Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Dexmedetomidine infusion on post-operative delirium (POD) in patients on pump coronary artery bypass grafting (CABG)

Protocol summary

Study aim
Determining the impact of dexmedetomidine infusion during coronary artery bypass grafting with cardiopulmonary bypass on the incidence of postoperative delirium

Design
A phase 3, double-blind, randomized controlled trial with parallel groups involving 100 patients. Randomization will be conducted using a block randomization method.

Settings and conduct
This double-blind randomized trial is conducted at Imam Reza and Ghaem Hospitals, Mashhad, on 100 on-pump CABG patients. After cognitive and psychological screening and informed consent, patients are randomly assigned to dexmedetomidine or control groups. Anesthesia and monitoring follow a uniform protocol. Study drug or placebo is infused until surgery ends. Delirium is assessed postoperatively in ICU by a nurse blinded to group allocation.

Participants/Inclusion and exclusion criteria
Adults (18–80 years) undergoing on-pump CABG are eligible with informed consent, normal cognition/psychological status (MMSE, PHQ-4), no pre-op delirium, or major organ failure. Exclusions: valve surgery, emergency CABG, dexmedetomidine allergy, coma/intubation, hearing loss, bradycardia, hypotension, early reoperation, or consent withdrawal.

Intervention groups
In the intervention group, intravenous dexmedetomidine infusion at 0.6 µg/kg/h starts after anesthesia induction and continues intraoperatively based on the patient's hemodynamic status. In the control group, an equal volume of normal saline is administered as placebo under the same conditions until the end of surgery.

Main outcome variables
Cognitive status is assessed using MMSE, and psychological status using PHQ-4 before surgery and postoperatively in ICU. Delirium is evaluated with CAM-ICU and Neecham scales. Vital signs are recorded every 15 minutes intraoperatively and in ICU.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250512065695N1**
Registration date: **2025-05-16, 1404/02/26**
Registration timing: **prospective**

Last update: **2025-05-16, 1404/02/26**
Update count: **0**

Registration date
2025-05-16, 1404/02/26

Registrant information

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Shiva Rezaeian Deloei
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-05-22, 1404/03/01
Expected recruitment end date
2025-11-21, 1404/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of Dexmedetomidine infusion on post-operative delirium (POD) in patients on pump coronary artery bypass grafting (CABG)

Public title
Dexmedetomidine infusion effect on post-operative delirium

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients scheduled for on-pump coronary artery bypass grafting (CABG) Informed consent Patients with sufficient cognitive function to participate in the study (assessed by MMSE) Psychological status: Patients with acceptable levels of depression and anxiety (assessed by PHQ-4) Absence of preoperative delirium: Patients without signs of delirium before surgery No severe hepatic or renal failure

Exclusion criteria:
Concurrent valve replacement surgery along with CABG Emergency CABG surgery Known allergy or hypersensitivity to dexmedetomidine Patients in a coma or intubated prior to surgery Patients with moderate to severe hearing impairment or deafness Bradycardia (heart rate <60 bpm) at the time of anesthesia induction Hypotension (systolic blood pressure <100 mmHg) at the time of anesthesia induction Need for reoperation within the first postoperative day Withdrawal of patient consent at any stage during hospitalization

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be allocated to the two study arms using a block randomization method. A total of 10 random blocks with variable sizes of 4 and 6 and differing sequences have been prepared. The contents of each block are sealed in opaque envelopes. As patients are enrolled, the envelopes are opened sequentially, and based on the sequence within the block, the patient is assigned to one of the study arms. Subsequently, after completing the first block, the next block is randomly selected, and this process continues until the final block is used and the last patient is assigned. As a result, with the allocation of the last entry in the final block, an equal number of patients will be assigned to each study arm, ensuring balance between the groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: The participant consented to be randomly allocated to either the intervention group or the control group after understanding the study procedures. Researcher: The researcher was not allowed bedside access prior to randomization to prevent any potential bias. Assessor: The assessor was unaware of the treatment received by the participant and solely recorded the outcomes

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Imam Reza Hospital Educational, Research and Treatment Center-Mashhad

Street address
Ibn Sina St., Imam Reza Hospital Square, Imam Reza Educational Research and Treatment Center

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Razavi Khorasan

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Approval date
2024-06-10, 1403/03/21

Ethics committee reference number
IR.MUMS.IRH.REC.1403.099

Health conditions studied

1

Description of health condition studied
on-pump coronary artery bypass graft surgery

ICD-10 code
Z95.1

ICD-10 code description
Presence of aortocoronary bypass graft

Primary outcomes

1

Description
Determining the incidence of confusion and delirium in

intervention and control groups

Timepoint

In the first and second days after surgery in the cardiac ICU, daily assessments will be conducted during each shift

Method of measurement

Neelon & Champagne Confusion Scale

2

Description

Determining the incidence of delirium in intervention and control groups

Timepoint

In the first and second days after surgery in the cardiac ICU, daily assessments will be conducted during each shift

Method of measurement

CAM-ICU Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous infusion of dexmedetomidine after the induction of anesthesia, starting at a dose of 0.6 micrograms per kilogram per hour, and continued until the end of the procedure based on the patient's hemodynamics.

Category

Prevention

2

Description

Control group: Normal saline infusion is initiated intravenously after the induction of anesthesia, starting with the same volume as dexmedetomidine, and continues throughout the procedure, adjusted according to the patient's hemodynamics, and is terminated at the end of the operation

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mashhad 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
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Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available