

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of midazolam - propofol versus midazolam - ketamin in sedative endoscopy in out patients since April until the end of November 2019 at the Ahvaz Imam Khomeini Hospital

#### Protocol summary

##### Study aim

Comparison of midazolam – propofol versus midazolam – ketamin in sedative endoscopy in out patients since April until the end of November 2019 at the Ahvaz Imam Khomeini Hospital

##### Design

A randomized controlled clinical trial with parallel randomized groups; double blind

##### Settings and conduct

After obtaining permission from the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, 78 patients Gastrointestinal Endoscopy in the Endoscopy Department of Imam Khomeini Hospital in Ahvaz. The study is selected as a double-blind randomized clinical trial. Prescription drugs are not known) 78 patients will be included in the study

##### Participants/Inclusion and exclusion criteria

Patients candidate for endoscopy; age 20 to 60 years old; weight 55 to 85 kg; being in ASA class one or two

##### Intervention groups

One group uses midazolam and propofol and the other group uses midazolam and ketamine.

##### Main outcome variables

Relaxation; Pain; Nausea and Vomiting; Duration of recovery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191201045566N1**

Registration date: **2020-09-06, 1399/06/16**

Registration timing: **retrospective**

Last update: **2020-09-06, 1399/06/16**

Update count: **0**

##### Registration date

2020-09-06, 1399/06/16

##### Registrant information

###### Name

Nazanin Ahesteh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3340 2531

###### Email address

mohamadlovely26@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-09-30, 1398/07/08

##### Expected recruitment end date

2019-10-20, 1398/07/28

##### Actual recruitment start date

2019-09-30, 1398/07/08

##### Actual recruitment end date

2019-10-12, 1398/07/20

##### Trial completion date

2019-10-12, 1398/07/20

##### Scientific title

Comparison of midazolam – propofol versus midazolam – ketamin in sedative endoscopy in out patients since April until the end of November 2019 at the Ahvaz Imam Khomeini Hospital

##### Public title

Comparison of midazolam – propofol versus midazolam – ketamin in sedative endoscopy in out patients

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All endoscopic patients Age 20 to 60 years Weight 55 to 85 kg Being in ASA class one or two

### Exclusion criteria:

Blood pressure history Diabetes Respiratory failure Liver problem Kidney problem Addiction Heart disease Drug allergy

## Age

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

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **78**

Actual sample size reached: **78**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple Randomization Method Individual Randomization Unit Randomization Tool: Statistical software

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is a double blind study after the patient is fully aware of the research and the researcher and patient are not aware of the type of prescription drugs.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz University City - Deputy of Research and Technology - Information Office

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

#### Approval date

2019-09-28, 1398/07/06

## Ethics committee reference number

IR.AJUMS.REC/1398/470

## Health conditions studied

### 1

#### Description of health condition studied

Endoscopy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Sedation

#### Timepoint

From the moment of injection and during injection and after waking up

#### Method of measurement

Based on the Ramsey variable

### 2

#### Description

Comparison of nausea and vomiting in two groups of midazolam - propofol with midazolam - ketamine in patients undergoing outpatient endoscopy

#### Timepoint

From the end of the procedure to the time of leaving the recovery

#### Method of measurement

Visual analoge scale

### 3

#### Description

Comparison of postoperative pain in patients in two groups of midazolam-propofol with midazolam-ketamine in patients undergoing outpatient endoscopy

#### Timepoint

At the beginning of the procedure, the end of the procedure and one hour after the end of the procedure

#### Method of measurement

Ambesh score

### 4

#### Description

Comparison of recovery time in patients between the two groups of midazolam-propofol with midazolam-ketamine in patients undergoing outpatient endoscopy

#### Timepoint

From the time the procedure was completed to the patient's alertness and appropriate response to questions, recovery time was considered (every 30 seconds, recovery was assessed).

#### Method of measurement

Less than 5 minutes fast, between 5-10 minutes medium and more than 10 minutes slow recovery

## 5

### Description

Comparison of hemodynamic changes in the two groups of midazolam-propofol with midazolam-ketamine in patients undergoing outpatient endoscopy

### Timepoint

Vital signs (including heart rate, systolic and diastolic blood pressure, and oxygen saturation) before, and during, induction

### Method of measurement

Heart rate per minute and systolic and diastolic blood pressure based on millimeters of mercury and arterial blood oxygen saturation

## 6

### Description

Age, sex and weight in patients in the two groups of midazolam - propofol with midazolam - ketamine in patients undergoing outpatient endoscopy

### Timepoint

On arrival

### Method of measurement

Age based on number of years of life and weight based on kg and sex based on phenotype

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Both groups were given fentanyl at a dose of 0.5 micrograms per kilogram. In group A, midazolam was administered intravenously at a rate of 0.5 micrograms per kilogram for each patient of standard weight, followed by bolus injection of 0.7 milligrams per kilogram of propofol. If necessary, an infusion of propofol at one-third of the initial dose was used

#### Category

Other

### 2

#### Description

Intervention group: Fentanyl was administered at a dose of 0.5 micrograms per kilogram. In group B, ketamine at a dose of 0.5 milligrams per kilogram was injected as a bolus and midazolam at a dose of 0.5 micrograms per kilogram, if necessary. Propofol infusion was used at a rate of one third of the initial dose.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

#### Name of recruitment center

Emam Khomeini hospital

#### Full name of responsible person

Nazanin Ahesteh

#### Street address

Azadegan St. - Imam Khomeini Medical Center of Ahvaz

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

۶۱۹۳۶۷۳۱۶۶

#### Phone

+98 61 3222 2922

#### Email

himam@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Badavi

##### Street address

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

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794 61357

##### Phone

+98 61 3336 7543

##### Email

jsmj@ajums.ac.ir

#### 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**

Dr Reza Baqbanian

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Khomeini Medical Center of Ahvaz, Azadegan St.

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Ahvaz

**Province**

Khuzestan

**Postal code**

6193673166

**Phone**

+98 61 3222 0168

**Email**

baghbanian-r@ajums.ac.ir

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr Reza Baqbanian

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Khomeini Medical Center of Ahvaz, Azadegan St.

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**Postal code**

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**Email**

baghbanian-r@ajums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Nazanin Ahesteh

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

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

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3336 7543

**Fax****Email**

mohamadlovely26@yahoo.com

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All potential data can be shared after unidentified individuals

**When the data will become available and for how long**

Start of access period 6 months after printing the results

**To whom data/document is available**

It will be available only to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

For the purpose of scientific research in the field of anesthesia and in compliance with medical ethics

**From where data/document is obtainable**

Ahvaz - University City - Ahvaz Jundishapur University of Medical Sciences - Central Library Building - First Floor - PO Box: 158 Postal Code: 15794-61357 Phone 3311-061 E-mail: info@ajums.ac.ir

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

Request by e-mail from the Central Library of Jundishapur University of Medical Sciences and then check the eligibility to provide data to individuals and then the availability of data

**Comments**