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

PATIENT INFORMATION SHEET

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IRAS: 328971; Sponsor: Queen Mary University of London

Principal Investigator: [please insert here]

Introduction

You are being invited to take part in a research study to help us improve our understanding on how the body responds to surgery and whether certain health patterns before surgery can predict infections or other complications. 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 before you decide whether or not you wish to take part. Talk to your family and friends about the study if you wish. Please 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 automatic bodily functions like control of heart rate or digestion may not work properly) might increase the risk of infections and other complications after undergoing surgery. This research will help us identify better ways to predict and reduce these risks with the ultimate goal of improving the care and recovery of surgical patients.

Why have I been invited?

We have invited you because you are going to have surgery under anaesthesia and a member of the clinical team has identified you as someone who may be suitable for our study.

Do I have to take part?

You don't have to take part if you don't want to. If you decide to take part, we will ask you to sign a consent form. 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 withdraw at any time, without giving a reason..

What will happen to me if I take part?

If you decide to participate in this study, the researcher will explain what the study involves and document your consent. This will take place either face to face or remotely (e.g. over the phone). You will receive a copy of the consent form for your records, and the original consent form will be

securely stored at the hospital. We will ensure all study visits align with your hospital appointments and no additional visits will be needed to take part in the study.

Your surgery will proceed as planned and your treatment will not change. However, there will be some additional steps as part of the study. This includes:

Completion of a questionnaire before surgery

You will be asked to complete a short questionnaire called the 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. This will be completed with a member of the research team either face to face when you come to hospital on the day of surgery or remotely (i.e. over the phone or using an online link sent to your email address or phone).

Heart rate monitoring

A small, adhesive heart rate monitor will be placed on your chest on the day of your surgery (before your surgery starts) and worn for up to three days afterward. This device will help us measure changes in your heart rate and how your body responds to surgery.

Blood samples

The research team at your hospital will also obtain additional blood samples (approximately three teaspoons) before surgery and on the day after surgery to check whether your heart shows signs of stress. Whenever possible, this will be done at the same time as your routinely collected blood samples. Please note the results from your blood tests will not be used by your doctor to manage 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 additional 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 patient care and by allowing us to collect information about the care you received during your hospital stay, 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 adhesive patch may irritate your skin, 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 by letting a member of your care team know. The data and blood samples that have already been collected will be kept by the study team. 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?

We will need to use information from you and from your medical records for this research project.

This information will include your [initials/ NHS number/ name/ contact details (telephone number and/or email address)]. People will use this information to do the research or to check your records to make sure that the research is being done properly. 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 instead.

Queen Mary University of London is the sponsor of this research and they responsible for looking after your information.

Queen Mary University of London is responsible for looking after your information. We will share your information related to this research project with the following typers of organisations.

- Universities
- NHS Trust Hospitals

Internation transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

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. We will keep your study data for a maximum of five years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records / your hospital / your GP]. If you do not want this to happen, tell us and we will stop
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

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

You can find out more about how we use your information:

- at http://www.jrmo.org.uk/ or by contacting the QMUL data protection officer: data-protection@qmul.ac.uk
- by asking one of the research team
- by sending an email to Priyanthi Dias (Study coordinator) on p.dias@qmul.ac.uk
- by ringing us on +44 (0)20 3594 0352

How will we keep your information safe and secure?

We will keep all information about you safe and secure by:

- ensuring only 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 will include initials only.
- People who do not need to know who you are will not be able to see your name or contact details.
- 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.

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. The study will be coordinated by the Critical Care and Perioperative Medicine Research Group at Queen Mary University of London. 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.

Is there any insurance in place for the trial?

The insurance that Queen Mary has in place provides cover for the design and management of the study as well as "No Fault Compensation" for participants, which provides an indemnity to participants for negligent and non-negligent harm. NHS indemnity scheme will apply to the conduct of the study at NHS sites.

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 five years after the study has completed. The data will be kept in a secure facility only accessible to authorised personnel. We will also ask you whether you would like to receive the study results.

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: