Robot assisted knee arthroplasty

Learning Effect Sub-Study

Chief Investigators:
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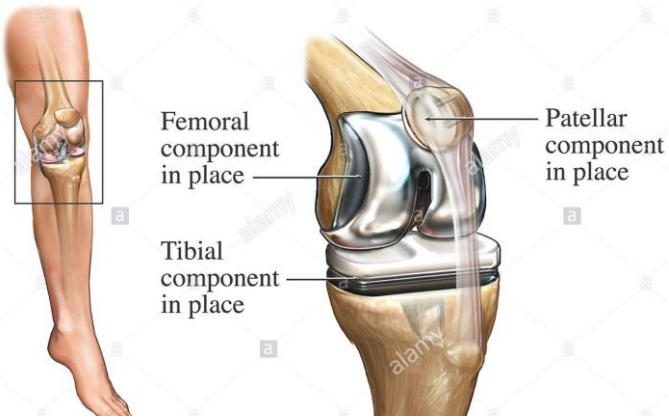
PARTICIPANT INFORMATION SHEET

You are invited to take part in our learning effect sub-study. Before you decide whether you would like to be involved, we would like you to understand why this study is necessary and what you would be asked to do.

Once you have read this information sheet, please feel free to discuss the study or ask any questions about the study with a member of the RACER team.

Background Information

Knee arthritis is a painful condition which can limit people's activities. When knee arthritis is very bad, it can be treated with a knee replacement. These operations are often very successful at reducing pain and improving the amount of activity someone can do. They can be painful in the few weeks after the operation, and many people still have some knee symptoms, even some time after surgery.



Picture 1. A knee replacement

For many years these operations have been undertaken by surgeons using their experience and skill, with a standard set of instruments. These are instruments that knee surgeons are very familiar with, and they have learned how to use them to get the best results. Currently, most surgeons perform knee replacements using standard instruments.

However, some surgeons have started using a robotic arm to help them perform a knee replacement. The surgeon holds the robotic arm during the operation and always remains in control. The robotic arm is used to move the instruments into the correct position by sensing the position of the leg. Those who think the robot is better believe its guidance helps with precision and improves overall results.

Picture 2. The parts of a robotic system for knee surgery

Your hospital now has this robotic system available and will be using this in the main Robotic Arthroplasty: a Clinical and cost Effectiveness

Randomised controlled trial (RACER) study to find out if robot assisted surgery improves outcomes after knee surgery.

Your surgeon is already very experienced in performing knee replacements using standard instruments and has had some training in the use of the robot system. However, before surgeons can take part in the main study, they need to have completed at least 10 operations using the robotic system. At present your surgeon is building up their experience with the robot.

Therefore, we are asking that you consider agreeing to your surgeon using the robotic system to help them with your knee replacement. This procedure follows the normal practice of NHS Trusts when a surgeon is learning a new technique.

Information about the surgery using the robotic system.

The robotic system we are testing is the Stryker MAKO system (see Picture 2). This is the most widely used robotic knee replacement system at present. It has been used many thousands of times, in the UK and abroad, and we can be confident it is safe. It has a CE mark and is licenced for use in the UK.

The surgeon starts the operation, and inserts some pins into the bone, at the top of the shin, often through two small (1cm) incisions. The pins

are used to show the computer where the bones are. The surgeon then performs the operation as usual, but instead of using their normal instruments, they use the robotic system to guide where they cut the bone. They will then insert the knee implants with cement in the normal way.

For NHS patients in your hospital, the surgeons are only allowed to use the robot to perform knee replacements for people who are taking part in this learning sub-study or the main study. You will not be able to request the robotic surgery outside of the study.

What is the purpose of this study?

We want to find out how, over time, the surgeons become more familiar with using the robotic system and whether this has any effect on the surgery itself.

In the near future, your surgeon will be involved in the main RACER study to find out whether knee replacement surgery using the robot assisted system is as good, or better than traditional surgery. To ensure this is a fair comparison the surgeons need to be familiar with both types of surgery. The trial will be looking at which operation is best.

Why have I been invited?

Your surgeon has recommended the best treatment for you is surgery

and you have agreed to undergo a total knee replacement. The NHS trust where you will have your surgery has a robotic system available and would like to use it in this learning sub-study.

