Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the sedative effect of intravenous lidocaine in patients undergoing Endoscopy with Propofol-Ketamine

Protocol summary

Study aim

Identifying the effect of intravenous lidocaine on reducing complications and unpleasant reactions in patients undergoing endoscopy with propofol-ketamine including pain reduction, reduction of nausea and vomiting, reduction of apnea frequency and hemodynamic instability, and reduction of length of stay in recovery

Design

The clinical trial with control group, double blind,Parallel group,randomised, phase 3 on 138 patients, patients with simple randomization of quadruple permutation block will be divided into two groups of intervention and control that the intervention group will receive Propofol, Ketamine and intravenous Lidocaine and the control group will receive Propofol and Ketamine.

Settings and conduct

Outpatient endoscopic candidates referred to the ahvaz imam khomeini hospital will be divided into intervention and control groups.The present study is double-blind so that patients and physicians will be unaware of the allocation of the control group and the intervention group.

Participants/Inclusion and exclusion criteria

patients between 18 to 65 years age who are candidates for endoscopy that classified as group 1 and 2 according to the American Society of Anesthesiology (ASA Class) and who do not have severe heart or lung disease, kidney or liver failure, and allergies to Propofol, Ketamine, or Lidocaine will be included in this study.

Intervention groups

Intervention group:receives 0.5 mg per kg of Propofol, 0.5 mg per kg of Ketamine and 1.5 mg per kg of intravenous Lidocaine Control group:receives 0.5 mg per kg of Propofol and 0.5 mg per kg of Ketamine

Main outcome variables

Sedation level, Hemodynamic instability, drug use level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220221054090N1**
Registration date: **2022-06-03, 1401/03/13**
Registration timing: **prospective**

Last update: **2022-06-03, 1401/03/13**
Update count: **0**

Registration date

2022-06-03, 1401/03/13

Registrant information

Name

Hossein Keshavarzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5677 8987

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ghossein.hk@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the sedative effect of intravenous lidocaine in patients undergoing Endoscopy with Propofol-Ketamine

Public title
Effect of intravenous Lidocaine in Endoscopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients under 18 to 65 years of age who are in groups 1 and 2 according to the American Society of Anesthesiology (ASA Class)
Exclusion criteria:
Patients with severe heart or lung disease are not included in this study Patients with Renal failure are not included in this study Patients with Liver failure are not included in this study Patients allergic to Propofol, Ketamine, or Lidocaine are not included in this study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **138**
Randomization (investigator's opinion)
Randomized
Randomization description
By easy sampling method, the patients who are eligible to enter the study are randomly divided into two groups of intervention and control. In this study, the individuals are divided into four quadratic block methods.A Is the person receiving the intervention, and B represents the person in the control group.Considering the quadruple block, instead of AABB code 0, instead of ABAB code 1, give ABBA code 2, BAAB code 3, BBAA code 4 and BABA code 5 to 9. Then, using the table of random numbers, we randomly select the starting point and then consider 21 numbers as rows or columns. Whatever number we encounter, we replace the corresponding permutation.Finally, by selecting 21 items from the table, a total of 138 people will be divided into two groups
Blinding (investigator's opinion)
Double blinded
Blinding description
After selecting the samples, the study participants, the endoscopist, and the principal investigator are unaware of the allocation, and the drugs are injected by an anesthesiologist who is aware of the allocation, and the data are collected 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 Educational-Research and Treatment Center of Ahvaz Jundishapur Universi
Street address
Golestan hospital,Golestan Ave,Golestan town
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2021-10-19, 1400/07/27
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1400.157

Health conditions studied

1

Description of health condition studied
Endoscopy,Sedation
ICD-10 code
T88.52
ICD-10 code description
Failed moderate sedation during procedure

Primary outcomes

1

Description
Total amount of Propofol consumed
Timepoint
From start to end of endoscopy
Method of measurement
Dose of drug

2

Description
Level of sedation
Timepoint
From start to end of endoscopy
Method of measurement
Ramsay Sedation Scale

3

Description
Amount of pain
Timepoint
From start to one hour after Endoscopy

Method of measurement
Visual Analogue Scale

4

Description
Amount of Nausea and Vomiting
Timepoint
From start to end of Endoscopy
Method of measurement
Visual Analogue Scale

5

Description
Time of recovery
Timepoint
From start to end of Endoscopy
Method of measurement
From end of endoscopy to full consciousness

6

Description
Hemodynamic instability
Timepoint
From start to end of Endoscopy
Method of measurement
Amount of Heart rate, mean arterial pressure and blood oxygen saturation changes

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The intervention group will receive Propofol 0.5 mg/kg and Ketamine 0.5 mg/kg, intravenous Lidocaine 2% 1.5 mg/kg made in Daroupakhsh company in Iran
Category
Treatment - Drugs

2

Description
Control group: The control group will receive propofol 0.5 mg/kg and ketamine 0.5 mg/kg
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
City
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6193673111
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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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06133110000
Phone
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itc@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
Hossein Keshavarzi

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)
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