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

Submission date
01/09/2023

Recruitment status
Recruiting

Registration date
13/09/2023

Overall study status
Ongoing

Last Edited
28/07/2025

Condition category
Surgery

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

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 December 2025

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

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Prof Gareth Ackland

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324653

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic, Prevention

Participant information sheet
See study outputs table

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexcom G7 sensor

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
15/12/2022

Completion date
30/12/2025

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

Age group
Senior

Lower age limit
50 Years

Upper age limit

100 Years

Sex
Both

Target number of participants
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

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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
30/09/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

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

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Sponsor type
University/education

Website
http://www.qmul.ac.uk/

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal, conference presentations and webcasts. Intent to publish the main paper as soon as possible after completion of the trial.

Intention to publish date
10/12/2025

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	13/08/2023	12/09/2023	No	Yes
Protocol file	version 3.0	13/08/2023	12/09/2023	No	No
Participant information sheet	version 6.0	30/05/2024	13/11/2024	No	Yes
Protocol file	version 5.0	24/04/2024	13/11/2024	No	No
Protocol article		24/05/2025	16/06/2025	Yes	No
Protocol file	version 6.0	13/03/2025	23/06/2025	No	No
Results article		24/07/2025	28/07/2025	Yes	No