Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

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

Public title
The effect of adding Ketamine to Dxmedetomidine 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
Isfehan
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

City

Isfahan

Province

Isfehan

Postal code

۸۱۹۵۱۶۳۳۸۱

Phone

+98 31 3386 6266

Fax

Email

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.

City
Isfahan

Province
Isfehan

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

Street address
Feyz hospital, Modares St

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Fax

Email
hamidshetabi@med.mui.ac.ir

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

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+98 31 3620 2020

Fax

Email
Hamidshetabi@med.mui.ac.ir

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

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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