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VITAL: a trial looking at which general anaesthesia technique is better for patient recovery following major non-cardiac surgery

Submission date
16/09/2021

Recruitment status
No longer recruiting

Registration date
29/09/2021

Overall study status
Completed

Last Edited
01/05/2025

Condition category
Surgery

[X] 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
Morethan 1.5 million major non-cardiac surgeriesare performedin the NHS each year. In the NHS, 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 or TIVA. The two techniquesmayhave important differences in how quickly and how well patients recover.
Many anaesthetists believe TIVA is just as safe as inhalational anaesthesia and provides better and faster recovery after surgery. However, others are not convinced that the benefits of using TIVA outweighs the increased cost of this method of anaesthesia. There is a distinct lack of data describing which method might be better. The VITAL trialwillmeasure the benefits of each technique in terms of patient recovery, survival and safety.Theresults will ensure that the best method of general anaesthesia is being used in the NHS, so that patients can go home quicker, and with reduced cost for the NHS.
VITAL is a multi-centre pragmatic randomised controlled trial, aiming to test whether TIVA (Total Intravenous Anaesthesia) is superior to inhalational anaesthesia.

Who can participate?
Patients undergoing elective major non-cardiac surgery who are 50 years or over will be eligible to take part in VITAL.

What does the study involve?
Following consent to take part, patients will be randomised to receive either TIVA or inhalational anaesthesia. Patients will then be followed up for 6 months following surgery to see how they’re doing. VITAL are working with another research programme called the Perioperative Quality Improvement Programme (PQIP). PQIP collect data about patient surgeries and use that to inform hospitals how they can improve their surgeries. A lot of the data collected for PQIP will also be used in VITAL.

What are the possible benefits and risks of participating?
You may not benefit directly from taking part in this trial. By allowing us to collect information

about the type of anaesthetic used during your surgery and how you recover, we hope to work out which type of anaesthetic is most effective in helping patients recover from surgery and help improve anaesthetic care of patients in the future. As we are comparing two standard practices, we do not anticipate any additional risks by taking part in this study. Anaesthesia is always necessary for anyone undergoing surgery and all anaesthesia carries some risk. Whether you are allocated to inhalational or TIVA general anaesthesia, your safety and care will be our utmost priority. Any additional medication that you may require will always be given such as painkillers, anti-sickness medication. There is the modest time commitment to completing questionnaires. Any answers you give, and data collected will only be used for the purpose of the trial, will be kept strictly confidential and not identify you by name.

Where is the study run from?
University of Warwick (UK)

When is the study starting and how long is it expected to run for?
November 2020 to October 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Joyce Yeung
Dr Shaman Jhanji
VITAL Trial Manager, VITAL@warwick.ac.uk

Study website
https://warwick.ac.uk/VITAL

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297034

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50027, NIHR130573, IRAS 297034

Study information

Scientific Title
Volatile vs Total intravenous Anaesthesia for major non-cardiac surgery: A pragmatic randomised triaL

Acronym

VITAL

Study objectives
In adult patients (aged ≥50 years) undergoing major non-cardiac surgery, does total intravenous anaesthesia (TIVA) lead to improved patient outcomes compared to inhalational volatile-based anaesthesia?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2021, Yorkshire & The Humber – Bradford Leeds Research Ethics Committee () NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0162

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Total intravenous anaesthesia (TIVA) compared to inhalational volatile-based anaesthesia

Interventions
VITAL is a multi-centre pragmatic efficient randomised controlled trial with health economic analysis. A 6-month internal pilot phase will seamlessly run into the main trial, on the condition that the pre-defined success criteria have been met. VITAL will compare the clinical and cost effectiveness of TIVA and inhalational anaesthesia. VITAL will use an efficient trial design led by the Peri-Operative Medicine Clinical Trials Network and partnering with an existing national cohort study hosted by the Royal College of Anaesthetists: the Perioperative Quality Improvement Programme, PQIP.
Using PQIP's prospective clinical dataset and existing NHS data sources, we will limit the burden of research for participants and data collection requirements.
VITAL will recruit 2,500 participants across approximately 40 NHS sites in the UK. Participants will be identified during pre-operative assessment clinics and/or theatre lists at participating centres. Participants will be randomly allocated to receive general anaesthetic either intravenously or by inhalation during their surgery. There will be no placebo or blinding. Adults aged 50 and over will be eligible for randomisation if they are undergoing elective major non-

cardiac
surgery under general anaesthesia (as per the PQIP inclusion criteria) and provide written informed consent to take part. Patients will not be eligible for randomisation if they have any known contraindications to TIVA or inhalational anaesthesia, if a clinician has refused trial entry, if the patient is undergoing a procedure where they are not expected to survive the next 30 days or if the patient has previously participated in VITAL. Patients who cannot provide informed consent or complete trial questionnaires will also be ineligible.
VITAL will include a nested pilot in 12 NHS sites, providing the opportunity to run the SWAT (see section below) and pre-determined success criteria (specified in the protocol) will have to be met in order to seamlessly transition into the main trial.