What will happen if I take part?

Before your surgery

If you decide to take part in this learning sub-study, you will be asked to sign a consent form. If you are unable to sign the consent form in person, the research nurse or clinician will book a telephone or video call with you to explain the study processes and confirm that you agree to participate. This phone call will be witnessed by someone from the NHS staff and we will document your decision in your medical notes. You should only give consent for the study if and when you are happy to take part.

After you have given consent, you will be asked to complete a questionnaire about you and your knee, and how the problems with your knee affect your life. This should take approximately 10-15 minutes to complete. A trained member of staff will also assess how much movement you have in your knee.

CT scan and X-rays

In the weeks before your operation, you will need to have a CT scan of your knee. Since everyone's bone positioning is a little different, the CT

scan is used to make a plan to best fit the knee replacement to your bones. Due to pressure on capacity in the NHS, it is possible that your CT scan will be booked at another centre. Your surgeon or research nurse will be able to provide you with the details of the location where you will have your CT scan.

The scan is performed with your knee in a CT scanner which is shaped like a narrow 'doughnut' (see picture 3). A short scan of your hips and ankles are also performed. The rest of your body will be outside of the scanner, so it does not feel like being in a small space, but it can be a little noisy.

Specialist planning software is used to plan the surgery using the robotic system. To make this plan, the CT scan images will be sent to the company that supplies the robot (Stryker, USA). These images will contain at least two identifiers (for example, your name, hospital number or date of birth), but these will only be seen by employees of Stryker to plan your operation and will not be shared with anyone else.

Because the CT scan is an additional procedure necessary when the robotic system is used, you will have a slightly higher dose of radiation to your body than if you did not have robotic-assisted surgery. The risk from this radiation is very low. The normal risk of getting life-threatening cancer at some point in life is 50%. With this additional scan, it increases to 50.03%.

On the day of the operation

When you come into hospital, but before your surgery, a member of staff will check that you are still happy to take part in this learning sub-study. You will receive the same high-quality care as any other patient.

Picture 3. A CT scanner.

During the operation

As the surgeons are learning the technique, the surgery may take a little longer (e.g. 15 to 30 minutes longer) than if they were using standard instruments.

A representative from Stryker and possibly another surgeon may be in theatre during the procedure to provide technical advice and support. This is a normal and often necessary part of delivering the surgery safely.

Images of the computer screens used during surgery are routinely saved

as a hospital record, but this does not include pictures of your knee. For this study, a copy of the images of the computer screens will be sent to researchers at University Hospitals Coventry and Warwickshire, and the University of Warwick.

Cleaning the robotic system

The robotic system includes cutting tools which are single use only, so they get replaced after each operation. The parts of the robot that are in the surgical area are sterilised. The large base of the robot is covered in a special sterile plastic drape which means that it does not actually touch anything during surgery.

After the operation

On the day after the operation, and for the following two days, a member of staff will come and ask you about the pain you feel in your knee. If you leave hospital before the third day after your operation, we will give you a form to fill in at home, or we will telephone you at home to ask how your pain is.

We will review your medical notes after you have left to find out how many painkillers or other treatments you received. We will use your blood test results to work out how much blood you may have lost, and we will take details about the operation and any other relevant treatments you received before or after the knee replacement.

Before you leave hospital, you will be given a discharge booklet

(including advice and exercises) which explains what you will have to do after the operation. If the surgical or physiotherapy team treating you think you need to see a physiotherapist after the operation, they will organise this for you. If not, they will give you exercises to do yourself. Your discharge booklet will help you with these exercises and guide you through the recovery.

You will receive a short questionnaire while you are in hospital, six weeks after the operation and further questionnaires to fill in 3, 6 and 12 months after the operation.

We will ask you to post the paper questionnaires back in the freepost envelope provided if for any reason you are not using the mobile app. The questionnaires are very important to know how you are doing. We will use your answers to find out if the number of robot assisted operations a surgeon has done affects how their patents feel in the longer term.

You will be invited to attend for an x-ray of the operated leg and a CT scan of the knee, three months after the operation. More details are given in the 'CT and X-ray' section above.

The RACER researchers are looking into using a mobile phone app as an option for those participants who prefer to use it to complete the questionnaires. We will need to provide your phone number to the app developers so they can enable the app to send you reminders to

complete your questionnaires. Your phone number will not be shared for any other purpose.

