Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 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 100 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 100 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

To improve the statistical power of the study and enhance the precision of effect size estimation, the sample size was increased from 60 to 100 participants. Preliminary analyses indicated that the initial sample size was insufficient to detect statistically significant differences between the study groups. Therefore, the sample size was revised to reduce the risk of Type II error and to improve the reliability and generalizability of the study findings. No other changes were made to the study design, including inclusion and exclusion criteria, intervention protocols, or group allocation methods.

Acronym

IRCT registration information

IRCT registration number: **IRCT20231021059795N1**
Registration date: **2024-04-20, 1403/02/01**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-20, 1405/03/30**
Update count: **1**

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
2024-03-10, 1402/12/20
Actual recruitment end date
2025-01-01, 1403/10/12
Trial completion date
2025-01-20, 1403/11/01

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: **100**
Actual sample size reached: **100**
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 ICDSC 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
Mehrdad Mesbah kiaei
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
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
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Province
Guilan
Postal code
4317734394
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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Street address
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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 obtainable
Person 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