Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of hemodynamic changes caused by induction of anesthesia with Ketamine-Propofol, and Etomidate in patients over 65 years old

Protocol summary

Study aim
Comparison of hemodynamic changes caused by induction of anesthesia with Ketamine-Propofol, and Etomidate in patients over 65 years old

Design
A parallel-group, triple-blind, randomized, phase 2 clinical trial on 90 patients. Random allocation software is used for randomization.

Settings and conduct
This is a three-blind randomized clinical trial that will be conducted on 90 patients in Al-Zahra Hospital, Isfahan. After the approval of the ethics committee of the university and obtaining the consent of the patients, the patients are randomly assigned into groups, in each group the desired intervention is applied and the clinical symptoms of the patient are recorded. The researcher who records the patient's symptoms, the analysts who collect the data analyzed during the study, and the patients did not know the type of intervention applied in each group, so they were all blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 65 years, candidate for elective surgery under general anesthesia, ASA class I and II, informed consent to participate in the study. Non-Inclusion criteria: history of drug, alcohol, and benzodiazepine use, BMI higher than 30, history of seizures, adrenal insufficiency, high blood pressure

Intervention groups
Intervention group A: Patients in this group first received 2 micrograms/kg of Fentanyl and 2mg of intravenous Midazolam. Then, they receive 0.6 mg/kg Atracurium and 1.5 mg/kg Lidocaine, as well as 0.3 mg/kg Etomidate at a rate of 0.1mg/kg/min to induce anesthesia. Intervention group B: Patients in this group first received 2 micrograms/kg of Fentanyl and 2mg of intravenous Midazolam. Then, they receive 0.6 mg/kg of Atracurium and 1.5 mg/kg of Lidocaine, as well as 1.5 mg/kg of Propofol at a rate of 0.5 cc/s and 0.5 mg/kg of Ketamine at a rate of 0.5 mg/kg/min to induce anesthesia.

Main outcome variables
Blood Pressure; Heart Rate; O2 Sat

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160307026950N46**
Registration date: **2022-09-24, 1401/07/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-24, 1401/07/02**
Update count: **0**

Registration date
2022-09-24, 1401/07/02

Registrant information

Name
Behzad Nazemroaya

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Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic changes caused by induction of anesthesia with Ketamine-Propofol, and Etomidate in patients over 65 years old

Public title

Comparison of hemodynamic changes caused by induction of anesthesia with Ketamine-Propofol and Etomidate

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 65 years old Candidate for elective surgery under general anesthesia Anesthesia class I and II according to ASA criteria Informed consent to enter the study

Exclusion criteria:

History of drug, alcohol and Benzodiazepine use BMI (Body Mass Index)>30 History of seizures Adrenal gland failure High Blood Pressure Candidate for Craniotomy surgery

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by the simple method in which each patient will be assigned a code using a random number table (Random allocation software) and Patients fall into one of two groups depending on whether these codes are even or odd. This continues until the number of patients in both groups reaches the required number.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a triple blind clinical trial; In this way, the patient is included in the study but does not know the type of intervention applied and is blind, the researcher who records the patient's symptoms is also different from the person who injects the drug and without knowing the type of drug only records the patient's symptoms during the study and therefore is kept blind. The analysts who analyze the data collected during the study also do not know the type of intervention applied in each group and are blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2022-07-19, 1401/04/28

Ethics committee reference number

IR.MUI.MED.REC.1401.162

Health conditions studied

1

Description of health condition studied

Hemodynamic changes in anesthesia induction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood Pressure

Timepoint

before induction of anesthesia, after induction of anesthesia, before laryngoscopy, 1, 3, 5 and 10 minutes after laryngoscopy

Method of measurement

Sphygmomanometer

2

Description

Heart Rate

Timepoint

before induction of anesthesia, after induction of anesthesia, before laryngoscopy, 1, 3, 5 and 10 minutes after laryngoscopy

Method of measurement

Electrocardiogram

3

Description
O2 Saturation
Timepoint
before induction of anesthesia, after induction of anesthesia, before laryngoscopy, 1, 3, 5 and 10 minutes after laryngoscopy
Method of measurement
Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group A: Patients in this group received 2 Micrograms/kg of fentanyl manufactured by Aburihan Pharmaceutical Company and 2mg of intravenous Midazolam manufactured by Elixir Pharmaceutical Company after connecting the monitoring devices and preparing vital sign recording devices. Then 0.6mg/kg Atracurium was manufactured by Caspian Pharmaceutical Company and 1.5mg/kg Lidocaine was manufactured by Caspian Pharmaceutical Company as well as 0.3mg/kg Etomidate was manufactured by Ayman Sahar Pharmaceutical Company at a rate of 0.1mg/kg/min for induction of anesthesia and after About three minutes of ventilation with a face mask, tracheal intubation is performed, and the patient's symptoms are measured and recorded.
Category
Diagnosis

2

Description
Intervention group B: Patients in this group received 2 Micrograms/kg of fentanyl manufactured by Aburihan Pharmaceutical Company and 2mg of intravenous Midazolam manufactured by Elixir Pharmaceutical Company after connecting the monitoring and preparing vital sign recording devices. Then 0.6mg/kg of Atracurium manufactured by Caspian Pharmaceutical Company and 1.5mg/kg of Lidocaine manufactured by Caspian Pharmaceutical Company and also 1.5mg/kg of Propofol produced by Darman Yab Daro Company at a speed of 0.5cc/s and 0.5mg/kg of Ketamine produced by Darman Yab Daro Company. are given at a rate of 0.5 mg/kg/min to induce anesthesia, and after about three minutes of ventilation with a face mask, tracheal intubation is performed and the patient's symptoms are measured and recorded.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Behzad Nazem Roaya
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Marzieh Soheyli Pur

Position
Anesthesiology resident

Latest degree
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Other areas of specialty/work
Anesthesiology

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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