GlucoVITAL – Observational mechanistic sub-study of the Volatile vs Total intravenous Anaesthetic for major non-cardiac surgery (VITAL) trial

PATIENT INFORMATION SHEET

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IRAS: 324653

Introduction

We are a research team from the Queen Mary University of London (QMUL) working with doctors and nurses at [insert Trust name]. Before you decide, it is important to understand why we are doing this research and what it involves. Please take your time to read the following information and decide whether or not you wish to take part. Talk to your family and friends about the study if you wish. Ask us if anything is unclear.

Why are we doing this research?

The aim of this study is to understand how the type of general anaesthesia administered during surgery can affect blood sugar levels. It will also help us understand whether by minimising blood sugar levels will reduce post-operative complications.

Why have I been invited?

We have invited you because have decided to participate in the VITAL trial.

Do I have to take part?

No. It is up to you to decide whether or not to take part in the study. If you decide to take part, we will ask you to sign a consent form.

What will happen to me if I take part?

Continuous blood glucose monitoring

To understand how the type of anaesthesia given during your surgery affects sugar levels during the surgical period, your glucose level will be monitored continuously. The device (Dexcom G7) is a sensor which is placed on upper arm that is routinely used in patients with diabetes (please see figure below). The recording will start on the day of your operation and last up to 10 days after surgery or hospital discharge, whichever comes first. Throughout your hospital stay, the local research team will come to see you and review your medical notes. An explanation of how the continuous glucose monitoring is being used and what wearing the sensor entails can be found using the following link: https://youtu.be/y6Ct6SJ7CAw

Blood samples

The research team at your hospital will also obtain a blood sample (approximately three teaspoons) before surgery and on the day after surgery (whenever possible, this will be done at the same time as your routinely collected blood samples) to check whether your heart shows signs of stress. If you agree, the blood samples obtained during the course of this study will also be used for closely related future ethically approved research. Please note this is optional and you can opt out of this. The samples will be stored for five years before being destroyed.

Follow-up

A member of the research team will come to see you during your hospital stay to ask about your wellbeing and collect information on your recovery.

What are the possible risks and benefits of taking part?

There is minimal risk of harm to either patients or investigators. You will be closely monitored throughout the study period to ensure the blood sugar patch is worn in a safe manner at all times.

What are the possible side effects?

The blood sugar patch may irritate your skin.

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

If you decide not to take part, or later to withdraw, this will not affect the standard of care you receive. You are free to stop taking part at any time, without giving a reason but the research team will keep your research data and the blood samples that have already been collected. You can find out what would happen with your data before you agree to take part in a study.

What if I am not happy about the study?

Taking part in the study does not affect the way you are cared for in hospital. However, if you have a concern about any aspect of this study, you should ask to speak with someone from the research team at the hospital, who will do their best to answer your questions. You can also contact them on the telephone number at the bottom of this information sheet. You may also contact your Patient Advisory Liaison Service (PALS) [change according to site-specific department name] if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone [insert local equivalent] or email [insert local equivalent]. You can also visit PALS [change according to site-specific department name] by asking at hospital reception. QMUL has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the study. These arrangements do not affect your right to pursue a claim through legal action.

How will we use information about you?

Authorised members of the research team at your hospital will need to access information from your medical records so that they can collect the information required for this research project. This information will include your initials only. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number and initials instead. We will keep all information about you safe and secure. Our procedures for handling,

processing, storage and destruction of data are compliant with the General Data Protection Regulation Guidelines 2018 and Data Protection Act 2018.

You can find more information on how researchers use information from patients on https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/. If you would like to receive a paper copy of this information, please ask the research team at your hospital.

Where can you find out more about how your information is used?

You can find out more about how your information is used:

- at http://www.jrmo.org.uk/ or by contacting the QMUL data protection officer: data-protection@qmul.ac.uk
- by contacting the trial coordinating team on p.dias@qmul.ac.uk
- by ringing us on +44 (0)20 3594 0352

What are your choices about how your information is used?

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. This is because research could go wrong if data is removed or changed.

Who is organising and funding the research?

The study is funded by the Efficacy and Mechanism Evaluation (EME) Programme and coordinated by the Critical Care and Perioperative Medicine Research Group at QMUL. QMUL will also act as the Sponsor and will also be data controller for this study. Your doctor will not receive any payment for including you in the study.

Who has reviewed the study?

All research in the NHS is reviewed by an independent Research Ethics Committee, to protect the interests of the patients who take part. This study has been reviewed and granted a favourable opinion by the NHS Research Ethics committee and has also been approved by the Health Research Authority.

What will happen to the results of this study?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. QMUL is

required by research regulations to keep the study data for a minimum of 5 years after the study has completed. The data will be kept in a secure facility only accessible to authorised personnel.

Thank you!

Thank you for considering taking part in this study and for reading this information sheet, which is yours to keep. If you decide to take part in the study, you will also be given a copy of your signed consent form.

Your study doctor is:	
Name:	Contact phone number:
Your research/ specialist nurse is:	
Name:	Contact phone number: