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VOLATILE VS TOTAL INTRAVENOUS ANAESTHESIA
FOR MAJOR NON-CARDIAC SURGERY

Participant Information Sheet

Volatile vs Total intravenous Anaesthesia for major non-cardiac surgery: A pragmatic randomised trial - VITAL

Introduction

You have been given this information sheet to read because you are going to have an operation under general anaesthetic. The hospital looking after you is taking part in a research trial called the VITAL trial. VITAL is a trial looking at whether one type of general anaesthesia is better than another for people having major surgery. We would like to invite you to take part in this trial. This information sheet will explain why the research is being done and what it means for you. As you go through the information sheet, one of our research team members will answer any questions you have. Please ask us if there is anything that is not clear.

What is the purpose of the trial?

When you go for major surgery, you will be given a general anaesthetic to send you off to sleep so you are unaware and do not feel pain during the operation. This research trial is comparing two standard ways of giving general anaesthesia. These are: (1) Inhalation anaesthesia where patient breathes in anaesthetic gas or (2) Total intravenous anaesthesia (TIVA) where medication is given through the patient's vein. Both ways are safe and routinely used during surgery. The anaesthetic doctor (anaesthetist) would normally make this decision but currently we do not know whether one type is better than the other. This trial will help us find out more information on how the type of general anaesthetic can influence your recovery and whether one way of giving general anaesthesia is better. A flowchart of the trial can be found below;

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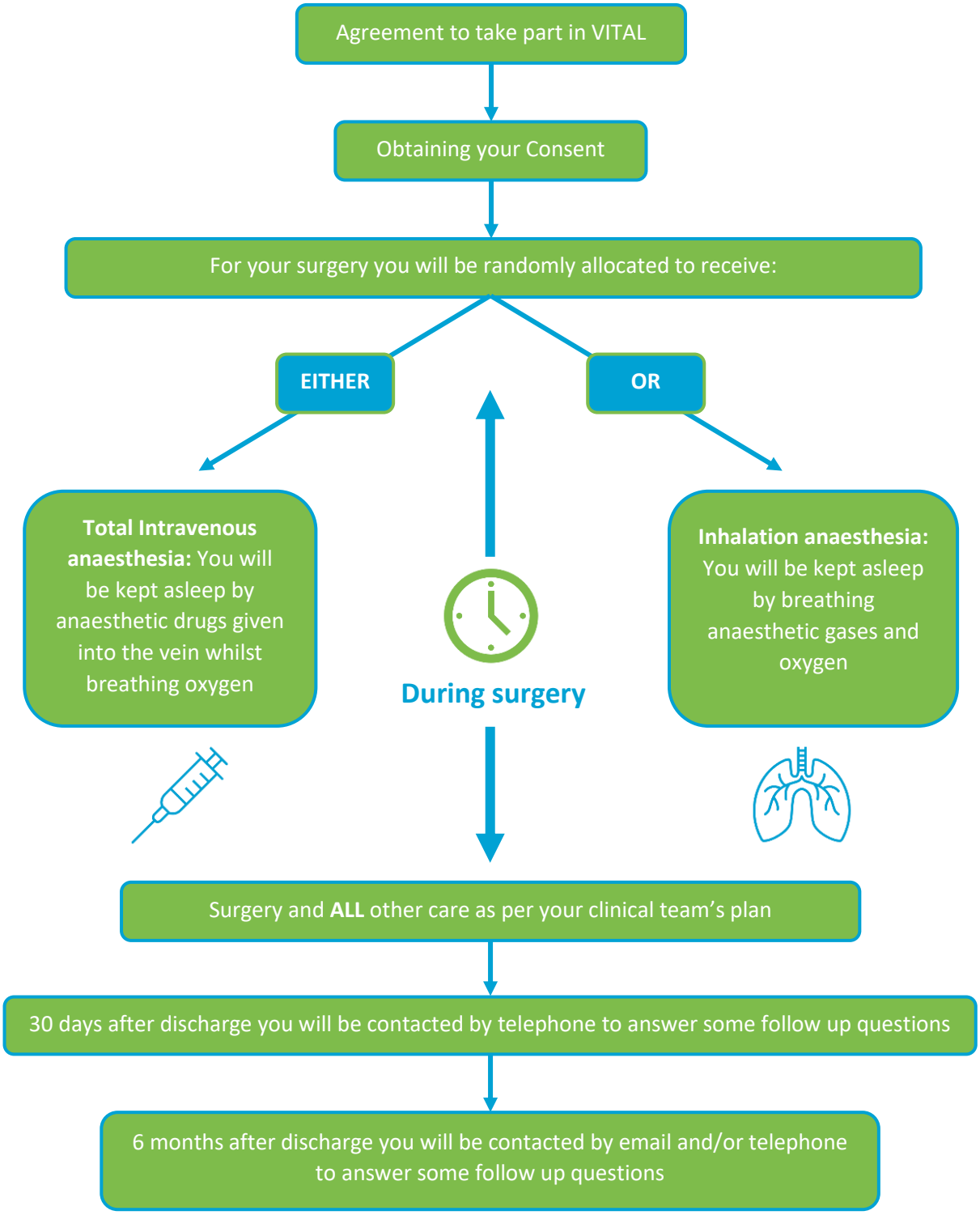
VITAL TRIAL DESIGN



