

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of using ketamine and midazolam compared to propofol and midazolam on vital signs during gastroduodenoscopy in children referred to Bandar Abbas medical centers

Protocol summary

Study aim

The findings of this study, considering the sensitivity of gastroduodenoscopy in children, can be helpful in finding a suitable combination of anesthetics and anesthetics.

Design

A randomized clinical trial, double-blind, phase 4 on 44 patients, using a table of random numbers for randomization.

Settings and conduct

According to the double-blind randomization method (in each of the groups, the desired drug is injected into the patient by an anesthesiologist, but the information required for the research is recorded by an independent researcher who does not know the type of drug and the study group. This study is conducted in Bandar Abbas Children's Hospital and Bandar Abbas Children's Clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having informed consent Children aged 2 to 16 years with ASA class 1 or 2 Exit criteria: Allergy to any of the drugs used in the study Emergency endoscopy Contraindications for prescribing ketamine

Intervention groups

In one group of patients, 0.03 mg/kg intravenous midazolam and 1 mg/kg propofol 1% will be given intravenously and they will undergo endoscopy. In the other group of patients, first, 0.03 mg/kg of intravenous midazolam and 1 mg/kg of intravenous ketamine are given and they undergo endoscopy. During the surgery, patients are under continuous heart monitoring and oxygen saturation percentage

Main outcome variables

Vital signs (blood pressure, heart rate, O2 saturation)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230228057558N1**

Registration date: **2023-11-27, 1402/09/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-27, 1402/09/06**

Update count: **0**

Registration date

2023-11-27, 1402/09/06

Registrant information

Name

Fatemeh Mohammad hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3641 4585

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of using ketamine and midazolam compared to propofol and midazolam on vital

signs during gastroduodenoscopy in children referred to Bandar Abbas medical centers

Public title

Comparison of the effect of using ketamine and midazolam compared to propofol and midazolam on vital signs during gastroduodenoscopy in children referred to Bandar Abbas medical centers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent Children aged 2 to 16 years ASA class 1 or 2 candidates for upper gastrointestinal endoscopy

Exclusion criteria:

Allergy to any of the drugs used in the study Emergency endoscopy Contraindications for prescribing ketamine (history of neurological and psychiatric diseases, history of brain space-occupying lesions, heart rhythm disorders)

Age

From **2 years** old to **16 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Generation of random numbers from the table of random numbers: Considering that 44 patients are needed in this study, a number is randomly selected in the table of random numbers and the two digits on the right side of it are taken into account. If these two digits were an even number, The patient is assigned to the intervention group (A) and if he is an individual, to the control group (B). For example, the number 73 was chosen in the table of random numbers, since the number 73 is an odd number, so the first sample will be assigned to the control group. In the table, random numbers move in rows from left to right, and with the above pattern, the method of assigning people to two groups is determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

In each of the groups, the desired drug is injected into the patient by an anesthesiologist, but the information required for the research is recorded by an independent researcher who does not know the type of drug and the study group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Shahid Mohammadi Hospital

City

Bandarabbas

Province

Hormozgan

Postal code

7916613885

Approval date

2022-12-28, 1401/10/07

Ethics committee reference number

IR.HUMS.REC.1401.328

Health conditions studied

1

Description of health condition studied

Gastrointestinal problems

ICD-10 code

K20-K31

ICD-10 code description

Diseases of oesophagus, stomach and duodenum

Primary outcomes

1

Description

The rate of sedation during pediatric gastroduodenoscopy

Timepoint

Before, during, and at the discharge from recovery

Method of measurement

Aldrete score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 0.03 mg/kg of intravenous midazolam and 1 mg/kg of propofol 1% will be given intravenously and they will undergo endoscopy.

Category

Treatment - Drugs

2

Description

Intervention group: receives intravenous midazolam 0.03 mg/kg and intravenous ketamine 1 mg/kg and undergo endoscopy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Samira Zanbag

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

شخصی

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

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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

No - There is not 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

Comparison effect of Ketamine and Midazolam versus Propofol and Midazolam for gastroduodenoscopy in children referred to Bandar Abbas medical centers

When the data will become available and for how long

One year after the publication of the article

To whom data/document is available

Authors and officials of Hormozgan University of Medical Sciences

Under which criteria data/document could be used

For use in statistical work and larger studies

From where data/document is obtainable

To the first author

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

Email the first author and request the use of the data

Comments