Participant Information Sheet

Functional & Immunological Outcomes after Laparoscopic and Robotic Rectal Cancer Surgery (FILTER)

We would like to invite you to take part in our research study. Your participation is entirely voluntary. Before you decide whether you wish to participate, you must understand why the research is being done and what it will involve. Please take this information sheet home, take your time to read through it, and make sure to ask any questions that you may have. You do not have to make an immediate decision.

What is the purpose of the study?

This study is part of a research project to investigate the role of a surgical technique in the treatment of rectal cancer. Rectal cancer is cancer located in the last 15 cm of the large bowel and is a common type of cancer. The treatment for this type of cancer is taking out the whole tumour with an operation. This used to be done with an open procedure, leaving a big scar. With the rise of laparoscopic (keyhole) surgery, we can do the same surgery with smaller wounds, leading to an earlier recovery. However, the standard laparoscopic surgery has its own limitations.

To try and overcome these limitations, new techniques have been introduced, one of which is the robotic technique. This robot (called 'Da Vinci') is a more flexible device with a wider range of controlled movements, is equipped with a 3D camera (leading to better vision) and allows for a more precise removal of the tumour.

We want to study which technique causes less harm to the surrounding structures, leading to a better outcome of the urological, sexual and bowel function. A way to measure the harm that is done by a surgery is by measuring the stress response in blood. Every surgery causes wounds that the body needs to heal. This healing process is more severe when larger wounds are made and can be measured in the blood.

Why have I been invited?

You are being asked to participate in this research as you have been offered an operation to remove the cancer found in your rectum. If you choose to participate, our research team will assess your situation once more to check if your situation fits our study goals and include you into our study.

What will happen if I take part?

If you agree to participate in this study, your procedure will go ahead just as your surgeon had planned. We will monitor your progress with a series of questionaries, surveys, and regular blood tests. We will collect blood samples from you before your surgery and whilst you are in the hospital after your surgery, on postoperative days 1, 3 and 5. This will not affect or delay any aspect of the care you receive.

Participating in this study does not alter the treatment that you receive in any other way. The surgeon remains free to perform the steps of your operation as they usually would, with either the robot-assisted or the laparoscopic approach. After you have your operation, the clinical team (including the research team) will gather further information about your recovery by reviewing your medical notes. You will receive follow-up questionnaires at 3, 6 and 12 months. With your permission we will inform your GP that you are part of the research study.

If your situation changes and you are deemed unable to make informed decisions after consenting, you will be withdrawn from the study. Identifiable data or tissue already collected with consent will be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out on or in relation to the participant. You will not receive any financial compensation for taking part in the study.

Do I have to take part?

No, participation is entirely voluntary. You will be given time to consider taking part. You are free to refuse to take part or to withdraw from the study at any time without having to give a reason. This will not affect your medical care or your relationship with anyone looking after you.

What will I have to do if I take part?

If you agree to take part in the study, you will be asked to sign a consent form before you have your operation as confirmation that you agree to take part. You will be given a copy of the consent form to keep. You can also keep this information sheet. We will ask you to complete some questionnaires before your surgery and after your surgery at 3, 6 and 12 months. These questionnaires take approximately 30 minutes to complete (times may vary between participants). We will also collect blood samples before your surgery and after your surgery on days 1, 3 and 5 of your hospital stay, for a total of approximately 13-17 mL of blood per day. Blood samples will be taken and processed by trained staff, analyzed by trained members of the research lab, securely stored at the PHU research lab, and destroyed at the end of the study in accordance with the Human Tissue Act.

What are the possible disadvantages or risks of taking part?

Taking part in this study will not add any additional risk to you than you would have as part of your surgery and postoperative recovery. We will be taking some blood tests as part of this study, but the risks associated with this are no greater than with routine blood sampling. As a part of this study we will also conduct measurements of your sphincter function (the muscle that closes your anus) before your surgery and at 12 months. This involves rectally inserting a small device that will measure the sphincter function. The sphincter measurements are an optional part of the study and there are no additional risks associated with this.

All surgeons taking part in this research are experts in bowel cancer surgery and have extensive experience. Both surgical techniques are part of standard care at our Trust, and the treatment you receive depends on availability of staff, equipment and operation rooms.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This will include your initials, NHS number, name, and contact details]. 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. We will keep all information about you safe and secure. 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. The data will be securely stored by our research department for a period of 15 years after completion of the trial.

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 and your hospital 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. This means that we won't be able to let you see or change the data we hold about you.

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/ or by asking one of the research team by ringing us on 02392286000 ext 5158.

Who has reviewed the study?

This study has been reviewed by the NHS South Central-Hampshire B Research Ethics Committee, who has given their favourable opinion for this project (*reference 22/SC/0051*), along with each of the NHS Trusts taking part in this research.

What will happen to the results of the research study?

Results of the study are likely to be published in medical journals. They may be used for scientific presentations and may be forwarded to health authorities worldwide. You will not be identified in any reports or publications resulting from the study. All participants will be sent a summary of the results, unless they opt out of this. If you would like to receive the full report, please feel free to ask your surgeon or a member of the research team.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the team looking after you, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Hospital's Patient Advice and Liaison Service (PALS):

Patient Advice and Liaison Service (PALS), A-level Atrium, Queen Alexandra Hospital	
Telephone	02392 286309
Email	PHT.PALS@porthosp.nhs.uk

Thank you for taking time to read this information sheet.

If you have any further questions or concerns regarding this project, please contact your study team on Tel: 02392286000 Ext 3529, Ext 6678 or Ext 4270.

Research Team

Principal Investigator:	Mr J.S. Khan
Clinical coordinator:	Rauand Duhoky
	Rauand.Duhoky@porthosp.nhs.uk
	Tel: 0239228600 Ext 3529
Senior Research Nurse:	Elizabeth Hawes
	Tel: 02392286000 Ext 4270
Specialist Research Nurse:	Bethany Armstead
	Tel: 02392286000 Ext 6678
Specialist Research Nurse:	Pedro Braga Sardo
	Tel: 02392286000 Ext 4520

Mr Jim Khan

Consultant Colorectal Surgeon, Portsmouth Hospital University NHS Trust

Tel: 02392286000