

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

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<b>Registration date</b> 29/09/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/05/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

More than 1.5 million major non-cardiac surgeries are performed in 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 techniques may have 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 trial will measure the benefits of each technique in terms of patient recovery, survival and safety. The results 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

## Contact information

**Type(s)**  
Scientific

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SW3 6JJ

### **Type(s)**

Public

### **Contact name**

Ms Claire Jacques

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

297034

### **Protocol serial number**

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  $\geq 50$  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

## **Study type(s)**

Other

## **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 analysed using qualitative methods.

#### **Intervention Type**

Procedure/Surgery

#### **Primary outcome(s)**

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

#### **Key secondary outcome(s)**

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.

#### **Completion date**

10/10/2024

## **Eligibility**

#### **Key inclusion criteria**

1. Age  $\geq 50$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

50 years

**Sex**

All

**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**  
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Wakefield  
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WF1 4DG

**Study participating centre**

**Morrison Hospital**

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Cwmrhydyceirw  
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**Study participating centre**

**Royal Surrey County Hospital**

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Guildford  
United Kingdom  
GU2 7XX

**Study participating centre**

**Weston General Hospital**

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Uphill  
Weston-super-mare  
United Kingdom  
BS23 4TQ

**Study participating centre**

**Chelsea and Westminster Hospital NHS Foundation Trust**

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369 Fulham Road  
London  
United Kingdom  
SW10 9NH

**Study participating centre**

**University Hospital of Wales**

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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**  
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Kilmarnock  
United Kingdom  
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**Study participating centre**  
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West Smithfield  
London  
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**Study participating centre**  
**Dartford and Gravesham NHS Trust**  
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**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road  
Sunderland  
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**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  
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**Study participating centre**  
**Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus**  
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## **Sponsor information**

**Organisation**  
University of Warwick

**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

## 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](mailto: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?
<a href="#">Protocol article</a>		27/06/2024	28/06/2024	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 1.0	26/05/2021	27/09/2021	No	Yes
<a href="#">Participant information sheet</a>	version 4.0	10/08/2023	01/11/2023	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes