Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study of administration of low dose ketamine with lidocaine on changes in heart rate and blood pressure during tracheal intubation under general anesthesia.

Protocol summary

Study aim
Determination and comparison of low-dose ketamine administration with lidocaine on heart rate and blood pressure changes during tracheal intubation

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 90 patients

Settings and conduct
In this three-blind randomized clinical trial study, 90 eligible patients referred to Al-Zahra Hospital in Isfahan will be included in the study and will be randomly divided into three groups. Patients are given a low dose of ketamine, lidocaine, or normal saline, respectively. The intervention will be carried out in such a way that the patient, the researcher and the statistical analyst will not have any knowledge of the type of intervention and the triple-blind conditions will be established. Then the hemodynamic parameters and complications of the patients will be evaluated and compared among the three groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria include the age group of 18 to 65 years, the American Association of Anesthesiologists (ASA) classification equal to one or two, candidates for elective and emergency surgeries under general anesthesia, and consent to participate in the study. Exclusion criteria include having a history of severe cardiovascular disease, having a history of arrhythmia, and having a history of taking blood pressure lowering drugs.

Intervention groups
First intervention group: patients in this group receive 0.5 mg/kg of ketamine. The second intervention group: patients in this group receive 0.5 mg/kg of lidocaine. Control group: patients in this group do not receive any of the cases of ketamine or lidocaine (half a cc of normal saline is prescribed).

Main outcome variables
Blood pressure; Heart beat; Oxygen saturation percentage (SPO2); Hemodynamic complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N56**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **prospective**

Last update: **2022-07-17, 1401/04/26**
Update count: **0**

Registration date
2022-07-17, 1401/04/26

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-22, 1401/05/31

Expected recruitment end date
2023-03-22, 1402/01/02

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of administration of low dose ketamine with lidocaine on changes in heart rate and blood pressure during tracheal intubation under general anesthesia.

Public title
Comparison of administration of low dose ketamine with lidocaine on changes in heart rate and blood pressure during intubation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age group 18 to 65 years American Society of Anesthesiologists (ASA) classification equal to one or two Candidate for elective and emergency surgeries under general anesthesia Consent to participate in the study
Exclusion criteria:
Having a history of severe cardiovascular disease Having a history of arrhythmia Having a history of taking blood pressure lowering drugs
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
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 90 eligible patients are randomly selected. For this, the letter A is written on 30 sheets, the letter B is written on 30 sheets, the letter C is written on 30 sheets, and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In order to achieve the triple-blind study, low dose of ketamine, lidocaine, and placebo will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A, B, and C. And is given daily to the anesthesiologist (researcher). Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.
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
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2022-01-01, 1400/10/11
Ethics committee reference number
IR.MUI.MED.REC.1400.721

Health conditions studied

1

Description of health condition studied
Candidate patients for surgery under general anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood pressure
Timepoint
in basic times (before induction of anesthesia, anesthesia, before tracheal tube removal) and 1, 3, 5, and 10 minutes after tracheal tube removal
Method of measurement
Monitoring device

2

Description
Heart beat
Timepoint

in basic times (before induction of anesthesia, anesthesia, before tracheal tube removal) and 1, 3, 5, and 10 minutes after tracheal tube removal

Method of measurement

Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: patients in this group receive 0.5 mg/kg of ketamine.

Category

Treatment - Drugs

2

Description

Second intervention group: patients in this group receive 0.5 mg/kg of lidocaine.

Category

Treatment - Drugs

3

Description

Control group: patients in this group do not receive any of the cases of ketamine or lidocaine (half a cc of normal saline is prescribed).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Behzad Nazemroaya

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Hezar Jarib Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Behzad Nazemroaya

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available