A National Perioperative Platform Trial to Improve Outcomes for Surgical Patients (PROTECT) Trial

PARTICIPANT INFORMATION SHEET

Version: 2.0 19.06.2025

Principal Investigator: [Insert PI name]

IRAS: 353122

We are a research team from Queen Mary University of London, working with doctors and nurses at [INSERT SITE NAME]. We are studying different ways to improve the health and well-being of surgical patients. Before you decide whether to take part, it is important to understand why this research is being done and what it involves. Please take time to read the following information. Talk to your friends and family about the study if you wish and ask us if anything is unclear.

Why are we doing this research?

Each year between five and eight million people have a surgical procedure in the NHS. While surgery is considered very safe, our research shows that on average one in six patients will experience some form of complication during or after surgery, which could impact their quality and quantity of life. This study aims to test new treatments or interventions to improve the health of patients before, during or after surgery. For example, by preventing and treating complications during or after surgery, or improving the quality of life before or after surgery.

Why have I been invited?

You have been invited because you are an adult, receiving investigation or treatment on a NHS surgical care pathway.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part in the study. If you decide to take part, you will be asked to sign a consent form. 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 decide not to take part, or later to withdraw, this will not affect any aspects of the care you receive.

What would taking part involve?

A member of the research team will contact you to discuss taking part in the study. They will talk to you about the study and ask if you have any questions, and if you are ready to make a decision about taking part. If you decline to take part, the research team will not contact you again. If you agree to take part, we will collect information about you and your medical treatment or care, including historical data in your medical records and you may be offered the opportunity to take part in one or more studies of new ways to look after patients who have surgery to help improve their health or quality of life. These will be discussed with you separately and you will be asked to provide consent to take part in each study.

While you remain a participant in the study, we will contact you periodically to ask you to complete questionnaires about your health, either by text message, email or telephone. If you undergo surgery, we will collect information about you before and after your operation. While you remain in hospital, we may visit you to record information or contact you to complete a questionnaire, which will take between two and five minutes per day. A carer or proxy may assist with completing the questionnaires if you are unable to do so. We will review your medical record, which may include contacting your General Practitioner. We will collect data about your health and well-being using national NHS databases including Hospital Episode Statistics or the equivalent databases in Wales, Scotland and Northern Ireland, and data from the Office for National Statistics. The last direct study contact will be 90 days after you undergo surgery. However, we may continue to collect information about your healthcare through national records.

What are the possible benefits of taking part?

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 disadvantages and risks of taking part?

Taking part in the study is unlikely to cause you harm. The main difference to your experience will be a small time commitment to answer questions about your health and recovery. There may be additional risks associated with the individual studies you could take part in and these will be clearly set out in the separate patient information(s) sheets for these studies.

What if I am not happy about the study?

Taking part in the study does not affect the way you are cared for. However, if you have a concern about any aspect of this study, you should ask to speak with someone from the

research team, who will do their best to answer your questions. You may also contact the doctors and nurses who lead the study at this hospital on the telephone number at the bottom of this information sheet. You can 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 in the unlikely event you experience harm as a direct result of the procedures you received during the study, you will be compensated. These special compensation arrangements apply where harm is caused to you that would not have occurred if you were not in the study. This does not affect your right to pursue a claim through legal action.

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

You are free to stop taking part at any time without giving a reason. If you decide to withdraw from the study this will not affect the standard of care you receive. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records and central NHS records. You will not be approached in person for collecting these data. If you do not want this to happen, tell us and we will stop. You can find out what would happen with your data before you agree to take part in the study.

How will my information be used?

Our procedures for handling, processing, storage and destruction of data are compliant with Data Protection Regulations. We will use information from you and your medical records for this research project and to check that the research is being done properly. Identifiable information will include your name, initials, Health Service Number, date of birth, age, sex at birth, postcode and contact details. Your information will be kept confidential and may be viewed by researchers, the Sponsor (and its representatives), regulatory authorities, and the NHS Trust/ Health Board, where it is relevant to this research.

We will securely send your identifying information from Queen Mary University of London to NHS England which is a government organisation that holds information on hospital admissions (Hospital Episode Statistics) and mortality data sourced from Civil Registration Data and supplied by NHS England on behalf of the Office for National Statistics (ONS) [change according to specific country of the United Kingdom]. We send the minimum amount of identifying information to make sure we get data about the right person. Your information is securely processed and stored on behalf of Queen Mary University of London by Swansea University, which coordinates this process and hosts the trial database.

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 unique study ID instead. We will keep all information about you safe and secure. Once we have finished the study, Queen Mary University of London will keep some of the data for up to 25 years at either Queen Mary University of London or Swansea University so we can check the results. After this, all documents will be destroyed. We will write our reports in a way that no-one can tell that you took part in the study.

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 to collect information about your health from your medical records and central NHS records. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the research to be reliable.

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

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

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to admin@protectresearch.org
- by ringing us on 020 3594 0352
- by emailing the QMUL data protection officer at: data-protection@qmul.ac.uk

Who is organising and funding the research?

The study is funded by the Barts Charity and the British Journal of Anaesthesia. Queen Mary University of London will act as the Sponsor and data controller for this study, which is run 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 London South East Ethics Committee and has also been approved by the NHS Health Research Authority.

What will happen to the results of this study?

We will prepare and publish scientific reports for each study in the PROTECT family. The results will be available to the hospitals that took part in the study. We may share the results at scientific meetings and publish them 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, including a plain English summary of the findings, will be published on the PROTECT trial website and you will be able to request a copy by contacting the study team via email: admin@protectresearch.org

Further Information

Further information will also be available on the study website protectresearch.org

Thank you for taking time to read this information sheet.

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