Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Intraoperative Awareness with Dexmedetomidine–Propofol Infusion versus Intravenous Xylocaine–Propofol Infusion in Patients Undergoing Coronary Artery Bypass Grafting: A Randomized Controlled Trial

Protocol summary

Study aim
To compare the effectiveness of dexmedetomidine plus propofol infusion versus intravenous xylocaine (lidocaine) plus propofol infusion in preventing intraoperative awareness among patients undergoing elective coronary artery bypass grafting (CABG) under general anesthesia.

Design
RCT

Settings and conduct
National hospital lahore

Participants/Inclusion and exclusion criteria
Patients aged 30–75 years, of either gender. Scheduled for elective isolated CABG under general anesthesia. ASA physical status III–IV. LVEF ≥35%. Able to provide written informed consent and complete the Modified Brice Interview postoperatively. Exclusion Criteria Emergency or combined cardiac surgery, or previous cardiac surgery. Allergy or contraindication to dexmedetomidine, propofol, or lidocaine. Neurological or psychiatric disorders affecting awareness assessment. Chronic use of sedatives, opioids, alcohol, or recreational drugs. Severe hepatic or renal disease, significant heart block/bradycardia, or need for preoperative mechanical circulatory/ventilatory support. Inability to complete postoperative interviews, or pregnancy/lactation.

Intervention groups
Patients in the intervention group will receive dexmedetomidine (1 µg/kg loading dose over 10 minutes, followed by 0.2–0.7 µg/kg/hour infusion) along with propofol infusion for maintenance of anesthesia during elective CABG. Propofol will be titrated according to the institutional anesthesia protocol to maintain an adequate depth of anesthesia. Standard intraoperative monitoring and anesthetic management will be the same for both groups.

Main outcome variables
Primary Outcome Variable Intraoperative awareness, assessed using the Modified Brice Interview at 24 and 72 hours after surgery.

General information

Reason for update

Acronym
RCT

IRCT registration information
IRCT registration number: **IRCT20240901062926N2**
Registration date: **2026-07-20, 1405/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-20, 1405/04/29**
Update count: **0**

Registration date
2026-07-20, 1405/04/29

Registrant information

Name
Muhammad Tayyeb

Name of organization / entity
Superior University

Country
Pakistan

Phone
+92 307 8625941

Email address
tayyabm851@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-22, 1405/02/02

Expected recruitment end date
2026-07-25, 1405/05/03
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Intraoperative Awareness with Dexmedetomidine–Propofol Infusion versus Intravenous Xylocaine–Propofol Infusion in Patients Undergoing Coronary Artery Bypass Grafting: A Randomized Controlled Trial

Public title
Intraoperative Awareness with Dexmedetomidine–Propofol Infusion versus Intravenous Xylocaine–Propofol Infusion in Patients Undergoing Coronary Artery Bypass Grafting: A Randomized Controlled Trial
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients aged 30–75 years. Patients of either gender.Patients scheduled for elective isolated Coronary Artery Bypass Grafting (CABG) under general anesthesia American Society of Anesthesiologists (ASA) physical status III or IV.Left ventricular ejection fraction (LVEF) ≥35% Patients who are able to understand the study protocol and provide written informed consent. Patients who are able to communicate postoperatively and complete the Modified Brice Interview.
Exclusion criteria:
Patients undergoing emergency CABG surgery.Patients scheduled for combined cardiac procedures (e.g., CABG with valve replacement or other cardiac surgeries).History of previous cardiac surgery (redo CABG).Known hypersensitivity or contraindication to dexmedetomidine, propofol, lidocaine (xylocaine), or any study medication.Pre-existing neurological disorders (e.g., stroke with cognitive impairment, epilepsy, dementia) or psychiatric illnesses that may interfere with the assessment of awareness.Chronic use of sedatives, opioids, alcohol, or recreational drugs.Severe hepatic dysfunction (Child–Pugh Class C) or severe renal impairment requiring dialysis.Significant conduction abnormalities (e.g., second- or third-degree atrioventricular block without a permanent pacemaker) or severe bradycardia (heart rate <50 beats/min).Patients requiring preoperative mechanical ventilation or intra-aortic balloon pump support.Patients with hearing impairment, language barriers, or inability to participate in postoperative interviews.Pregnant or lactating women.
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients who provide written informed consent will be randomly allocated in a 1:1 ratio to either the Dexmedetomidine Propofol group (Group D) or the Xylocaine–Propofol group (Group X) using a computer-generated randomization sequence. Group allocation will be concealed using sequentially numbered, opaque, sealed envelopes, which will be opened immediately before induction of anesthesia by an anesthesiologist not involved in postoperative outcome assessment. This process will ensure unbiased allocation of participants to the two study groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be conducted as a single-blinded randomized controlled trial. The participants will be unaware of the treatment group to which they are assigned (Dexmedetomidine–Propofol or Intravenous Xylocaine–Propofol). An anesthesiologist who is not involved in data collection will prepare and administer the study medications according to the randomization sequence. The investigator responsible for postoperative assessment of intraoperative awareness using the Modified Brice Interview and data analysis will remain blinded to the group allocation. The anesthesiologist administering anesthesia cannot be blinded due to the differences in drug preparation and administration protocols. This blinding approach is intended to minimize assessment bias while ensuring patient safety throughout the perioperative period.
Placebo
Not used
Assignment
Parallel
Other design features
none

