Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone
+98 71 3641 4585

Email address
fatimaaaa.mh@gmail.com

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
Street address
Bandar Abbas- Shahid Mohammadi Hospital
City
Bandar abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3334 5000
Email
info@hums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Samira Zanbag
Street address
Bandar Abbas-Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3334 5000
Email
info@hums.ac.ir
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
Behnaz Darban
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Bandar Abbas-Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 912 084 5006
Email
Darban.sam@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Samira Zanbag
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Bandar Abbas-Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 913 357 6114
Email
samira.zanbagh66@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
nasim abdi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Bandar Abbas-Shahid Mohammadi Hospital

City
bandar abbas

Province
Hormozgan

Postal code
7916613885

Phone
+98 917 364 0376

Email
Abdidoc22@gmail.com

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