

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name

Shiva Rezaeian Deloei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3604 6080

Email address

shivarezaeian7388@gmail.com

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		ensuring balance between the groups.	
Scientific title		Blinding (investigator's opinion)	
The effect of Dexmedetomidine infusion on post-operative delirium (POD) in patients on pump coronary artery bypass grafting (CABG)		Double blinded	
Public title		Blinding description	
Dexmedetomidine infusion effect on post-operative delirium		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	
Purpose		Placebo	
Treatment		Used	
Inclusion/Exclusion criteria		Assignment	
Inclusion criteria:		Parallel	
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		Other design features	
Exclusion criteria:		Secondary Ids	
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		empty	
Age		Ethics committees	
From 18 years old to 80 years old		1	
Gender		Ethics committee	
Both		Name of ethics committee	
Phase		Research Ethics Committees of Imam Reza Hospital Educational, Research and Treatment Center- Mashhad	
3		Street address	
Groups that have been masked		Ibn Sina St., Imam Reza Hospital Square, Imam Reza Educational Research and Treatment Center	
- Participant - Investigator - Outcome assessor		City	
Sample size		Mashhad	
Target sample size: 100		Province	
Randomization (investigator's opinion)		Razavi Khorasan	
Randomized		Postal code	
Randomization description		9137913316	
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,		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

Shiva Rezaeian

Street address

Ahmedabad St

City

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Province

Razavi Khorasan

Postal code

9919991766

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2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Shiva Rezaeian

Street address

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

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaqodi

Street address

Daneshgah Street - next to Howezeh Cinema - Qureshi Building - Research and Technology Vice-Chancellor

City

Mashhad

Province

Razavi Khorasan

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Fax

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vcresearch@mums.ac.ir

Web page address

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****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Shiva Rezaeian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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

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Full name of responsible person

Leila Mashhadi

Position

Assistant professor

Latest degree

Subspecialist

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

Shiva Rezaeian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Web page address**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