Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the sedative efficacy of propofol-ketamine combination versus propofol-ketamine plus lidocaine spray in outpatient endoscopy

Protocol summary

Study aim

Comparison of the sedative efficacy of propofol-ketamine combination versus propofol-ketamine plus lidocaine spray in outpatient endoscopy

Design

The clinical trial has two intervention groups, with parallel, double-blind groups randomized on 154 patients, 77 people in each group. Randomization is based on 4 random shifts.

Settings and conduct

After connecting the monitors to the patients in both groups, first the vital signs including systolic and diastolic blood pressure, heart rate and blood oxygen saturation percentage are measured and record the result in the file,a vein is taken from the cubital area. In the first group, 0.5 mg per kg of propofol plus 0.5 mg per kg of ketamine and in the second group 0.5 mg per kg of propofol and 0.5 mg per kg of ketamine and then 2 puffs of spray. 10% lidocaine equals 20 grams.Then the amount of sedation is measured based on Ramsay score and the nausa and vomiting of patients based on visual analogue score from the end of the procedure until the time of recovery will be recorded.

Participants/Inclusion and exclusion criteria

Candidate patients for endoscopy who require anesthesia in the age range of 18 to 65 years old with Classification of Group 1 American Society of Anesthesiologists (ASA Class I) are selected as inclusion criteria. As exclusion criteria,the patient's unwillingness to participate in the study,age less than 18 years or more than 65 years,cardiovascular disease ,kidney failure or liver failure,drug addiction,having contraindication to propofol ketamine or lidocaine spray or patient with esophageal or gastric perforation during the procedure,Changing the type of procedure during endoscopy or the need for surgery are excluded from the study.

Intervention groups

In the first intervention group, Propofol Ketamine and in the second intervention group, Propofol Ketamin plus Lidocaine spray is used.

Main outcome variables

sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201027049160N1**
Registration date: **2020-11-04, 1399/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-04, 1399/08/14**
Update count: **0**

Registration date

2020-11-04, 1399/08/14

Registrant information

Name

Sheida Kiamohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the sedative efficacy of propofol-ketamine combination versus propofol-ketamine plus lidocaine spray in outpatient endoscopy

Public title
Comparison of sedative efficacy of propofol-ketamine versus propofol-ketamin plus lidocaine spray outside the operating room
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients for endoscopy who require anesthesia In the age range of 18 to 65 years old Classification of Group 1 American Society of Anesthesiologists (ASA Class I) are selected as inclusion criteria
Exclusion criteria:
the patient's unwillingness to participate in the study Age less than 18 years or more than 65 years They have cardiovascular disease They have kidney failure or liver failure They are addicted Contraindicated propofol ketamine or lidocaine spray Esophageal or gastric perforation during the procedure Esophageal or gastric bleeding during the procedure Changing the type of procedure during endoscopy or the need for surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **154**
Randomization (investigator's opinion)
Randomized
Randomization description
The number of patients will be randomly divided into four groups based on the case number.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to double blind the study, the patient's degree of sedation is recorded according to a modified Ramsay standard during the procedure by another person who does not know the medication prescribed to the patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی جندی شاپور اهواز
Street address
Golestan Hospital, Golestan BLVD
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2020-06-07, 1399/03/18
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1399.011

Health conditions studied

1

Description of health condition studied
Sedation management of patients referred for Endoscopy and reduce their anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
A score of 5 or 6 Ramsay criteria in the questionnaire. Ramsay sedation criteria including 6 scores is as follows: 1. Completely awake and anxious 2. Quiet and calm with enough cooperation 3. Asleep and wakes up with a verbal command 4. Asleep and woke up with mild stimulation, but gives a strong reaction to painful stimuli 5. Slow reaction to painful stimuli 6. Lack of reaction to painful stimulition
Timepoint
5 minutes after the procedure, 10 minutes after the procedure, 15 minutes after the procedure
Method of measurement
Verbal measurement criteria

Secondary outcomes

1

Description
Recovery time
Timepoint
Recovery time is defined as fast (less than 5 minutes), medium (between 5 to 10 minutes) and slow (more than

15 minutes)

Method of measurement

Patient's appropriate answers to questions

2

Description

nausa and vomiting of patients based on visual analogue score from the end of the procedure until the time of recovery will be recorded.

Timepoint

Every 5 minutes

Method of measurement

It is expressed by the person herself/himself

3

Description

Blood pressure

Timepoint

Every 5 minutes

Method of measurement

Blood pressure monitor

4

Description

Heart beat

Timepoint

Every 5 minute

Method of measurement

Cardaic monitor

5

Description

Arterial blood oxygen saturation

Timepoint

Every 5 minutes

Method of measurement

Respiratory monitor

Intervention groups

1

Description

Control group: The group receiving Propofol Ketamin for sedation during Endoscopy.

Category

Treatment - Drugs

2

Description

Intervention group: The group receiving Propofol Ketamin plus Lidocaine spray for sedation during Endoscopy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Reza Akhondzade

Street address

No.1519 , Shahid Ahvazian Ave, Azadegan St. Ahvaz Imam Khomeini 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 Akhondzade

Street address

Unit 3,Second floors,Ferdos Building,NO.57,Second West Street,Phase One,Chamran Blvd,kianpars

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rezaakh@hotmail.com

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 Akhondzade

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Reza Akhondzade

Position
Associate professor

Latest degree
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Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
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Sheida Kiamohammadi

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
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
The Excel file contains the identification code, reference to the file number and the registered information, except for the documents that can be provided.

When the data will become available and for how long
6 months after printing the results until 10 years later

To whom data/document is available
All those who officially correspond with the Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Under which criteria data/document could be used
Documents can be used for systematic review studies and meta-analysis

From where data/document is obtainable
Vice Chancellor for Research Ahvaz Jundishapur University

What processes are involved for a request to access data/document
After approval from the Vice Chancellor for Research, the data file will be provided to the Vice Chancellor and then the data will be shared with other researchers or emailed to them.

Comments