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PQIP and VITAL

You may have already been approached about the Perioperative Quality Improvement Programme (PQIP). PQIP measures complications, survival and patient reported outcomes (via questionnaires) with the aim to improve patient experiences after major surgery. PQIP and VITAL have decided to work together as they want to use the same data to improve patients' experience of major surgery. If you decide to participate in VITAL, some of your clinical data collected for PQIP will be shared with the VITAL trial team at the University of Warwick. Any additional data required for VITAL will also be entered and held on the PQIP database. For this reason, you will need to take part in PQIP in order to take part in VITAL.

Why are we approaching you about the trial?

VITAL is running in about 40 NHS hospitals across the UK, and is hoping to recruit 2500 participants. The hospital where your operation takes place is taking part in the VITAL trial. You have been chosen because you are having surgery under general anaesthesia and you are suitable to receive general anaesthesia by either inhalational or TIVA.

Why are we comparing standard types of general anaesthesia?

Both methods of providing general anaesthesia are commonly used and the choice is mainly down to the anaesthetic doctor. Some anaesthetic doctors prefer to use TIVA because effects wear off quickly, but we do not know whether this also makes recovery quicker. TIVA also costs more compared to inhalational anaesthesia. We do not know which type of general anaesthesia is best for patient recovery. This research trial will help us find out if either way is better so anaesthetic doctors can choose the right method to help patients recover quicker and they can go home earlier.

What would taking part involve?

A member of the research team will contact you to discuss the trial further. They will ask if you have had a chance to read this information and let you ask any questions you may have.

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If you do decide that you would like to take part in the trial, the researcher will document your consent, and you will get a copy of this to keep – the original will be stored with all the trial documentation at the hospital. Your operation will take place as planned. When you have your operation, you will receive general anaesthesia either through breathing (inhalation) or through your vein (intravenous). All other elements of your medical care will be the same. The way in which you will receive general anaesthesia will be randomly allocated by a computer and will be entirely by chance. This is not influenced by the researchers or your preference. There is an equal chance of you being selected for either group.

We will visit you 3 times during your hospital stay to collect information on your recovery using PQIP study questionnaires which will take about 10 minutes to complete. A carer may assist with completing the questionnaires where appropriate. We will record what anaesthesia you received and collect information about your health for six months after your surgery. We will collect your phone number in order to ring you to complete a questionnaire at 30 days after your surgery, and your email or phone number to contact you to complete a questionnaire at 6 months after your surgery. This will help us work out which general anaesthesia helps patients recover better and quicker.

What are the possible benefits of taking part?

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.

What are the possible disadvantages and risks of taking part?

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 carry 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

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you may require will always be given such as painkillers, anti-sickness medication. There is 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.

Do I have to take part?

It is entirely up to you whether you take part in the trial or any other part of the research. If you decide not to take part in the trial, then you will continue to receive your routine clinical care as usual, and this will not be affected in any way.

What if something goes wrong?

The trial is looking at two ways of giving general anaesthesia that are routine practice in the NHS, so it is unlikely that anything will go wrong as a result of taking part in this trial. If you are unhappy about any aspect of your treatment, please speak to your treating doctor.

If you have a concern about any aspect of this study, you should first speak to the local research team who will do their best to answer your questions. You can contact the research nurse on [Insert contact details]. If you remain unhappy and wish to complain formally, you can do this by contacting [Insert local PALs team contact details].

This trial is covered by the NHS and University of Warwick's insurance and indemnity cover. Any complaint about the way you have been dealt with during the trial or any possible harm you may have suffered will be addressed. If you wish to speak to someone from the sponsor team about any service you were unhappy about during your time participating in VITAL trial, you can do this by contacting the person below, who is a senior University of Warwick official and is independent of this trial:

Deputy Director/ Head of Research Governance Research & Impact Services
University House, University of Warwick
Coventry CV4 8UW

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Tel: 02476 575733

Email: researchgovernance@warwick.ac.uk

In the event that you have been harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Warwick or the relevant NHS organisation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to You.

