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Visual and auditory hallucinations following cardiac surgery

Submission date
22/07/2025

Recruitment status
No longer recruiting

Registration date
29/07/2025

Overall study status
Completed

Last Edited
28/07/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Contact information

Type(s)
Principal investigator

Contact name
Dr Haitham Abu Khadija

ORCID ID
https://orcid.org/0000-0002-2336-3125

Contact details
P.O.Box1, DerechPasternak1
Rehovot
Israel
76100
+972 0526391486
haithamab1@clalit.org.il

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Mohammad Alnees

ORCID ID
https://orcid.org/0000-0002-5577-8499

Contact details
Al , Awda Street
Bethlehem
Palestine, State of
P400
+970 0599240098
S11743633@stu.najah.edu

Type(s)
Principal investigator

Contact name
Dr Nizar Abu Hamdeh

ORCID ID
https://orcid.org/0009-0000-4209-0137

Contact details
Al , Awda Street
Bethlehem
Palestine, State of
P400
+972 59-590-2745
s12042043@stu.najah.edu

Type(s)
Principal investigator

Contact name
Dr Abdalaziz Darwish

ORCID ID
https://orcid.org/0000-0002-3231-3672

Contact details
rafidia
nablus
Palestine, State of
P400
+972 59-202-6839
abdalaziz.darwish@najah.edu

Type(s)
Principal investigator

Contact name
Dr Duha Najajra

ORCID ID
https://orcid.org/0009-0007-3561-2380

Contact details
Beit Hanina
Jerusalem
Israel
90805
+972 52-643-6745
s12240420@stu.najah.edu

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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
-
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