Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the Effect of Three Different Ketamine doses on Quality of Sedation in Bronchoscopy

Protocol summary

Study aim
Determining and comparing the effect of three different doses of ketamine on the quality of sedation in bronchoscopy

Design
Clinical trial with 3 parallel groups; double-blind, randomized, phase 2 on 90 patients; for randomization using Randomization and Minimization software

Settings and conduct
Study place: Operating room of Al-Zahra Hospital in Isfahan, Type of blindness: double blinding, method of blindness:Randomization is performed by an expert who is not a member of the research team and the codes will be kept in a sealed envelope until the end of the study. Preparation of drugs and its injection will be performed by an anesthesiologist who had no role in collecting information

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who are candidates for Bronchoscopy; Patients Age over 18 years; ASA Class 1 and 2 Non-inclusion criteria: Mental Disorders; History of Chronic Sedative Drug use; Drug and Alcohol use disorders; any Allergy to the Medications use in this study; Take Sedative or Analgesics 24 hours before the Procedure

Intervention groups
Intervention group 1: ketamine 0.2mg/kg is added to the pump syringe containing propofol and intravenous bolus dose is gradually injected until reaches the sedation level Score Ramsey 3 and then bronchoscopy is performed and the infusion is continued. Intervention group 2: ketamine 0.4mg/kg is added to the pump syringe containing propofol and intravenous bolus dose is gradually injected until it reaches the sedation level Score Ramsey 3 and then bronchoscopy is performed and the infusion is continued. Intervention group 3: ketamine 0.5 mg/kg is added to the pump syringe containing propofol and intravenous bolus dose is gradually injected until it reaches the sedation level Score Ramsey 3 and then bronchoscopy is performed and the infusion is continued.

Main outcome variables
Sedation level based on Ramsay score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039326N17**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**
Update count: **0**

Registration date
2020-12-10, 1399/09/20

Registrant information

Name
Hamidreza Shetabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3620 2020

Email address
hamidshetabi@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Three Different Ketamine doses on Quality of Sedation in Bronchoscopy

Public title
Effect of Ketamine on Sedation in Bronchoscopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for Bronchoscopy Being at the age over 18 years old Patients whit ASA class 1 and 2
Exclusion criteria:
Patient disinclination Mental disorders History of chronic sedative drug use Opioid and alcohol use disorders History of any allergy to any medications use in the study Take sedative or analgesics 24 hours before the procedure
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into three groups based on the table created by randomization software (Randomization and Minimization). Randomization is performed by an expert who is not a member of the research team, and each code will be stored in a sealed envelope until the end of the study. On the day of surgery, patients enter the operating room based on the numbers assigned to them
Blinding (investigator's opinion)
Double blinded
Blinding description
On the day of surgery, patients enter the operating room based on the numbers assigned to them. The medications will be prepared and injected by an anesthesiologist who has no role in collecting the information. An observer who is unaware of the grouping of patients and prescribes drugs records the results of the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Al-Zahra Hospital; Sofe bolevard
City
Isfahan
Province
Isfehan
Postal code
8174675731
Approval date
2020-11-09, 1399/08/19
Ethics committee reference number
IR.MUI.MED.REC.1399.704

Health conditions studied

1

Description of health condition studied
Bronchoscopy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sedation level based on Ramsay score
Timepoint
During the operation every 5 minutes and then in recovery room every 15 minutes, until recovery from recovery room
Method of measurement
questionnaire

Secondary outcomes

1

Description
Heart Rate
Timepoint
Before the operation, During the operation every 5 minutes and then in recovery every 15 minutes, until recovery from recovery
Method of measurement
monitoring

2

Description
Systolic blood pressure
Timepoint
Before the operation, During the operation every 5 minutes and then in recovery every 15 minutes, until recovery from recovery
Method of measurement
monitoring

3

Description
Diastolic blood pressure
Timepoint
Before the operation, During the operation every 5 minutes and then in recovery every 15 minutes, until recovery from recovery
Method of measurement
monitoring