Expenses and Payments

We expect that research visits will be in-line with your routine clinic appointments, so you will not need to make any extra trips to hospital. There will be no payments or travel expenses for taking part in this research. At the end of your participation in the trial, you will receive a voucher as a small token of our appreciation, as an acknowledgement of the time commitment taken to complete all the trial questionnaires. This will be arranged through your hospital research team.

What will happen if I don't want to carry on with the trial?

Taking part in the trial is entirely voluntary. If you do not want to continue in the trial, you can withdraw at any time without giving a reason and without it affecting your care in any way. If you decide to withdraw from the trial, you can choose to have no further participation in VITAL, in which case no further data will be collected on you for the VITAL trial, and you will not be contacted for VITAL trial data. Data may still be held and collected by PQIP unless you also ask to withdraw from PQIP. We may have to keep the information about you that we have already collected for safety reasons. Your rights to access, change or move your information are limited as we need to manage your information in specific ways for the research to be reliable and accurate. In the unlikely event that you lose the ability to complete the trial questionnaires, a clinician may choose to withdraw you from the trial on your behalf. In this instance, we will continue to collect some information about your health and recovery

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from your medical records, but you will no longer be contacted to complete any trial questionnaires.

What is the Study Within the VITAL Trial?

As part of VITAL, we are also interviewing patients, carers and staff to understand how best to talk with patients and their carers about taking part in research.

As this is a separate part of the VITAL trial, you may be asked separately to take part in these interviews if you have:

- Declined to take part in the VITAL trial
- Consented to take part in the VITAL trial
- Withdrawn from the VITAL trial

As with the main VITAL trial, it is entirely up to you if you want to take part, and your decision will not affect your medical care.

How will my information be used?

Hospital staff and University of Warwick staff will collect information from your medical records, GP records and other NHS data sources for this research trial in accordance with the University of Warwick's standard procedures.

We will only use information that we really need to for this research trial. The research team at your hospital will have a record of your name and contact details to use for follow-up. The hospital will record trial data (eg. Information about your surgery and recovery), and most of these will be entered onto the PQIP system, for use by PQIP and VITAL. Some additional data that PQIP doesn't need may be passed straight to University of Warwick staff using secure methods, such as information about if you want to withdraw from the VITAL trial, or any safety-related data. To safeguard your rights, information collected which identifies you by name will be kept to a minimum. Trial data will be held securely and will only be accessible to authorised staff. Individuals from the University of Warwick and regulatory organisations may look at your medical and research records to check the accuracy of the research trial. The

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people who analyse the information will not be able to identify you by name – instead a trial-specific code will be used.

Will my taking part in this trial be kept confidential?

The University of Warwick is the Sponsor for VITAL, and Warwick Clinical Trials Unit will manage the trial. The University of Warwick and The Royal College of Anaesthetists (who own PQIP) will use the information you provide and information from your hospital records to carry out the trial and will act as joint as data controllers. This means that together, they are responsible for using your information. The University of Warwick and the hospitals taking part in the trial will keep information about you for the duration of your trial and a minimum of 10 years after the trial has finished so that we (the trial team at Warwick Clinical Trials Unit) can check the results. If you agree to take part in this trial, anonymised information we collect may be shared with other research teams for future projects.

For further information regarding how we will use your data, please refer to the University of Warwick Research Privacy Notice which is available here: https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice (Copy of this document is available from the research team) or by contacting the Information and Data Compliance Team at GDPR@warwick.ac.uk.

You can also find out more about how we use your information here: **www.hra.nhs.uk/patientdataandresearch** (Copy of this document is available from the research team).

How have patients and the public been involved in this trial?

Patient and public representatives are part of our team and they have helped us make sure that patient views remain central to how the research is designed and carried out. Patients and public representatives will continue to work closely with us as part of the research team

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throughout the duration of the trial. They will also work with us on how to analyse the data and share the results with others.

What will happen to the results of this trial?

Once the trial is complete, we will prepare and publish a report. The results will be available to the hospitals that took part in the trial. We may share information relating to the trial in scientific meetings and it may be published in scientific journals. You will not be identified in any reports or publications and none of the information will be able to be traced to you personally. The results of the trial will be published on the VITAL website http://warwick.ac.uk/VITAL .

Further Information

Further information about the trial will also be available on the trial website (http://warwick.ac.uk/VITAL).

Thank you for taking time to read this information sheet.

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