Portsmouth Hospitals University NHS Trust

Department of Upper Gastrointestinal and Bariatric Surgery
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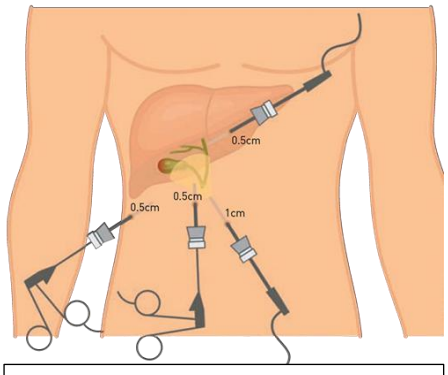
Study Title: Surgical Techniques: Robotic versus conventional Laparoscopic cholecystectomy IN benign Gallbladder disease (STARLING trial).

You are invited to take part in a clinical research study because you are due to have surgery to remove your gallbladder. This study compares the use of robotic surgery with laparoscopic surgery for the surgical removal of the gallbladder. assess Both treatment options are currently used in the QA Hospital in equal measures. We are keen to formally assess whether there are and differences between robotic and laparoscopic surgery for surgical outcomes (in terms of post-operative complication rates (the data to date suggests there is not). We will also assess the duration of surgery), clinical outcomes (how fast you recover, postoperative pain, complications) and we will measure your quality of life in questionnaires at 7 days and 30 days post operatively .

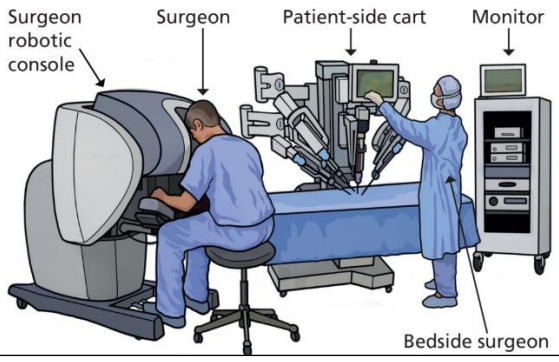
Both robotic and laparoscopic approaches are forms of minimally invasive surgery, i.e. using instruments fitting through small incisions or cuts in the abdomen. The surgical resection (removal of the gallbladdder) is called a cholecystectomy.

Participation in this study involves randomly allocating participants to undergo their planned cholecystectomy with either robotic surgery or laparoscopic surgery. When describing the surgery, the term “robot assisted” or “laparoscopic assisted” can also be used and this helps to refer to the types of surgical instruments the surgeon uses for the operation.

Laparoscopy is a term for keyhole surgery of the abdomen. This keyhole surgery can be performed in the conventional way, where the surgeon holds the instruments, OR with a robot holding the instruments, where the surgeon moves the instruments using a console. This is also called robot-assisted laparoscopy.



laparoscopic cholecystectomy, where the surgeon holds the instruments through keyhole incisions.



Robot-assisted laparoscopic cholecystectomy, or robotic cholecystectomy. The surgeon moves the instruments through keyhole incisions whilst sitting at a console.

The use of robotic surgery, or robot-assisted surgery, is a technique increasingly being adopted by surgeons in the UK. The robot is a tool that allows the surgeon to move instruments with more

precision, the surgeon makes the movements, the robot does not operate independently. The surgeons have been trained in both laparoscopic and robotic techniques.

Your participation requires you to do the following in addition to normal care around your procedure;

- Fill out questionnaires about your health and quality of life before surgery, 7 days after surgery and 30 days after surgery. These questionnaires can be filled out online, or over the phone. You do not have to attend the hospital for this follow-up.

Participation is voluntary: Taking part in any study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

Your decision on whether or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Queen Alexandra Hospital.

Alternatives to participation: If you do not take part in the study, both surgical options are still available, laparoscopic-assisted or robot-assisted resection of your gallbladder. Your doctor will discuss these options with you before you decide whether to take part in this study. You can also discuss the options with your local doctor.

Benefits from participation in this study cannot be guaranteed, however the study aims to further medical knowledge, and through your participation, greater treatment options in the future may help other patients with gallbladder problems.

Possible risks and disadvantages: Your study doctor or members of the study team will discuss risks and inconveniences of routine surgical care given for your illness. There are risks from any surgery and your doctor will discuss these with you. There are also risks associated with anaesthesia, which will be required for the surgery. These risks are no different from having surgery outside of this study.

