Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

The Effect of Intravenous Erythropoietin Administration at the Time of Anesthesia Induction on the Incidence of Delirium, Hemodynamic Stability, and Time to Tracheal Extubation in Patients Undergoing Coronary Artery Bypass Graft Surgery

Protocol summary

Study aim

Evaluating the effect of intravenous erythropoietin administration at the time of anesthesia induction on the incidence of postoperative delirium, hemodynamic stability, and time to tracheal extubation in patients undergoing coronary artery bypass graft (CABG) surgery in the cardiac intensive care unit.

Design

This randomized, triple-blind, placebo-controlled Phase II trial includes 104 CABG patients allocated 1:1 to intervention or control groups. Block randomization (size 4) was generated via Excel RAND function. Sample size (52/group; total 104) was calculated with 95% confidence and 80% power, accounting for dropouts.

Settings and conduct

This trial at Shahid Beheshti University hospitals involves CABG patients receiving erythropoietin (150 IU/kg) or placebo at induction. Outcomes include delirium (ICDSC), hemodynamics, and extubation time. It is triple-blind (patient, anesthesiologist, assessor, statistician) using identical coded syringes.

Participants/Inclusion and exclusion criteria

Occurrence of postoperative stroke or hemorrhage Receipt of high-dose opioids in the ICU: more than 2400 mcg of fentanyl equivalent within 24 hours (equivalent to a mean of 100 mcg/hour) or 240 mg of morphine equivalent within 24 hours (equivalent to 10 mg/hour) Prolonged surgery duration exceeding 3 hours Concurrent valve surgery BMI > 38 kg/m² Need for re-operation

Intervention groups

Intervention Group: Patients in this group will receive a single intravenous (IV) dose of erythropoietin at 150 IU/kg body weight administered at the time of anesthesia induction. Control Group: Patients in this group will receive an equivalent volume of normal saline as a placebo, administered intravenously (IV) at the time of anesthesia induction.

Main outcome variables

Incidence of postoperative delirium; Hemodynamic stability; Time to tracheal extubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231021059795N2**
Registration date: **2026-06-10, 1405/03/20**
Registration timing: **prospective**

Last update: **2026-06-10, 1405/03/20**
Update count: **0**

Registration date

2026-06-10, 1405/03/20

Registrant information

Name

Maryam Aligholizadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date
2026-09-23, 1405/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Intravenous Erythropoietin Administration at the Time of Anesthesia Induction on the Incidence of Delirium, Hemodynamic Stability, and Time to Tracheal Extubation in Patients Undergoing Coronary Artery Bypass Graft Surgery

Public title
The effect of intravenous erythropoietin administration at the time of anesthesia induction on the incidence of delirium, hemodynamic stability, and time to tracheal extubation in patients undergoing coronary artery bypass graft (CABG) surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 40 to 80 yearsASA physical status classification I, II, or IIINo history of postoperative deliriumNo underlying psychiatric disorders or use of antipsychotic medicationsNo history of alcohol consumption or cerebrovascular disease
Exclusion criteria:
Occurrence of postoperative stroke or hemorrhage. Receipt of high-dose opioids in the ICU: more than 2400 mcg of fentanyl equivalent within 24 hours (equivalent to a mean of 100 mcg/hour) or 240 mg of morphine equivalent within 24 hours (equivalent to 10 mg/hour). Prolonged surgery duration exceeding 3 hours.Concurrent valve surgery. BMI > 38 kg/m². Need for re-operation
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: **104**
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
Blinding Method: This study will be conducted as a triple-blind trial. To achieve this, after generating the random sequence using Excel software, the intervention drug (Erythropoietin) and the placebo (Normal Saline) will be prepared in identical, unlabeled syringes. A unique numeric code will be assigned to each syringe, and the key linking codes to the specific treatments will be kept in sealed, opaque envelopes, accessible only in emergency situations. In this study: Patients are blinded to the type of treatment received (Erythropoietin or Placebo). The Anesthesiologist administering the drug is unaware of the syringe contents and administers the injection solely based on the assigned code. Outcome Assessors, including trained ICU nurses responsible for recording delirium scores (ICDSC), hemodynamic parameters, and tracheal extubation time, are blinded to the patients' group assignments. The Statistical Analyst will remain blinded to the group allocations until the completion of data analysis. All personnel involved in data collection will receive adequate training prior to the study commencement to ensure the integrity of the blinding process.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
تهران- بزرگراه شهید چمران - خیابان یمن - خیابان اعرابي، دانشگاه علوم پزشکی و خدمات بهداشتی درمانی شهید بهشتی- ساختمان شماره دو ستاد دانشگاه- طبقه ششم
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Province
Tehran
Postal code
23872206
Approval date
2025-11-23, 1404/09/02

Ethics committee reference number
IR.SBMU.REC.1404.003

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

3

Description of health condition studied
Hemodynamic stability
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
Every 6 hours after surgery for up to 72 hours
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)

3

Description
hemodynamic stability
Timepoint
Every 6 hours after surgery for up to 72 hours
Method of measurement
Invasive monitoring devices (IBP, CVP, EKG, pulse oximetry) and arterial blood gas (ABG) analysis are used to record hemodynamic and respiratory parameters.

Secondary outcomes

empty

Intervention groups

1

Description
Patients will receive a single intravenous dose of erythropoietin (150 IU/kg) at the time of anesthesia induction.
Category
Treatment - Drugs

2

Description
Patients will receive an equivalent volume of normal saline as a placebo, administered intravenously at the time of anesthesia induction.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Modares Hospital
Full name of responsible person
Maryam Aligholizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Deputy Director of Research and Technology
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Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Siavash Sangi

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

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

En 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