Perioperative complications and autonomic dysfunction assessed by the COMPASS-31 assessment tool (PeriCOMPASS-31)

PATIENT INFORMATION SHEET

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Principal Investigator: [please insert here]

IRAS: 328971

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 nervous system affects recovery after surgery. We are particularly interested in how autonomic dysfunction (a condition where involuntary bodily functions like heart rate or digestion may not work properly) might increase the risk of infections and other complications after surgery. This research will help us identify ways to better predict and reduce these risks, ultimately improving the care and recovery of surgical patients.

Why have I been invited?

You have been invited because you are scheduled to have surgery under anaesthesia.

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?

If you decide to participate in this study, the researcher will explain the process and document your consent. You will receive a copy of the consent form for your records, and the original will be securely stored at the hospital. Your operation and standard care will proceed as planned, with some additional steps as part of the study. This includes:

Completion of questionnaire before surgery

You will be asked to complete a short questionnaire called Composite Autonomic Symptom Score 31 (COMPASS-31) which focusses on different aspects of how your body functions. The questionnaire itself contains 12 to 31 questions, depending on your answers and should take approximately 5-10 minutes to complete.

Heart rate monitoring

A small heart rate monitor will be placed on your forearm using a soft elastic band before surgery and worn for 5-10 minutes. This device will help us measure changes in your heart rate and how your body could respond to surgery. The name of the device is Polar Verity Sense optical heart rate sensor (Polar Electro Oy, Kempele, Finland), and it is a CE-marked device used in a clinical setting. We will apply and remove the device within one setting, so you don't have to keep or return the device for us.

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. Please note the results from your blood tests will not be used in the clinical management of your care because 1) this is currently not standard practice and 2) the results will only be analysed at the end of the study. 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.

What are the possible benefits of taking part in the study?

You may not benefit directly from taking part in this study. By taking part in studies looking at new ways to improve the care you receive and by allowing us to collect information about your healthcare, we hope to improve the health outcomes for surgical patients in the future.

What are the possible risks of taking part in the study?

The blood sample collection process might cause minor discomfort, such as a small bruise or slight pain at the site where the blood is taken. If you wear a heart rate monitor, there is a small chance that the band may irritate your skin or leave temporary pressure marks, causing redness or itching. These effects are generally mild and temporary.

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 King Saud bin Abdulaziz University for Health Sciences and Queen Mary University of London. Queen Mary University of London will act as sponsor and the tstudy will be coordinated by the Critical Care and Perioperative Medicine Research Group. 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: