

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of sedation of midazolam and Ketamine with propofol and Ketamine in patients referring to endoscopy to Imam Khomeini Hospital in Ahwaz

Protocol summary

Study aim

Comparison of the effect of midazolam and ketamine with propofol and ketamine in sedation to patients referring to endoscopy

Design

Randomized double-blind randomized controlled clinical trial based on 128 endoscopic candidate patients with two parallel groups. Randomization is performed by sealed.envelope.com.

Settings and conduct

In this double-blind clinical trial, 128 candidates for endoscopy in Imam Khomeini Hospital in Ahwaz in 2019-2020 were examined. Individuals were randomly assigned to the groups. (The patients and the evaluator are unaware of the drug combination) In the first group, midazolam was prescribed 0.5 µg/kg + 1 mg /kg of ketamine for each patient with standard weight. In the second group, ketamine was used at the dose of 1 mg / kg + 0.5 µg/ kg of propofol. Then the patient outcomes were recorded and compared between the groups. The depth of relaxation was assessed using the Ramsey criterion. Data analysis was analyzed in SPSS software version 25.

Participants/Inclusion and exclusion criteria

Satisfaction to enter the study; Simultaneous use of some painkillers during colonoscopy; Having a body mass index between 21 and 24 Dissatisfaction with studying; Have a history of high blood pressure, diabetes, respiratory failure and liver and kidney disease, and a history of addiction, heart disease and drug dependence.

Intervention groups

Group (group A) Midazolam and ketamine and for the other group (group B) propofol and ketamine will be prescribed.

Main outcome variables

sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200610047723N1**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **retrospective**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Mojtaba Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3292 3985

Email address

mojtababagheri1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedation of midazolam and Ketamine with propofol and Ketamine in patients referring to endoscopy to Imam Khomeini Hospital in Ahwaz

Public title

Sedation of midazolam and ketamine with propofol and ketamine in endoscopy

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Having a body mass index between 21 and 24
Satisfaction to enter the study The patient is a candidate for endoscopy

Exclusion criteria:

Have a history of high blood pressure, diabetes, respiratory failure and liver and kidney disease, and a history of addiction, heart disease and drug dependence. Simultaneous use of some painkillers during endoscopy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Subject were grouped into two parts, with the four block randomization method. The randomization is accomplished by: sealdenvelope.com .Block randomization works by randomizing participants within blocks such that an equal number are assigned to each treatment. Allocation proceeds by randomly selecting one of the 6 blocks, AABB, ABAB, ABBA, BBAA, BAAB and BABA and substitution (number = n/4) till Sample size is accomplished.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to be blind, the patient has no information about which group she/he is in

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Esfand St., Shahr-e-Daneshgahi, Golestan Blvd

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Khouzestan

Postal code

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Approval date

2020-02-20, 1398/12/01

Ethics committee reference number

IR.AJUMS.REC.1398.388

Health conditions studied

1

Description of health condition studied

sedation for endoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sedation

Timepoint

One hour after the procedure

Method of measurement

(VAS) Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Midazolam is administered intravenously at a dose of 0.05 micrograms per kilogram for each patient of standard weight, followed by 1 mg per kilogram of ketamine as a bolus injection. The need for propolis injection is used at the rate of one third of the initial dose.

Category

Diagnosis

2

Description

Control group: Ketamine is administered as 1 mg per

kilogram as bolus, and propofol is injected at 0.5 micrograms per kilogram. If necessary, midazolam is injected at one-third of the initial dose.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Ehsan Karimi

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Imam Khomeini Educational and Medical Center,
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Baghbanian

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Grant name**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

Reza.baghbanian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ehsan Karimi Namch

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

Others

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

curd Data file

When the data will become available and for how long

6 month after publish till 10 year after publish in Scientific journals

To whom data/document is available

how formally Correspondence to research vice-chancellor of university

Under which criteria data/document could be used

for using in secondary study

From where data/document is obtainable

research vice-chancellor of university website or correspondent author of article

What processes are involved for a request to access data/document

after get permission of research vice-chancellor of university data were send

Comments