4

Description
Mean Atrial Pressure
Timepoint
Before the operation, During the operation every 5 minutes and then in recovery every 15 minutes, until recovery from recovery
Method of measurement
monitoring

5

Description
Percentage of arterial oxygen saturation
Timepoint
Before the operation, During the operation every 5 minutes and then in recovery every 15 minutes, until recovery from recovery
Method of measurement
monitoring

6

Description
Complications during the procedure (hypo tension, hypertension, tachycardia, bradycardia, pain ...)
Timepoint
During the operation every 5 minutes minutes
Method of measurement
questionnaire

7

Description
Complications in recovery (vomiting nausea ...)
Timepoint
in recovery every 15 minutes, until recovery from recovery
Method of measurement
questionnaire

8

Description
Duration of stay in recovery
Timepoint
per minutes
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group 1 (The first group of Ketamine 0.2 mg/kg): Propofol 1.5 mg/kg is drawn into the pump syringe and according to the grouping, Ketamine is added to Propofol and the syringe volume is reduced to 15 ml. Sedation is started by gradual bolus injection of 50-100mcg / kg Propofol based on pump syringe Reaching the desired sedation level 3 based on Ramsey Continuation of sedation continues at an infusion rate of 50-100mcg / kg Propofol. If more sedation is needed, 0.5 mg / kg Propofol (5 mg/ml) will be injected in all three groups. If you feel pain during the procedure in all three groups of Fentanyl 1mcg / kg and if you feel pain in recovery, Apotel will be used at a dose of 15 mg/kg.
Category
Treatment - Drugs

2

Description
Intervention group 2 (the second group of ketamine 0.4 mg/kg): Propofol 1.5 mg / kg is drawn into the pump syringe and according to the grouping, Ketamine is added to Propofol and the syringe volume is reduced to 15 ml.Sedation is started by gradual bolus injection of 50-100mcg / kg Propofol based on pump syringe Reaching the desired sedation level 3 based on Ramsey Continuation of sedation continues at an infusion rate of 50-100mcg / kg Propofol.If more sedation is needed, 0.5 mg / kg Propofol (5 mg / ml) will be injected in all three groups. If you feel pain during the procedure in all three groups of Fentanyl 1mcg / kg and if you feel pain in recovery, Apotel will be used at a dose of 15 mg / kg.
Category
Treatment - Drugs

3

Description
Intervention group 3 (the third group of ketamine 0.5mg / kg): Propofol 1.5 mg / kg is drawn into the pump syringe and according to the grouping, Ketamine is added to Propofol and the syringe volume is reduced to 15 ml.Sedation is started by gradual bolus injection of 50-100mcg / kg Propofol based on pump syringe Reaching the desired sedation level 3 based on Ramsey Continuation of sedation continues at an infusion rate of 50-100mcg / kg Propofol.If more sedation is needed, 0.5 mg / kg Propofol (5 mg / ml) will be injected in all three groups. If you feel pain during the procedure in all three

groups of Fentanyl 1mcg / kg and if you feel pain in recovery, Apotel will be used at a dose of 15 mg / kg.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-zahra hospital

Full name of responsible person
Hamidreza Shetabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghju

Street address
Building No. 4; Vice Chancellor for Research and Technology; Isfahan University of Medical Sciences and Health Services; Hezar Jerib street

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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Hamidraza Shetabi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Al-Zahra Hospital; Sofe bolevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Hamidraza Shetabi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

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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
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Data include sedation and hemodynamic indices and complications in all three intervention groups after unidentifiable individuals can be shared.

When the data will become available and for how long
6 months after publication of paper

To whom data/document is available
Academic and medical researchers

Under which criteria data/document could be used
Use for research and treatment purposes

From where data/document is obtainable
Email of the person in charge of public accountability: Hamidshetabi@med.mui.ac.ir

What processes are involved for a request to access data/document
Upon request, it will be sent via email if available within a maximum of 1 month

Comments