A randomised trial to identify the association between glucose levels and the type of anaesthesia in patients undergoing major noncardiac surgery

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
01/09/2023		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
13/09/2023	Ongoing	[X] Results		
Last Edited	Condition category	[] Individual participant data		
18/09/2025	Surgery			

Plain English summary of protocol

Background and study aims

More than 1.5 million major operations not involving the heart are performed in the NHS each year. General anaesthesia is most often given with an inhaled anaesthetic gas. A commonly used alternative is to give anaesthesia using anaesthetic drugs given into the veins, a technique called total intravenous anaesthesia (TIVA). These two types of anaesthetic may have important differences in affecting how the body uses blood sugar for several days after surgery. Higher blood sugar often occurs after surgery, making cells work less well. High blood sugar levels make inflammation and injury to important organs like the heart and brain worse and increase the risk of infections. Recovery after surgery is far slower if glucose levels are higher during and after the operation. Remarkably, for the vast majority of individuals who are not diabetic, blood sugar is not checked at all after surgery. This is because of the previous lack of available technology that can monitor blood sugar without the need for lots of unpleasant blood tests that require much more nursing care. The VITAL trial measures the effect of each anaesthetic technique by assessing recovery, complications and safety. This study is designed to add no extra steps/inconvenience for VITAL participants. It asks whether intravenous anaesthesia achieves more normal control of blood sugar than inhalational anaesthesia. If intravenous anaesthesia improves blood sugar control, we would expect to see fewer complications in individuals most at risk of developing higher blood sugar after major surgery.

Who can participate?

Patients more than 50 years old who are undergoing planned surgery and are already taking part in the VITAL trial, which is testing whether intravenous anaesthesia is superior to inhalational anaesthesia

What does the study involve?

Participants are randomly allocated to receive either intravenous or inhalational anaesthesia. The researchers will monitor blood sugar non-invasively using a painless device placed in the upper arm during the operation under anaesthesia to see how blood sugar changes after each

type of anaesthetic. They will measure whether there is damage to the heart using blood tests, from samples taken routinely before and the morning after surgery. Blood tests from a teaspoon of blood taken before and 24 hours after surgery will assess why blood sugar changes from levels before surgery. These tests will help identify individuals who may benefit from blood sugar monitoring after surgery in the future. This study will help us understand whether intravenous anaesthesia minimises high blood sugar levels that promote complications after noncardiac surgery, compared to inhalational anaesthesia- particularly in individuals most at risk of developing higher blood sugar levels.

What are the possible benefits and risks of participating? Individuals with, or susceptible to, insulin resistance before non-cardiac surgery may benefit from an anaesthesia approach that is more personalised. This study will help improve recovery from surgery for elderly patients, find out about the long-term harm than can result from anaesthesia, and study if the correct approach could help reduce the risk of complications after surgery. There are minimal risks for research participants.

Where is the study run from? Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for? September 2023 to October 2026

Who is funding the study? National Institute for Health and Care Research (UK)

Who is the main contact? Prof. Gareth Ackland, g.ackland@qmul.ac.uk

Contact information

Type(s)

Principal investigator

Contact name

Prof Gareth Ackland

ORCID ID

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

324653

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

157967, IRAS 324653, CPMS 56485

Study information

Scientific Title

GlucoVITAL – randomised trial of Volatile vs Total intravenous Anaesthetic for major non-cardiac surgery

Acronym

GlucoVITAL

Study objectives

To identify the association between intraoperative glucose levels and the mode of anaesthesia (total intravenous anaesthesia vs inhalational) in patients undergoing major noncardiac surgery.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 17/08/2023, London - Fulham Research Ethics Committee (2 Redman Place, Stratford Health Research Authority, London, E20 1JQ, United Kingdom; +44 (0)207 104 8084; fulham. rec@hra.nhs.uk), ref: 23/PR/0677

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Diagnostic, Prevention

Health condition(s) or problem(s) studied

Major elective noncardiac surgery under general anaesthesia

Interventions

Following the provision of informed consent, participants will be enrolled into the study.

Real-time continuous glucose monitoring will be measured using a Dexcom G7 sensor. The patient will wear these monitors continuously from induction of anaesthesia to up to 10 days postoperatively (maximum usage duration for each sensor) or hospital discharge whichever occurs sooner.

Blood samples (approximately 15 ml) will be collected to measure:

- 1. Blood-gas measurements for glucose
- 2. Myocardial injury
- 3. Presence and/or development of insulin resistance
- 4. Leukocyte and metabolic profiles

Participants will be contacted by telephone on Day 30 (+ 2 days) to collect data on hospital readmission and any postoperative complications that are classed as Clavien-Dindo Severity Grade II or above.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dexcom G7 sensor

Primary outcome(s)

Current primary outcome measure as of 23/06/2025:

Blood glucose measured using Blood-Gas measurements for glucose before surgery, at the end of surgery and on day one after surgery

Previous primary outcome measure:

- 1. Blood-gas measurements for glucose before surgery, at the end of surgery and on day one after surgery
- 2. Continuous glucose measurements using continuous glucose monitoring up to 10 days after surgery or hospital discharge, whichever is sooner

Key secondary outcome(s))

