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Perioperative complications and autonomic function assessed by the COMPASS-31 tool

Submission date
27/11/2025

Recruitment status
Recruiting

Registration date
18/12/2025

Overall study status
Ongoing

Last Edited
18/12/2025

Condition category
Nervous System Diseases

[_] 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
As people age, the nervous system becomes damaged, including the part responsible for controlling the speed at which the heart beats. This control is particularly important in patients undergoing surgery, where abnormal control can cause the organs of the body to not work properly and delay recovery from surgery. A loss of autonomic function (a condition where involuntary bodily functions like heart rate or digestion may not work properly) might increase the risk of infections and other complications after surgery. This research will help to identify ways that better predict and reduce these risks, ultimately improving the care and recovery of surgical patients.

The Composite Autonomic Symptom Score-31 (COMPASS-31) score may provide an in-depth assessment of these autonomic abnormalities in different organs before surgery. This scale includes up to 31 questions to identify organ dysfunction. However, preoperative COMPASS-31 has not been examined or related to how well patients recover after surgery.

This study aims to use a series of questions to see whether patients who are at most risk of complications can be identified before they have their surgery to improve surgical care in the future.

Who can participate?
Patients aged ≥ 50 years and over undergoing elective major noncardiac surgery under general anaesthesia and expected to require at least an overnight stay in hospital.

What does the study involve?
periCOMPASS-31 is an observational study, and the operation and usual care will proceed as planned. The research team will approach potentially eligible participants to discuss the study and obtain consent. The study involves the following additional steps:

Completion of the questionnaire before surgery
Participants will be asked to complete a short questionnaire, the Composite Autonomic

Symptom Score-31 (COMPASS-31), about different aspects of how their body functions. It contains 12 to 31 questions, depending on your answers, and should take about 5 to 10 minutes to complete.

Heart rate monitoring
Participants will have their heart rate measured using a heart-rate monitor from the day of surgery until up to three days after their surgery. This device will help us measure changes in your heart rate and how your body responds to surgery.

Blood samples
A small blood sample (about three teaspoons) will be taken to check whether their heart shows signs of stress. Those results will not guide clinical care because this testing is not standard practice; instead, the results will be analysed at the end of the study. If participants agree, any remaining sample may be stored for closely related, future ethically approved research. Please note that participants can opt out of this.

What are the possible benefits and risks of participating?
The participants may not benefit directly from taking part. By taking part, participants help to find better ways to care for surgical patients in the future.

Blood sampling may cause minor discomfort, such as a small bruise or slight pain at the needle site. The adhesive heart-rate monitor may mildly irritate the skin, causing temporary redness or itching. These effects are generally mild and temporary.

The progress of each participant will be followed from consent and surgery to a 30-day check after the operation. No extra clinic visits are required.

Where is the study run from?
The study is coordinated by the Critical Care and Perioperative Medicine Research Group at Queen Mary University of London (UK), based at the William Harvey Research Institute, Charterhouse Square, London.

When is the study starting and how long is it expected to run for?
November 2025 to November 2027.

Who is funding the study?
1. King Saud bin Abdulaziz University for Health Sciences (SA)
2. Queen Mary University of London (UK)

Who is the main contact?
1. Main study contact (general enquiries): Clinical Trial and Research Manager Priyanthi Dias, Queen Mary University of London, p.dias@qmul.ac.uk.
2. Scientific lead: Chief Investigator Professor Gareth Ackland, William Harvey Research Institute, QMUL, g.ackland@qmul.ac.uk.
3. Sponsor queries: QMUL Joint Research Management Office, research.governance@qmul.ac.uk (Dr Mays Jawad).

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Additional identifiers

Integrated Research Application System (IRAS)
328971

PROSPERO
CRD420251175235

Study information

Scientific Title
Perioperative complications and autonomic function assessed by the COMPASS-31 tool: multicentre, observational, mechanistic cohort study

Acronym
periCOMPASS-31

Study objectives
Primary objective:
-To identify an association between infectious complications within 30 days of surgery and autonomic function before surgery using the Composite Autonomic Symptom Score-31 tool.
Secondary objectives:
-To identify an association between cardiovascular morbidity within 30 days of surgery and autonomic dysfunction before surgery using the Composite Autonomic Symptom Score-31.

Mechanistic objectives:
- To establish the relationship between frailty assessment and Composite Autonomic Symptom Score-31.
- To establish the relationship between measures of heart rate variability and Composite Autonomic Symptom Score-31.
-To explore the relationship between COMPASS-31 score, ex vivo inflammatory response in whole blood and infectious complications within 30 days of surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/10/2025, Wales Research Ethics Committee 6 Swansea (Floor 4, Institute of Life Science 2, Swansea University, Swansea, SA2 8PP, United Kingdom; +44 (0)1792 295678; Wales.REC6@wales.nhs.uk), ref: 25/WA/0226

Study design
Multi-centre observational cohort study across surgical services in NHS hospitals.

Primary study design
Observational

Study type(s)
Diagnostic, Prevention

Health condition(s) or problem(s) studied
Autonomic function in people undergoing major noncardiac surgery under general anaesthesia

Interventions
Composite Autonomic Symptom Score-31 within 30 days after surgery.

Intervention Type
Other

Primary outcome(s)
1. Autonomic function measured using the Composite Autonomic Symptom Score-31 (COMPASS-31) score at baseline before surgery

Key secondary outcome(s))
Individual components of the COMPASS-31 questionnaire assessing autonomic function: orthostatic intolerance, vasomotor, secretomotor, gastrointestinal, bladder, and pupillomotor abnormalities collected prior to the participant undergoing surgery.

Completion date
15/11/2027

Eligibility

Key inclusion criteria
1. Patients aged ≥ 50 years and over undergoing elective major noncardiac surgery under general anaesthesia expected to require at least an overnight stay in hospital.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
100 years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Lack of capacity or refusal to provide written informed consent
2. Inability to complete questionnaires
2. American Society of Anesthesiologists (ASA) score of I

Date of first enrolment
15/11/2025

Date of final enrolment
15/11/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal London Hospital
Whitechapel Road, Whitechapel
London
England
E1 1BB

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
England
SW3 6JJ

Study participating centre
Royal Free Hospital
Pond St
London
England
NW3 2QG

Study participating centre

Newham General Hospital
Glen Road
London
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E13 8SL

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Not defined

Funder Name
King Saud bin Abdulaziz University for Health Science

Alternative Name(s)
, King Saud bin Abdulaziz University for Health Sciences, KSAU-HS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Saudi Arabia

Funder Name
Queen Mary University of London

Alternative Name(s)
Queen Mary Uni of London, Queen Mary, Queen Mary and Westfield College, The London Hospital Medical College, St Bartholomew's Hospital Medical College, Westfield College, East London College/Queen Mary College, QMUL, QM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	19/09/2025	18/12/2025	No	Yes
Protocol file	version 1.0	08/07/2025	18/12/2025	No	No