New information: Sometimes during the course of a study, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research study. If you decide to withdraw, your study doctor will make arrangements for your regular treatment to continue. If you decide to continue in the research study, you will be asked to sign a new consent form confirming that you have been made aware of the new information. On receiving new information, your study doctor might consider it to be in your best interest to withdraw you from the study. If this happens, your study doctor will explain the reasons and arrange for your health care to continue.

Withdrawing from the study: If you decide to withdraw from the study, please notify a member of the study team as soon as possible. This notice will allow your study doctor to discuss any health risks or special recommendations linked to withdrawing.

Unexpected cessation: This study may be stopped unexpectedly. Possible reasons include:

- Unacceptable side effects from the use of robot-assisted surgery,

End of the study: A decision about the most suitable treatment for you will be made in consultation with you and your study doctor at that time. Your study doctor will inform you about your own results where relevant. Once the study is complete and the results are known, a written plain-English summary of the results of the study will be made available to your study doctor for discussion with you.

How will we use information about you? We will need to use information from you and your medical records for this research project. This information will include you're your initials, NHS number 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.

Portsmouth Hospitals University NHS Trust is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure.

Your data will not be shared outside the UK.

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 15 years. The study data will then be fully anonymized and securely archived or destroyed.

Where can you find out more about how your information is used? You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team, see contact details at the end of this document.
- by sending an email to our Data Protection Officer at lucy.long@nhs.net or phoning 023 9228 1288
- by ringing the Research Department on 02392 286236 or emailing pho-tr.researchoffice-groupmailbox@nhs.net
- NOTE: At least one of these sources must be able to point people directly to the sponsor's Data Protection Officer.

Complaints and compensation: If you suffer any injuries or complications as a result of this study, contact the study team as soon as possible to be assisted with arranging suitable medical treatment.

If you remain unhappy or concerned, you can make a formal complaint to the hospital Patient Advice and Liaison Service (PALS) who can be contacted by phone on 023 9228 6309 or by email **pho-tr.phtpals@nhs.net**.

You will be receiving standard medical care during this trial. If you unfortunately experience a complication during your procedure, you will receive the required medical care, but there will be no special compensation available as these risks are part of the procedure rather than related to the trial.

If in the event you are harmed due to negligence during the course of the research trial, the normal NHS complaints system is available to you should you wish to pursue legal action against the sponsor Portsmouth Hospital University NHS Trust or the NHS site where you received your care.

Organisation and funding of the study: This study led by Mr. G.I. van Boxel, is sponsored by Portsmouth Hospitals University NHS Trust and coordinated by the department of Upper GI surgery within the Portsmouth Hospitals University NHS Trust. Funding to conduct the study has been received by the Intuitive Foundation (https://www.intuitive-foundation.org).

Study outcome: The anonymise results of the study will published in an academic journal to inform the medical community of the results of our trial. This typically takes 9-12 months to be produced, reviewed and published. We will share the publication with the study participants.

Study reviews: All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. They are there to protect you. This study has been given a favourable opinion by London – Hampstead Research Ethics Committee as well as the Health Research Authority. This means they have read about the study, interviewed the lead researcher and have no concerns with this project.

It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the Sponsor, Portsmouth Hospitals NHS Trust or a delegated third party of the Sponsor, and UK research governance authorities, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What will happen to the results of the study? You will be informed of the results of the study at the end of the study, there will be an option to attend a presentation on the study results. If you wish to stay up to date as the study progresses, there is the option to join our newsletter.

What if I have any questions? If you have any questions which have not been answered by this information sheet, please contact the study team for help with these using the details at the end of this information sheet.

What happens next? Having read this information sheet, if you wish to take part, you will be approached to sign a consent form for the trial. Should you have any questions or concerns, these can be discussed and addressed prior to providing consent. You will then undergo your procedure according to which arm of the trial you are allocated to, and the anonymised data will be collected from this.

Thank you for taking the time to read this and considering whether you wish to participate.

Further information:

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Portsmouth data protection officer
pho-tr.informationgovernance@nhs.net
Tel: 02392281288

UK Information Commissioner's Office
You have the right to complain directly to the Information Commissioner's Office if you would like to complain about how we process your personal data:
https://ico.org.uk/global/contact-us/