Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of different doses of ketamine on prevention of fentanyl induced coughing during general anesthesia induction

Protocol summary

Study aim
Determining the effect of different doses of ketamine on the prevention of fentanyle-induced coughing during general anesthesia induction

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 56 patients

Settings and conduct
In this randomized three-blind randomized clinical trial, 56 eligible patients referred to Al-Zahra Hospital in Isfahan will be included in the study and randomly divided into 4 groups. Before fentanyl injection, patients are given different doses of ketamine or normal saline. The intervention will be performed in such a way that the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention and the triple-blind conditions will be established. Then cough severity and hemodynamic parameters of patients will be evaluated and compared between the four groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients who are candidates for surgery under general anesthesia using fentanyl, in the age group of 18-65 years, have one or two American Society of Anesthesiologists (ASA), and consent to participate in the study. Exclusion criteria included underlying diseases, history of allergies to the studied drugs, smoking, addiction, Having had upper respiratory infections in the past month, using medications that interfere with the study over the past two weeks.

Intervention groups
Intervention group 1: Patients in this group receive ketamine at a dose of 0.15 mg/kg intravenously. Intervention group 2: Patients in this group receive ketamine at a dose of 0.20 mg/kg intravenously. Intervention group 3: Patients in this group receive ketamine at a dose of 0.25 mg/kg intravenously. Control group: Patients in this group receive normal saline at a dose of 0.20 mg/kg intravenously.

Main outcome variables
Cough intensity; Blood pressure; heart rate; oxygen saturation (SPO2)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N55**
Registration date: **2022-06-21, 1401/03/31**
Registration timing: **prospective**

Last update: **2022-06-21, 1401/03/31**
Update count: **0**

Registration date
2022-06-21, 1401/03/31

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-22, 1401/04/31

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of different doses of ketamine on prevention of fentanyl induced coughing during general anesthesia induction

Public title
Effect of different doses of ketamine on prevention of fentanyl induced coughing

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age category 65-18 years Candidate for surgery under general anesthesia using fentanyl American Society of Anesthesiologists (ASA) I or II Satisfaction to participate in the study

Exclusion criteria:
Underlying diseases (including heart failure, respiratory, liver, kidney, myocardial ischemic disease, myocardial infarction, hypertension above 140/90 mm Hg, tachycardia (heart rate above 100 beats per minute), depression, asthma, chronic cough) History of allergy to the studied drugs Smoking, addiction Having an upper respiratory infection within the last month Use of drugs such as angiotensin converting enzyme inhibitors (ACEIs), antidepressants (over the past two weeks), and steroids (over the past two weeks) that interfere with the study

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: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 56 eligible patients are randomly selected. For this, the letter A is written on 14 sheets, the letter B is written on 14 sheets, the letter C is written on 14 sheets, and the letter D is written on 14 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, different doses of Ketamine 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, C, and D. 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
2022-05-21, 1401/02/31

Ethics committee reference number
IR.MUI.MED.REC.1401.079

Health conditions studied

1

Description of health condition studied
Candidate patients for surgery under general anesthesia using fentanyl

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of cough

Timepoint
Every 3 minutes during induction of anesthesia from the time of drug injection until 10 minutes after endotracheal intubation

Method of measurement
Fentanyl-Induced Cough Scale (FIC)

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Every 3 minutes during induction of anesthesia from the time of drug injection until 10 minutes after endotracheal intubation
Method of measurement
Monitoring device

2

Description
Diastolic blood pressure
Timepoint
Every 3 minutes during induction of anesthesia from the time of drug injection until 10 minutes after endotracheal intubation
Method of measurement
Monitoring device

3

Description
Hear rate
Timepoint
Every 3 minutes during induction of anesthesia from the time of drug injection until 10 minutes after endotracheal intubation
Method of measurement
Monitoring device

4

Description
Oxygen saturation (SPO2)
Timepoint
Every 3 minutes during induction of anesthesia from the time of drug injection until 10 minutes after endotracheal intubation
Method of measurement
Monitoring device

Intervention groups

1

Description
Intervention group 1: Patients in this group receive ketamine at a dose of 0.15 mg / kg intravenously within 10 seconds, one minute before fentanyl injection.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in this group receive ketamine at a dose of 0.20 mg / kg intravenously within 10 seconds, one minute before fentanyl injection.
Category
Treatment - Drugs

3

Description
Intervention group 3: Patients in this group receive ketamine at a dose of 0.25 mg / kg intravenously within 10 seconds one minute before fentanyl injection.
Category
Treatment - Drugs

4

Description
Control group: Patients in this group receive normal saline at a dose of 0.20 mg / kg intravenously within 10 seconds one minute before fentanyl injection.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Azim Honarmand
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
honarmand@med.mui.a.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
City
Isfahan
Province
Isfehan
Postal code
8174673461

Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
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
Azim Honarmand
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
honarmand@med.mui.a.ir

Person responsible for scientific 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
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
honarmand@med.mui.a.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Nasim Cheshmaviz
Position
General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Fax
Email
Nasimchesm75@gmail.com

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