Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Khouzestan

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
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Khouzestan
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۶۱۹۳۶۷۳۱۶۶
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+98 61 3222 2922
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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,
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15794 61357
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
Nazanin Ahesteh
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Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Ahvaz Jundishapur University of Medical Sciences, Shahr-e-Daneshgahi, Esfand St., Golestan Blvd.
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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