- 1. DAH30 is a continuous number between 0 and 30, reflecting the total number of days that a patient spends alive and at home within 30 days after surgery. In this definition, home reflects any place other than hospital. If a patient dies within those 30 days, their value is set to 0. DAH30 captures the development of all-cause complications which prevents patients leaving hospital after surgery.
- 2. Increase in serum high sensitivity troponin-T (Elecsys, Roche Diagnostics) concentration of:
- 2.1. An absolute value of 15 ng L-1 on day one after surgery OR
- 2.2. An increase of 5 ng L-1 from the preoperative value on day one after surgery when the preoperative value of 15 ng L-1
- 3. Incidence of postoperative infection within 30 days after surgery. This is defined as one or more of the following infections of Clavien-Dindo grade II or greater:
- 3.1. Superficial surgical site infection
- 3.2. Deep surgical site infection
- 3.3. Organ space surgical site infection
- 3.4. Pneumonia

- 3.5. Urinary tract infection
- 3.6. Laboratory-confirmed bloodstream infection
- 3.7. Infection, source uncertain; this is defined as an infection which could be more than one of the above but it is unclear which

Completion date

02/10/2026

Eligibility

Key inclusion criteria

Current inclusion criteria as of 13/11/2024:

- 1. Patients aged 50 years and over
- 2. Elective major noncardiac surgery under general anaesthesia (as per PQIP inclusion criteria)
- 3. Written informed consent for study participation

Previous inclusion criteria:

- 1. Patients aged 50 years and over undergoing elective major noncardiac surgery under general anaesthesia and consented to the VITAL trial
- 2. Written informed consent for study participation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

50 years

Upper age limit

100 years

Sex

All

Total final enrolment

450

Key exclusion criteria

Current exclusion criteria as of 13/11/2024:

- 1. Known contraindication to either total intravenous anaesthesia or inhalational anaesthesia
- 2. Clinical refusal
- 3. Procedures where the participant is not expected to survive for 30 days
- 4. Previous participation and completion in the GlucoVITAL trial
- 5. Patients unable to give informed consent or complete questionnaires

Previous exclusion criteria:

- 1. Known contraindication to either total intravenous anaesthesia or inhalational anaesthesia
- 2. Clinical refusal
- 3. Procedures where the participant is not expected to survive for 30 days
- 4. Previous participation and completion in the VITAL trial
- 5. Patients unable to give informed consent or complete questionnaires

Date of first enrolment

15/09/2023

Date of final enrolment

02/08/2025

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre
The Royal Marsden NHS Foundation Trust

Fulham Road London United Kingdom SW3 6JJ

Study participating centre Golden Jubilee Hospital Glasgow

Agamemnon Street Clydebank United Kingdom G81 4DY

Study participating centre Croydon Health Services - Community Serv

Croydon Health Services Croydon University Hospital 530 London Road Thornton Heath United Kingdom CR7 7YE

Study participating centre

Liverpool University Hospitals NHS Foundation Trust

Royal Liverpool University Hospital Prescot Street Liverpool United Kingdom L7 8XP

Study participating centre Leeds Teaching Hospitals NHS Trust

St. James's University Hospital Beckett Street Leeds United Kingdom LS9 7TF

Study participating centre Chelsea & Westminster Hospital

369 Fulham Road London United Kingdom SW10 9NH

Study participating centre Newham General Hospital

Glen Road London United Kingdom E13 8SL

Study participating centre

Heartlands Hospital

Bordesley Green East Bordesley Green Birmingham United Kingdom B9 5ST

Study participating centre Croydon University Hospital

London Road Croydon United Kingdom CR7 7YE

Study participating centre Watford General Hospital

60 Vicarage Road Watford United Kingdom WD18 0HB

Study participating centre Barking Hospitals

Upney Lane Barking United Kingdom IG11 9LX

Study participating centre Royal National Orthopaedic Hospital

Brockley Hill Stanmore United Kingdom HA7 4LP

Study participating centre The Whittington Hospital

Magdala Avenue London United Kingdom N19 5NF

Sponsor information

Organisation

Queen Mary University of London

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request. Enquiries can be sent to the email address p.dias@qmul.ac.uk. Ideally, the Chief Investigator (CI), Prof. Gareth Ackland, should be contacted first with the enquiry for CI approval. Data would typically only be available to share at the end of the study. All data shared will be anonymised. Consent from participants was required and obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type Results article	Details	Date created 24/07/2025	Date added 28/07/2025	Peer reviewed?	Patient-facing? No
Protocol article		24/05/2025	16/06/2025		No
Other files	GP letter version 1.0	25/04/2024	18/09/2025	No	No
Other files	Informed Consent Form version 2.0	06/01/2025	18/09/2025	No	No
Other files	Participant Invitation Letter version 4.0	12/06/2024	18/09/2025	No	No
Participant information sheet	version 3.0	13/08/2023	12/09/2023	No	Yes
Participant information sheet	version 6.0	30/05/2024	13/11/2024	No	Yes
Participant information sheet	version 7.0	13/03/2025	18/09/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>	version 3.0	13/08/2023	12/09/2023	No	No
<u>Protocol file</u>	version 5.0	24/04/2024	13/11/2024	No	No
<u>Protocol file</u>	version 6.0	13/03/2025	23/06/2025	No	No
<u>Protocol file</u>	version 6	13/03/2025	18/09/2025	No	No