# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of sedative effect of ketamine with propofol in patients undergoing colonoscopy

## Protocol summary

**Study aim**
Sedation with Ketamine and propofol in patients undergoing colonoscopy
**Design**
This study is a double-blind clinical trial that will be conducted with parallel and randomized groups on 120 patients.
**Settings and conduct**
This study was conducted at Imam Khomeini Hospital in Ahvaz and is triple -blind. After selecting the samples, the participants in the study, the endoscopic physician and the principal investigator are not aware of the allocation method and the drugs are injected by an anesthesiologist who is aware of the allocation and the data collection is done by them.
**Participants/Inclusion and exclusion criteria**
Entry conditions include colonoscopy candidate patients who are between the ages of 18 and 65 and do not suffer from cardiovascular diseases, kidney or liver failure. Exclusion criteria include the patient's unwillingness to participate in the study; intestinal perforation during the procedure; esophageal or stomach or intestinal bleeding during the procedure; changing the type of procedure during colonoscopy or the need for surgery during the procedure.
**Intervention groups**
In group A, lidocaine 1.5 mg/kg, fentanyl 1 µg/kg and ketamine 0.5 mg/kg are prescribed. In group B, lidocaine 1.5 mg/kg, fentanyl 1 µg/kg and propofol 0.5 mg/kg are used.
**Main outcome variables**
Sedation; pain

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20220706055402N3**
Registration date: **2023-02-19, 1401/11/30**
Registration timing: **prospective**

Last update: **2023-02-19, 1401/11/30**
Update count: **0**
**Registration date**
2023-02-19, 1401/11/30

**Registrant information**
**Name**
Fatemeh Moftakhar
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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+98 61 3338 3372
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2023-02-20, 1401/12/01
**Expected recruitment end date**
2023-04-21, 1402/02/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of sedative effect of ketamine with propofol in patients undergoing colonoscopy

**Public title**
Sedative effect of ketamine with propofol in colonoscopy
**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age range of 18 to 65 years old Patient willingness to participate in the study Patients who are in the American Society of Anesthesiology class 1 and 2.

**Exclusion criteria:**

The patient's unwillingness to participate in the study Intestinal perforation during the procedure Esophageal or stomach or intestinal bleeding during the procedure Changing the type of procedure during colonoscopy or the need for surgery during the procedure

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

With the easy sampling method, the referring people who are eligible to enter the study are randomly divided into two intervention and control groups. In this study, the division of people is done by the four permutation block method. In this method, A represents an individual. is the one who receives the intervention and B represents the person who is placed in the control group. Considering the block of four, replace AABB with code 0, replace ABAB with code 1, replace ABBA with code 2, replace BAAB with code 3, replace with BBAA code 4 and BABA we give the code 5 to 9. Then, using the table of random numbers, we randomly choose a starting point and after that we consider 21 numbers in a row or column. Considering the order of the numbers in the table, for each We will replace the corresponding number with the number we found. Finally, by selecting 21 numbers from the table of allocation, the total of 120 people will be divided into two groups.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

After selecting the samples, the participants in the study, the endoscopic physician and the principal investigator are not aware of the allocation method and the drugs are injected by an anesthesiologist who is aware of the allocation and the data collection is done by them

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Golestan hospital, Ahvaz Jundishapur University of Medical Sciences

**Street address**

Golestan hospital,Golestan Ave,Golestan town

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135733118

**Approval date**

2022-12-13, 1401/09/22

**Ethics committee reference number**

IR.AJUMS.HGOLESTAN.REC.1401.159

## Health conditions studied

### 1

**Description of health condition studied**

Colonoscopy

**ICD-10 code**

T88.52

**ICD-10 code description**

Failed moderate sedation during procedure

## Primary outcomes

### 1

**Description**

Level of sedation

**Timepoint**

From start to end of colonoscopy

**Method of measurement**

Ramsay Sedation Scale

### 2

**Description**

Amount of pain

**Timepoint**

From start to one hour after colonoscopy

**Method of measurement**

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Lidocaine 1.5 mg/kg, fentanyl 1 µg/kg and ketamine 0.5 mg/kg are prescribed.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: Lidocaine 1.5 mg/kg, fentanyl 1 µg/kg and propofol 0.5 mg/kg are used.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam khomeini Hospital
**Full name of responsible person**
Reza Akhondzadeh
**Street address**
Imam Khomeini hospital,Azadegan street
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Mehrnoosh Zakerkish
**Street address**
Ahvaz University of medical science,Golestan street,Golestan town
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**Grant name**
Ahvaz University of Medical Sciences
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Ahvaz 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**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Fatemeh Moftakhar
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available