

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

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

Study aim

Determining the effect of different doses of ketamine on the prevention of fentanyl-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

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

Isfahan

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

Heart 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 Hospital, Sefeh Blvd., Tohid Street

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8174675731

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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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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

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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

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Nasim Cheshmaviz

Position

General Practitioner

Latest degree

Medical doctor

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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