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
NATIONAL HOSPITAL & MEDICAL CENTER
Street address
national hospital
City
lahore
Postal code

2246

Approval date

2025-05-25, 1404/03/04

Ethics committee reference number

REF: NHMC/IRB/114

Health conditions studied

1

Description of health condition studied

Intraoperative awareness is the unintended recall of events experienced during general anesthesia. It is a rare but serious complication that can result in psychological distress, anxiety, sleep disturbances, and post-traumatic stress disorder (PTSD). Patients undergoing coronary artery bypass grafting (CABG) are at a higher risk of intraoperative awareness because anesthetic doses are often reduced to maintain cardiovascular stability. This study aims to compare the effectiveness of dexmedetomidine–propofol infusion versus intravenous xylocaine–propofol infusion in reducing the incidence of intraoperative awareness in patients undergoing elective CABG.

ICD-10 code

Y93

ICD-10 code description

Activity codes

Primary outcomes

1

Description

Intraoperative awareness, assessed using the Modified Brice Interview conducted at 24 hours and 72 hours after surgery. Patients reporting explicit recall of intraoperative events will be considered to have experienced intraoperative awareness.

Timepoint

24 hour and 72 hours

Method of measurement

Modified Brice Interview Interpretation0 No intraoperative awareness (no explicit recall of intraoperative events).1 Possible intraoperative awareness (uncertain or vague recall requiring further evaluation).2 Definite intraoperative awareness (clear explicit recall of intraoperative events).Interpretation:0: No awareness1: Possible awareness2: Definite awareness

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

NATIONAL HOSPITAL & MEDICAL CENTER

Full name of responsible person

Dr. Ahmad Tariq

Street address

national hospital

City

lahore

Postal code

2246

Phone

+92 333 4699734

Fax

+92 333 4699734

Email

drahmed6196@gmail.com

Web page address

https://nationalhospital.org/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Hospital & Medical Center

Full name of responsible person

National Hospital & Medical Center

Street address

national hospital

City

lahore

Postal code

2246

Phone

+92 307 8625941

Fax

+92 307 8625941

Email

tayyabm851@gmail.com

Web page address

https://nationalhospital.org/

Grant name

https://nationalhospital.org/

Grant code / Reference number

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

Yes

Title of funding source

National Hospital & Medical Center

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

National Hospital & Medical Center

Full name of responsible person

Dr Ahmad Tariq

Position

consultant

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

national hospital

City

lahore

Province

Punjab

Postal code

2246

Phone

+92 307 8625941

Fax

+92 307 8625941

Email

drahmed6196@gmail.com

Web page address

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Person responsible for scientific inquiries

Contact

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Email

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Person responsible for updating data

Contact

Name of organization / entity

National Hospital & Medical Center

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Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

DATA

When the data will become available and for how long

6 month

To whom data/document is available

open access

Under which criteria data/document could be used

educational purpose

From where data/document is obtainable

National Hospital

What processes are involved for a request to access data/document

email

Comments

thankful