Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of two drug combinations: Etomidate-Sufentanil with Ketamine-Sufentanil-Midazolam on changes in heart rate and blood pressure after laryngoscopy and endotracheal intubation

Protocol summary

Study aim
To determine and compare the effects of two different combinations Etomidate-Sufentanil with Ketamine-Sufentanil-Midazolam on heart rate and blood pressure changes after laryngoscopy and endotracheal intubation

Design
Three arm clinical trial with study control group, parallel group trial of 96 patients with blinded outcome assessment. Randomisation was centralised and computerised with randomized allocation software.

Settings and conduct
A clinical trial on 96 patients who will refer to the operating room center of Al-Zahra Hospital in Isfahan in the years 2020-2021. Patients, the physician who will collect the data, and the statistician who will analyze the data will not be informed about the patient's study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18 to 65 years, Patients with ASA I or ASA II, Patients who are candidates for elective surgery under general anesthesia requiring tracheal intubation. Exclusion criteria: Patients with cardiac, hepatic and renal insufficiency, patients with drug addictions, patients with airway anomalies

Intervention groups
First group receive Etomidate 0.3 milligram per kilogram plus Sufentanil 0.1 microgram per kilogram, Atracurium and Lidocaine. Second group receive Ketamine 0.5 milligram per kilogram plus Sufentanil 0.1 microgram per kilogram plus Midazolam 0.07 milligram per kilogram, Atracurium and Lidocaine. Third group which is the control group receive Etomidate 0.3 milligram per kilogram, Atracurium, Lidocaine and also normal saline.

Main outcome variables
Systolic blood pressure; Diastolic blood pressure; Mean blood pressure; Arterial oxygen saturation; Mean heart rate; ST-T changes in electrocardiogram

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090129001615N4**
Registration date: **2020-10-28, 1399/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-28, 1399/08/07**
Update count: **0**

Registration date
2020-10-28, 1399/08/07

Registrant information

Name
Azim Honarmand

Name of organization / entity
Alzahra hospital

Country
Iran (Islamic Republic of)

Phone
+98 31 3668 0048

Email address
honarmand@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of two drug combinations: Etomidate-Sufentanil with Ketamine-Sufentanil-Midazolam on changes in heart rate and blood pressure after laryngoscopy and endotracheal intubation

Public title
Comparison of the effect of two drug combinations: Etomidate-Sufentanil with Ketamine-Sufentanil-Midazolam during laryngoscopy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with ASA (American Society of Anesthesiologists) grade:1 or 2 Patients aged 18 to 65 years Patients who need tracheal intubation and general anesthesia

Exclusion criteria:
Patients with heart failure disease Patients who are addicted to drugs Patients with airway anomalies Patients with hepatic failure disease Patients with renal failure disease Patients with over 65 years or under 18 years

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using Random Allocation software version 2.0. Ninety-six patients will be divided into 8 blocks of 12 members. For example, the first block will be included 12 patients that will be ordered non sequentially. The unit of randomization will be individualized. For allocation concealment, the physician administering the study drugs will not be informed from sequence of group assignment.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Blinding will be performed as such: The physician who will collect the patient’s data and the statistician who will analyze data, have no information from the study group assignments. The study drugs will be injected by similar syringes in volume and color and they also will be administered for patients after induction of anesthesia so the patients will have no information about the injected drugs.

Placebo
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
Hezarjerib Ave.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-08-31, 1399/06/10

Ethics committee reference number
IR.MUI.MED.REC.1399.438

Health conditions studied

1

Description of health condition studied
patients who need general anesthesia with tracheal intubation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Systolic blood pressure mean in each group

Timepoint
Before intervention and 1, 3, 5 and 10 minutes after laryngoscopy

Method of measurement
Blood pressure manometer

2

Description
Diastolic blood pressure mean in each group

Timepoint
Before intervention and 1, 3, 5 and 10 minutes after laryngoscopy

Method of measurement

Blood pressure manometer

3

Description
Heart rate mean in each group
Timepoint
Before intervention and 1, 3, 5 and 10 minutes after laryngoscopy
Method of measurement
Heart monitoring device

Secondary outcomes

1

Description
Arterial oxygen saturation mean in each group
Timepoint
Before intervention and 1, 3, 5 and 10 minutes after laryngoscopy
Method of measurement
Pulse oximeter

2

Description
Electrocardiogram ST-T changes relative frequency in each group
Timepoint
Before intervention and 1, 3, 5 and 10 minutes after laryngoscopy
Method of measurement
Electrocardiogram

Intervention groups

1

Description
Intervention group 1: Patients will receive Etomidate (10 cc ampoules, 2 milligrams per cc, made by Abu Reihan Pharmaceutical Company) in the amount of 0.3 milligrams per kilogram body weight and Sufentanil (5 microgram ampoules per milliliter, made by the service institute Razavi drug) in the amount of 0.1 micrograms per kilogram of body weight. Both drugs will be injected intravenously and at the beginning of induction of anesthesia.
Category
Prevention

2

Description
Intervention group 2: Patients will receive Ketamine (50 milligrams per milliliter ampoule, made by Razavi Pharmaceutical Services Institute) in the amount of 0.5 milligrams per kilogram body weight, Sufentanil in the amount of 0.1 micrograms per kilogram body weight and Midazolam (5 milligrams per milliliter ampoule, made by Razavi Pharmaceutical Services Institute) in the amount of 0.07 milligrams per kilogram body weight. Both drugs will be injected intravenously and at the beginning of induction of anesthesia.
Category
Prevention

3

Description
Control group: Patients will receive Etomidate in the amount of 0.3 milligrams per kilogram body weight as well as normal saline (manufactured by Samen Pharmaceutical Company) as a placebo. Both will be injected intravenously and at the beginning of induction anesthesia.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al zahra hospital
Full name of responsible person
Kimia Karimian
Street address
Al Zahra hospital, Shohadayeh Sofeh Blvd.
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Isfehan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Azim Honarmand
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honarmand@med.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
Azim Honarmand

Position
professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
There is no collected data yet. After collecting patients' information and making patient’s identities unrecognizable, all the information will be published in an article.

When the data will become available and for how long
Since the publication of the article

To whom data/document is available

Researchers working in academic, scientific and industrial institutes

Under which criteria data/document could be used

Data publication will be done for additional statistical analysis after verifying the validity of the research center or the researcher who has requested the data.

From where data/document is obtainable

Dr Azim Honarmand honarmand@med.mui.ac.ir

What processes are involved for a request to access data/document

The request for data will be answered 1 to 2 weeks after receiving email from the research center or the researcher.

Comments