

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of prescribing intravenous ketamine during induction of anesthesia on the incidence of delirium and the time of endotracheal tube removal in patients undergoing coronary artery bypass surgery

Protocol summary

Study aim

the effect of prescribing intravenous ketamine during induction of anesthesia on the incidence of delirium and the time of endotracheal tube removal in patients undergoing coronary artery bypass surgery

Design

A clinical trial with a control group, three blinded, randomized, phase 3 will be conducted on 60 patients. The rand function of Excel software will be used for randomization.

Settings and conduct

This study is a three-blind clinical trial. The researcher and the patients do not know the type of intervention in the groups. The anesthesiologist who prescribes the medicine and the person who evaluates the patient will be separate. The statistical analyst will also be unaware of the group and treatments of the patients. Through block randomization, patients will be placed in two groups of ketamine or placebo. Incidence of delirium and extubation time will be evaluated.

Participants/Inclusion and exclusion criteria

Entry criteria: ages between 40 and 80 years old, ASA class I, II and III Exclusion criteria: history of postoperative delirium, underlying mental illness, use of antipsychotic drugs, postoperative bleeding, valvular surgery, need for re-surgery

Intervention groups

The number of 60 patients who are candidates for CABG surgery are divided into two groups receiving ketamine and the placebo group. Patients who, after induction of anesthesia, receive an intravenous dose of ketamine with a dose of 0.5 mg/kg to a maximum of 50 mg as an infusion in 100 cc of serum in a maximum time of 5 minutes; Ketamine group and patients who receive the same volume of 0.9 normal saline as placebo are called placebo group.

Main outcome variables

Registration of delirium in the relevant checklist during the first 24 and 48 hours of admission to the intensive care unit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231021059795N1**

Registration date: **2024-04-20, 1403/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-20, 1403/02/01**

Update count: **0**

Registration date

2024-04-20, 1403/02/01

Registrant information

Name

Maryam Aligholizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4351 2673

Email address

gholizade001@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-09, 1403/01/21

Expected recruitment end date

2024-05-10, 1403/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of prescribing intravenous ketamine during induction of anesthesia on the incidence of delirium and the time of endotracheal tube removal in patients undergoing coronary artery bypass surgery

Public title

The effect of prescribing intravenous Ketamine in the anesthesia of patients undergoing coronary artery bypass surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages between 40 and 80 years ASA class I, II III

Exclusion criteria:

Having a history of postoperative delirium The presence of underlying mental illness Taking antipsychotic drugs Having a history of alcohol consumption Presence of cerebrovascular disease Perform valvular surgery BMI > 38 kg/m2 Postoperative stroke Postoperative bleeding Longer operation time than usual Need for re-surgery History of underlying lung disease

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method will be used using blocks of six in random order. Then the patients who will meet the entry criteria; According to the block randomization method, they will be placed in groups (in this method, the treatment blocks are moved back and forth randomly and different situations can be created with blocks of length 6 for two groups, for example: ABCABC-BACABC-ABCBAC-ABCCBA... and The mentioned situations continue until the sample volume is filled). Blocks will be randomly selected with Excel software and at the disposal of a researcher who has no involvement in choosing the type of intervention; Placed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

A numerical code will be assigned to each of the rings of

the randomly generated chains. Then, the drug regimen is placed in envelopes according to random chains, and after sealing it, a specific number is written on the envelopes, and these envelopes are placed in a box in random order. Blinding: This research will be triple blind. The researcher does not know the type of intervention in the groups. Patients do not know the type of drug group. The anesthesiologist who prescribes the drug and the person who evaluates the patient will be separate, and the patient's information will be recorded based on the ICDS checklist and the time of extraction by the trained nurses of the special care department who have received sufficient training and explanations before the research and from the group and treatments. Patients are unaware. Also, the statistical analyst will be unaware of the group and treatments of the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Hemmt Ave, Department of Anesthesia Technology, School of Allied Medical Sciences, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-12-31, 1402/10/10

Ethics committee reference number

IR.IUMS.REC.1402.833

Health conditions studied**1****Description of health condition studied**

Delirium

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

2

Description of health condition studied

Extubation time

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Incidence rate of delirium after cardiac surgery

Timepoint

In the first 24 hours and the second 24 hours after the operation

Method of measurement

Intensive Care Delirium Screening Checklist (ICDSC)

2

Description

Extubation time

Timepoint

Up to the first 12 hours of the postoperative period

Method of measurement

Registering patients' extubation time (according to hours: during the first 4 hours after entering the ward, the first 6 hours after entering the ward, the first 8 hours after entering the ward, the first 12 hours after entering the ward)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous ketamine with a dose of 0.5mg/kg up to a maximum of 50mg will be administered as an infusion in 100cc of 0.9% normal saline serum in a maximum time of 5 minutes during the induction of anesthesia and after the administration of anesthetic drugs.

Category

Prevention

2

Description

Control group: the same volume as the intervention group of 0.9% normal saline placebo in 100cc of 0.9% normal saline serum in a maximum time of 5 minutes as an infusion, as a placebo that will be administered during induction of anesthesia and after the administration of anesthetic drugs.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The educational, therapeutic and research center of Hazrat Rasool Akram (PBUH)

Full name of responsible person

Mehrdad Mesbah kiaei

Street address

Tehran-Starkhan-Kh.Niyaish-Corner of Mansouri Street-Hospital of Hazrat Rasool Akram (PBUH)

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 81161

Email

Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shahnam Sedigh Maroufi

Street address

Hemmt Ave, Department of Anesthesia Technology, School of Allied Medical Sciences, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 4711

Email

paramedicine@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Maryam Aligholizadeh

Position

MSC of Anesthesia Education Student

Latest degree

Master

Other areas of specialty/work

MSC of Anesthesia Education Student

Street address

No. 52, Shahid Miri Alley, Rudaki Street, Koi Vahedi

City

Bandar Anzali

Province

Guilan

Postal code

4317734394

Phone

+98 13 4351 2673

Email

gholizade001@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

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Phone

+98 13 4351 2673

Email

gholizade001@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

Maryam Aligholizadeh

Position

MSC of Anesthesia Education Student

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+98 13 4351 2673

Email

gholizade001@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

-Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long

Access period 6 months after publication of results

To whom data/document is available

-It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

-No special conditions are considered.

From where data/document is obtainablePerson responsible for the study: Maryam Aligholizadeh
gholizade001@gmail.com**What processes are involved for a request to access data/document**

After receiving the applicant's email, the documents will be sent in a short period of time.

Comments