Once consented, participants will be randomised using an Interactive Voice Response System (IVRS) to receive either TIVA or inhalational anaesthesia during their surgery. Both methods of anaesthesia will be administered by experienced anaesthetists and delivered according to local guidelines.

Data collection will be largely completed via data entry into the PQIP database. We are largely recording clinical data already collected as part of standard care. This includes; surgical and anaesthesia details, recovery data and variables relating to post-operative complications. In addition, participants will be asked to complete questionnaires on Day 1, Day 3, day of discharge, Day 30 and 6 months. These will relate to quality of recovery, quality of life, accidental awareness and health resource use.

STUDY WITHIN A TRIAL (SWAT)
Within VITAL, a small qualitative study will be undertaken to examine ways of consenting participants into complementary studies. The study will consist of interviews with participants of VITAL, patients who declined to take part in VITAL, and staff members involved in consenting participants into the trial. The study will recruit from 4 NHS Trusts, and will only run during the pilot phase of the VITAL trial. Any findings will be fed into the training and consent process for the main trial. Potential participants of the SWAT will be contacted by a trained qualitative researcher following verbal consent to have their contact details recorded. The researcher will then contact potential participants to provide the SWAT PIS and discuss the study, give them time to ask questions, and if they're happy to proceed, obtain written informed consent to take part in the study. They will then take part in a semi-structured interview exploring their experiences of the consenting process (or if they declined VITAL, the reasons for declining). Interviews may take place in person or over the phone, and will be audio-recorded. The recordings will then be submitted to an external company to provide transcripts, which will be analysised using qualitative methods.

Intervention Type
Procedure/Surgery

Primary outcome measure
Days alive and at home at 30 days (DAH30) measured using patient records

Secondary outcome measures
1. Days alive and at home at 90 days (DAH90) measured using patient records
2. 30-Day and 90-Day and six-month mortality measured using patient records
3. Quality of recovery after anaesthesia (QoR-15) day 3 post-op

4. Patient satisfaction with anaesthesia (Bauer questionnaire) day 1 post-op.
5. Awareness under anaesthesia measured using the Brice questionnaire day 3 and day 30 post-op.

Overall study start date
01/11/2020

Completion date
10/10/2024

Eligibility

Key inclusion criteria
1. Age >=50 years
2. Elective major non-cardiac surgery under general anaesthesia (as per PQIP inclusion criteria)
3. Written informed consent for trial participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
50 Years

Sex
Both

Target number of participants
Planned Sample Size: 2,500; UK Sample Size: 2,500

Total final enrolment
2508

Key exclusion criteria
1. Known contraindication to either TIVA or inhalational anaesthesia
2. Clinician refusal
3. Procedures where the participant is not expected to survive for 30 days
4. Previous participation in VITAL trial
5. Patient unable to give informed consent or complete questionnaires

Date of first enrolment
01/01/2022

Date of final enrolment
10/04/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
The Royal Marsden Hospital
Fulham Road
Chelsea
London
United Kingdom
SW3 6JJ

Study participating centre
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

Study participating centre
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Freeman Hospital
Newcastle Upon Tyne Hospital Trust
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Barking, Havering and Redbridge University Hospitals NHS Trust
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Rotherham District Hospital
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital

Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Whipps Cross Hospital
Whipps Cross Road
London
United Kingdom
E11 1NR

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Croydon University Hospital
London Road
Croydon
United Kingdom
CR7 7YE

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
University Hospital of North Tees
Hardwick Road
Stockton-on-tees
United Kingdom
TS19 8PE

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre

Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Pinderfields General Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Weston General Hospital
Grange Road
Uphill
Weston-super-mare
United Kingdom
BS23 4TQ

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London

United Kingdom
SW10 9NH

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Golden Jubilee National Hospital
Agamemnon Street
Clydebank
United Kingdom
G81 4DY

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Great Western Hospitals NHS Foundation Trust
Great Western Hospital
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
The Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
United Kingdom
CF72 8XR

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
University Hospital Crosshouse
Kilmarnock Road
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
St. Bartholomews Hospital
West Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Dartford and Gravesham NHS Trust
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Study participating centre
Sunderland Royal Hospital
Kayll Road

Sunderland
United Kingdom
SR4 7TP

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Guys and St Thomas Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
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NG7 2UH

Sponsor information

Organisation
University of Warwick

Sponsor details
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Coventry
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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Funder Name
National Institute for Health Research (NIHR) (UK)

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 high-impact peer-reviewed journal

Intention to publish date
01/04/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
Data will be made available to researchers whose full proposal for their use of the data has been approved by the VITAL Trial Management Group and whose research group includes a qualified statistician. Data will be provided after completion of a data sharing agreement. Data sharing agreements would be set up by the Sponsor. Anonymised data will be made available for approved specified purposes only. Requests for data should be made to VITAL@warwick.ac.uk.
Start date: 2 years after publication of the main study results
End date: 5 years after publication of the main study results

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	26/05/2021	27/09/2021	No	Yes
HRA research summary			28/06/2023	No	No
Participant information sheet	version 4.0	10/08/2023	01/11/2023	No	Yes
Protocol article		27/06/2024	28/06/2024	Yes	No