Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the effects of propofol - ketamine and propofol- fentanyl drug regimens on sedation in children undergoing upper endoscopy

Protocol summary

Study aim

Comparison of the effects of propofol - ketamine and propofol- fentanyl drug regimens on sedation in children undergoing upper endoscopy

Design

A double-blind, randomized clinical trial study with parallel groups and phases 3 on 50 patients. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct

In this study, children aged 1 to 10 who are candidates for upper endoscopy at Urmia Motahari Hospital will be included. This study will be a double-blind study and the patient and the researcher who will evaluate the outcomes will be blinded to the allocation of patients into groups.

Participants/Inclusion and exclusion criteria

In this study, 50 children aged 1-10 years who are candidates for upper endoscopy will be included. Emergency endoscopies, patients who do not fast for 6 hours and patients with a disease history such as cerebral palsy or neuromuscular disorders will be excluded from the study.

Intervention groups

In the first group, induction of anesthesia will be performed with 0.05 mg/kg of midazolam, 1 mg/kg of propofol, 1 mg/kg of ketamine and 0.02 mg/kg of atropine and in the second group, the induction of anesthesia will be performed with 0.05 mg/kg of midazolam, 1 mg/kg of propofol, 2 mcg/kg of fentanyl and 0.02 mg/kg of atropine, and then the patients in both groups will be placed in the left lateral decubitus position and upper gastrointestinal endoscopy will be performed by pediatric gastroenterologist.

Main outcome variables

Sedation score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516033992N13**
Registration date: **2023-03-30, 1402/01/10**
Registration timing: **prospective**

Last update: **2023-03-30, 1402/01/10**
Update count: **0**

Registration date

2023-03-30, 1402/01/10

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3222 2010

Email address

karami.t@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of propofol - ketamine and

propofol- fentanyl drug regimens on sedation in children undergoing upper endoscopy

Public title
Comparison of the effects of propofol - ketamine and propofol- fentanyl drug regimens on sedation in endoscopy
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Children undergoing upper endoscopy Age between 1-10 years
Exclusion criteria:
Emergency endoscopies Patients who do not fast for 6 hours. Patients with a disease history such as cerebral palsy or neuromuscular disorders
Age
From **1 year** old to **10 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be implemented. Patients will be allocated to two groups based on generated numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted as a double-blind clinical trial. The patient and The person who will assess the outcomes will be blind to the allocation of patients into two groups. Induction of anesthesia with drug regimens will be done by an anesthesiologist (other than the outcome assessor) and the names of the groups will be coded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2023-02-01, 1401/11/12
Ethics committee reference number
IR.UMSU.REC.1401.389

Health conditions studied

1

Description of health condition studied
Sedation during endoscopy
ICD-10 code
T88.52
ICD-10 code description
Failed moderate sedation during procedure

Primary outcomes

1

Description
Sedation score
Timepoint
During endoscopy
Method of measurement
Evaluation by the endoscopist

Secondary outcomes

1

Description
Recovery time
Timepoint
After induction of anesthesia
Method of measurement
Minute

2

Description
Need for additional anesthesia drug
Timepoint
After induction of anesthesia

Method of measurement
No/yes

Intervention groups

1

Description
Intervention group: In the first group, induction of anesthesia will be performed with 0.05 mg/kg of midazolam, 1 mg/kg of propofol, 1 mg/kg of ketamine and 0.02 mg/kg of atropine and then the patients will be placed in the left lateral decubitus position and upper gastrointestinal endoscopy will be performed by pediatric gastroenterologist.
Category
Treatment - Other

2

Description
Intervention group: In the second group, the induction of anesthesia will be performed with 0.05 mg/kg of midazolam, 1 mg/kg of propofol, 2 mcg/kg of fentanyl and 0.02 mg/kg of atropine, and then the patients will be placed in the left lateral decubitus position and upper gastrointestinal endoscopy will be performed by pediatric gastroenterologist.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Motahari Hospital
Full name of responsible person
Dr.Tohid Karami
Street address
Kashani Ave., Shahid Motahhari hospital., Urmia., Iran.
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karami.t@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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gholizadeh.s@umsu.as.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Tohid Karami
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Motahhari hospital., Kashani Ave, Urmia, Iran.
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Person responsible for scientific

inquiries

Contact

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Person responsible for updating data

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Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Not applicable

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data will not be published individually and the results will be available as the published article.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Researchers

Under which criteria data/document could be used
Not applicable

From where data/document is obtainable
Email address of the corresponding author: karami.t@umsu.ac.ir

What processes are involved for a request to access data/document
Email address of the corresponding author: karami.t@umsu.ac.ir

Comments