Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 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 Sience 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

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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 Etomidite 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

1

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

1

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

1

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 monitorinng

2

Description
Apnea (the cessation of breathing for 10 secounds)
Timepoint
Continuously
Method of measurement
Observation of respiratory movements and pulse oximeter changes

3

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 recovey 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
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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
Street address
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 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
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