

Visual and auditory hallucinations following cardiac surgery

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| Submission date 22/07/2025 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input checked="" type="checkbox"/> Protocol |
| Registration date 29/07/2025 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 28/07/2025 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Patients undergoing major heart surgeries such as coronary artery bypass grafting (CABG) or valvular surgery sometimes experience hallucinations after their operation, meaning they might see or hear things that are not real. These hallucinations can cause stress, slow down recovery, and negatively impact overall well-being. This research aims to identify why these hallucinations occur and if certain factors, such as gender (male or female), type of surgery, medical history, mechanical ventilation duration, kidney function, or medications used during and after surgery, increase the risk. The study is specifically interested in understanding if CABG and valvular surgery have different risk factors.

Who can participate?

Adult patients who have had heart surgery across multiple hospitals in Palestine.

What does the study involve?

Patients will be monitored closely for the first 7 days after surgery to record whether they experience any visual or auditory hallucinations.

What are the possible benefits and risks of participating?

The main goal is to help healthcare professionals identify which patients are at higher risk, allowing better preparation, closer monitoring, and improved care after heart surgery. The results could also lead to strategies that help reduce these disturbing experiences, making recovery smoother and improving patients' quality of life.

Participation involves minimal risk. The study requires patients to answer questions about their experiences post-surgery and allows access to their clinical data. Some may find questions about hallucinations distressing. Participation is voluntary, and participants may withdraw at any time without impact on their care.

Where is the study run from?

Palestinian Clinical Research Center, Palestine

When is the study starting and how long is it expected to run for?
September 2022 to June 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mahammad Alnees, a2011z2012z2013@gmail.com

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Protocol serial number

VAACS-2022-CORE01

Study information

Scientific Title

VAACS study: predictors and outcomes of visual and auditory hallucinations following coronary artery bypass grafting and valve replacement surgery – a prospective multicenter cohort

Acronym

VAACS

Study objectives

To estimate the incidence and identify independent predictors of visual and auditory hallucinations in the early postoperative period following CABG or valve surgery.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 12/09/2022, Institutional Review Board (IRB) at An-Najah National University (Faculty of Medicine and Health Sciences, An-Najah National University, Nablus, 44839, Palestine, State of; +970 9 2345113; s11743633@stu.najah.edu), ref: 2022/8

Study design

Prospective cohort study

Primary study design

Observational

Study type(s)

Other, Quality of life, Treatment, Safety

Health condition(s) or problem(s) studied

Postoperative neuropsychiatric complications, visual hallucinations, auditory hallucinations, cardiac surgery, cognitive dysfunction.

Interventions

This is a prospective observational cohort study.

Participants undergoing CABG or valve surgery were screened and enrolled postoperatively.

Data collection included:

* Daily assessment of hallucinations using the Questionnaire for Psychotic Experiences (QPE) for up to 7 days post-surgery or until discharge (whichever comes first).

* Collection of clinical, demographic, medication, and perioperative data.

* No interventions were administered beyond routine clinical care.

Total observation period: up to 7 days.

Total follow-up: until hospital discharge.

Intervention Type

Other

Primary outcome(s)

Occurrence of postoperative visual and auditory hallucinations measured using the QPE tool within 7 days of surgery.

Key secondary outcome(s)

Hallucination severity measured using the Questionnaire for Psychotic Experiences (QPE) severity scale within 7 days of surgery.

Completion date

30/06/2025

Eligibility**Key inclusion criteria**

1. Adults aged 18 years or older
2. Scheduled for elective or semi-elective cardiac surgery (either isolated CABG or valvular surgery)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

1332

Key exclusion criteria

1. Inability to provide informed consent or complete the questionnaire (e.g. language barrier or severe cognitive impairment)
2. Known history of major psychiatric or neurological disorders that could confound hallucination assessment (such as schizophrenia or dementia)
3. Parkinson's disease
4. Blindness (precluding visual hallucinations assessment)
5. Active alcohol or substance abuse
6. Clinical diagnosis of delirium at the time of screening
7. Pre-existing chronic hallucinations or psychotic disorders
8. Emergency surgery cases

9. Patients on mechanical circulatory support, given their distinct risk profiles for neuropsychiatric complications

Date of first enrolment

20/09/2022

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

Palestine, State of

Study participating centre

Palestinian Clinical Research Center

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Bethlehem

Palestine, State of

P400

Sponsor information

Organisation

An-Najah National University

ROR

<https://ror.org/0046mja08>

Organisation

Palestinian Clinical Research Center

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised participant data that support the findings of this study will be available upon reasonable request after publication of primary results. Data requests must be accompanied by a clear scientific rationale, approved study protocol, and a signed data-sharing agreement. Requests can be submitted directly to the corresponding author/principal investigator, Dr Mahammad Alnees, a2011z2012z2013@gmail.com.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | | 28/07/2025 | No | No |