dilution 1 mg/kg Propofol and 0.1 mg/kg Etomidate were same as color, smell and volume.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees
<u>1</u>
Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
7th Floor; Building No.2; Shahid Beheshti University of Medical Sciences; Arabi Ave; Daneshjoo Blvd; Velenjak
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2020-05-11, 1399/02/22
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.360
Health conditions studied
<u>1</u>
Description of health condition studied
Complications of sedation during endoscopic procedure
ICD-10 code
T81
ICD-10 code description
Complications of procedures, not elsewhere classified
Primary outcomes
<u>1</u>
Description
Blood pressure changes
Timepoint
Immediately before anesthesia and after anesthesia (first minute, 5th minute, 10th minute and 15th minute) will be monitored and recorded.
Method of measurement
Blood pressure monitoring
<u>2</u>
Description
Apnea (the cessation of breathing for 10 seconds)
Timepoint
Continuously
Method of measurement
Observation of respiratory movements and pulse oximeter changes
<u>3</u>
Description
Frequency of Laryngospasm (closure of the vocal cords and lack of air transfer to the lungs and vice versa)

Timepoint

Continuously

Method of measurement

Observation

4**Description**

Duration of Laryngospasm (during time from closure of the vocal cords and lack of air transfer to the lungs and vice versa to bag valve mask ventilation)

Timepoint

Continuously

Method of measurement

Cornometer

5**Description**

Duration of Anesthesia recovery.

Timepoint

once at recovery room.

Method of measurement

Cornometer

6**Description**

nausea and vomiting

Timepoint

Continuously

Method of measurement

Observation

7**Description**

Agitation

Timepoint

After anesthesia (first minute, 5th minute, 10th minute and 15th minute) will be monitored and recorded.

Method of measurement

Sedation Scale for Agitation score,

8**Description**

Heart rate changes

Timepoint

Immediately before anesthesia and after anesthesia (first minute, 5th minute, 10th minute and 15th minute) will be monitored and recorded.

Method of measurement

puls oximetry

9**Description**

Respiratory rate changes

Timepoint

Immediately before anesthesia and after anesthesia (first minute, 5th minute, 10th minute and 15th minute) will be monitored and recorded.

Method of measurement

Chest movement per minute

10**Description**

Awakening from sedation

Timepoint

Getting to recovery unit until obey the commands and communication with parents

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: In this group, Propofol 1%, 1 mg / kg will be injected intravenously immediately before endoscopy.

Category

Treatment - Drugs

2**Description**

Intervention group 2: In this group, Etomidate 0.2%, 0.1 mg/kg will be injected intravenously immediately before endoscopy.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mofid Children's Hospital affiliated to Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Chavoshi

Street address

7th Floor; Building No.2; Shahid Beheshti University of Medical Sciences; Arabi Ave; Daneshjoo Blvd; Velenjak

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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

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7th Floor; Building No.2; Shahid Beheshti University of Medical Sciences; Arabi Ave; Daneshjoo Blvd; Velenjak

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zarghi@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

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Chavoshi

Position

Fellowship of pediatric anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Biochemistry

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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

Tahereh Chavoshi

Position

Fellowship of pediatric anesthesiology.

Latest degree

Specialist

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

Tahereh Chavoshi

Position

Fellowship of pediatric anesthesiology.

Latest degree

Specialist

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

Demographic information of intervention groups;

Complications of sedation in intervention groups

When the data will become available and for how long

At the end of the study

To whom data/document is available

All of them have aimed secondary research.

Under which criteria data/document could be used

For secondary research.

From where data/document is obtainable

Mofid Children's Hospital affiliated to Shahid Beheshti

University of Medical Sciences-anesthesia research

center-Dr. Tahereh Chavoshi

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

Requesting by email.

Comments