

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of the effect of adding low doses of Ketamine to Dexmedetomidine and Propofol on the sedative quality and hemodynamic response in Children during Upper Gastrointestinal Endoscopy

#### Protocol summary

##### Study aim

Determining the effect of adding ketamine to dexmedetomidine and propofol on the quality of sedation and hemodynamic response in pediatric endoscopy

##### Design

Two arm clinical trial with parallel, double-blind, randomized groups using a random number table, phase three groups on 52 patients.

##### Settings and conduct

The patient and the data collector were unaware of the drug and drug groups used. Three syringes (dexmedetomidine 4 milliliter per Milliliter, propofol 4 milligram per milliliter , ketamine 1 milligram per milliliter) will be prepared and injected. Patients are evaluated and recorded every five minutes based on Ramsey criteria and variables.

##### Participants/Inclusion and exclusion criteria

1- Patients 2 to 12 years old 2- Consent of the patient or parents to participate in the study ; 1- ventricular atrial block (Grade 2 or 3 ) in electrocardiography 2- Slow heart rate 3- QTc more than 550 Millisecond in electrocardiography 4- Severe heart failure 5- low blood pressure (systolic blood pressure less than 90 mmHg or diastolic blood pressure less than 60 mm Hg) 6- Liver disease 7- Using any analgesic drug 8- History of chronic pain syndromes, 9- history of any allergy to the drug used in the design

##### Intervention groups

Patients in the first group (group D) will receive dexmedetomidine and patients in the second group (group M) will receive propofol for sedation during surgery. The sample size in each group was 26 people

##### Main outcome variables

Depth of relaxation; ; blood pressure ; Heart rate; Recovery time; Duration of anesthesia; Intraoperative complications; Desaturation cases; Complications in

recovery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039326N21**

Registration date: **2022-06-01, 1401/03/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-06-01, 1401/03/11**

Update count: **0**

##### Registration date

2022-06-01, 1401/03/11

##### Registrant information

##### Name

Hamidreza Shetabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3620 2020

##### Email address

hamidshetabi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-09-20, 1401/06/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of adding low doses of Ketamine to Dexmedetomidine and Propofol on the sedative quality and hemodynamic response in Children during Upper Gastrointestinal Endoscopy

**Public title**

The effect of adding Ketamine to Dexmedetomidine and Propofol on the sedative quality and hemodynamic response in Children during Upper Gastrointestinal Endoscopy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Consent of the patient or parents to participate in the study Patients aged 2 to 12 years

**Exclusion criteria:**

ventricular atrial block (Grade 2 or 3 ) in electrocardiography Slow heart rate QTc more than 550 Millisecondon electrocardiography Severe heart failure low blood pressure (systolic blood pressure less than 90 mmHg or diastolic blood pressure less than 60 mmHg) Liver disease Use of any analgesic drug (due to possible drug interactions with the two drugs used in the study and the possibility of influencing the conclusion and prejudice of anesthesia) History of any allergy to the drug used in the design (dexmedetomidine and propofol)

**Age**

From **2 years** old to **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **52**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using a random sequence generated from random allocation software, patients were enrolled individually in the two groups receiving ketamine-dexmedetomidine (DK) and ketamine-propofol (KP) were included in the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study is double blinded. Patient and researcher are unaware of patient groups and type of medication. The medications are prepared by an anesthetist who is unaware of the grouping of patients and is worn by an aluminum foil and encoded by an anesthetist. Demographic information; Sedation level. The quality of pain relief and hemodynamic variables and complications are collected by a patient who is not aware

of the type of drug and patient grouping

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of medical sciences, Hezar Jarib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2021-12-11, 1400/09/20

**Ethics committee reference number**

IR.MUI.MED.REC.1400.683

**Health conditions studied****1****Description of health condition studied**

Anesthesia for endoscopy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Sedation depth

**Timepoint**

Every 5 minutes during procedure and every 10 minutes in recovery

**Method of measurement**

Ramsey Sedation criteria

**Secondary outcomes****1****Description**

Blood pressure

**Timepoint**

Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

**Method of measurement**

Blood pressure barometer

**2**

**Description**

Heart rate

**Timepoint**

Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

**Method of measurement**

Pulse oximeter

**3**

**Description**

Recovery time

**Timepoint**

After completing the intervention until the withdrawal from the recovery

**Method of measurement**

Minute Numbers

**4**

**Description**

Surgery time

**Timepoint**

From the beginning of the surgery

**Method of measurement**

Minute Numbers

**5**

**Description**

Duration of anesthesia

**Timepoint**

From the time of anesthesia injection to the time of consciousness

**Method of measurement**

Minute Numbers

**6**

**Description**

Complications (bradycardia, apnea)

**Timepoint**

Before intervention, every 5 minutes after the intervention and every 10 minutes after the end of the intervention for 30 minutes

**Method of measurement**

Monitoring

**7**

**Description**

Incidence of complications in recovery

**Timepoint**

Every 10 minutes after the end of the intervention for 30

minutes

**Method of measurement**

Patient monitoring and observation

**Intervention groups**

**1**

**Description**

Intervention group: In dexmedetomidine group (Dk), patients will receive 1-0.7 micrograms per kilogram of dexmedetomidine and then bolus ketamine 0.4 mg per kilogram in 50 ml of normal saline for 10 minutes followed by infusion of dexmedetomidine at 50 micrograms per kilogram per hour and ketamine 0.4 micrograms per kilogram per hour.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: In Propofol group (kp), patients will receive 100-50 micrograms per kilogram of Propofol and then bolus ketamine 0.4 mg per kilogram in 30 ml of normal saline for 10 minutes followed by infusion of Propofol at 50 micrograms per kilogram per hour and ketamine 0.4 micrograms per kilogram per hour.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Imam Hussein Children's Educational and Medical Center

**Full name of responsible person**

Hamidreza Shetabi

**Street address**

Imam Hossein Children's Educational and Medical Center - Imam Khomeini St. - before Esteghlal Square - Isfahan

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emamhossein\_hospital@mui.ac.ir

**Sponsors / Funding sources**

# 1

## Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

شقایق حق جوی جوانمرد

**Street address**

Vice chancellor of research and technology of university, Isfahan University of Medical Sciences, Hezarjarib St.

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**Postal code**

7346181746

**Phone**

+98 31 3668 0048

**Email**

Research@mui.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Isfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamidreza Shetabi

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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+98 31 3620 2020

**Fax****Email**

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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**  
Unidentifiable individual data of participants including hemodynamic indicators and complications can be

shared in all two groups.

**When the data will become available and for how long**  
6 month after publication of paper

**To whom data/document is available**  
Academic and medical researcher

**Under which criteria data/document could be used**  
Use for research and treatment purpose

**From where data/document is obtainable**  
Email of person in charge of public accountability ,Dr Hamidreza Shetabi: hamidshetabi@med.mui.ac.ir

**What processes are involved for a request to access data/document**  
After the request, it will be sent by email, if possible, within a maximum of one month.

**Comments**