

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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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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7346181746

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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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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