

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 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, Jihad 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

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Urmia University of Medical Sciences, Resalat street, Jihad 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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karami.t@umsu.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Tohid Karami

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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