If you need help filling any of the questionnaires or using the mobile application, please let us know. If you agree, we can send you a reminder that the questionnaire is due, based on the contact information that you give us. A researcher might also contact you by phone to help you complete the questionnaires or may talk to you in clinic.

You will be seen by your surgeon or a member of their team at various times during the recovery period. If you have not been able to complete the postal questionnaires, we may ask you to do so when you come to clinic.

Do I have to take part?

No, it is up to you whether or not to take part. If you do decide to take part, you are still free to change your mind and withdraw from the study at any time without having to give a reason. Deciding to withdraw, or not to take part, will not affect the quality of your care in any way.

What are the possible disadvantages and risks of taking part?

There are general risks with any operation. After a knee replacement, it is normal to experience some early pain, swelling, bruising and some drowsiness or sickness from painkillers. Numbness over the knee and some stiffness is also normal. Risks of having a knee replacement include

continued or worse pain, infection, wound problems, stiffness, injury to structures around the knee such as nerves or vessels, need for further surgery including redoing the knee replacement, blood clots in the leg or lung, or death.

The additional risk from taking part in the study is very small. The pins in the bone used in operations involving the robotic system could cause a fracture of the bone, but this is thought to be rare (less than one in every 1,000 cases).

We do not know of any other risks associated with taking part. However, when undertaking something new, there is always a small risk that something unexpected will happen; but, as the robotic system has been used many thousands of times worldwide, we think this is very unlikely.

What are the possible benefits of taking part?

Taking part in this study may not have any direct benefits for you. However, this study will help the future planning of surgeon training in the use of these robotic systems.

What if new information becomes available?

Sometimes during the course of a study, new information becomes available about the treatments that are being studied. If this happens, a member of the team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, you can

discuss your continued care with your doctor. If you decide to continue in the study, you might be asked to sign an updated consent form.

What happens when the research study ends?

You will be in the study for one year. If you are having any problems with the knee either after this time, or before, your general practitioner can refer you back to hospital to continue your care.

As we described earlier, this is the first part of a larger study and as the surgeons and teams become familiar with using the robotic system, they will be involved in the clinical trial called RACER which will be comparing robot assisted knee replacement surgery verses traditional surgery. This will be taking place for the next few years. Your involvement in this early stage of this study is very valuable and will ensure that we can provide results that can be used to shape the future of care for those with knee problems like yourselves.

Will my taking part in this study be kept confidential?

University Hospitals Coventry and Warwickshire, and the University of Warwick are the sponsors for this study. The University of Warwick will

act as the data controller and will be using information from you and your medical records in order to undertake this study. This means that the University of Warwick are responsible for looking after your information and using it properly. The University of Warwick and your

NHS site will keep identifiable information about you for a minimum of 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will make sure we minimise the amount of personally identifiable information we use.

Please follow the link below to find out how the University of Warwick handle your personal data processed in connection with the study:

https://warwick.ac.uk/services/sim/privacynotices/research/

Relevant information from you and your medical records (e.g. medical history and images) will be collected by your NHS site for this research study in accordance with our instructions. Your NHS site will use your name, NHS number, hospital number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

The information collected from you and your medical records, by your NHS site, will be securely passed to the University of Warwick. The only people in the University of Warwick who will have access to information that identifies you (name, NHS number, hospital number, contact details and additional contacts information) will be people who need to

contact you to remind you to complete study questionnaires, to follow-up with you about any missing information or to audit the data collection process. The University of Warwick will keep the contact information you provide for the full duration of the follow-up period. Your additional contacts personal data will not be shared or disclosed to any third parties external to the University of Warwick.

Some of your personal information, which may include your postcode, date of birth, sex and NHS number may be used for linking with other NHS datasets including NHS Digital and other Central UK NHS bodies to find out what has happened to you and your knee in the future. These data will all be handled in the strictest confidence in line with GDPR and the Data Protection Act 2018 and to the high standard expected of all NHS bodies.

Individuals from University Hospitals Coventry and Warwickshire, and the University of Warwick regulatory organisations may look at your medical and research records to check the accuracy of the research study.

When you agree to take part in a research study, confidential information (which does not identify you in any way) about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and

care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research**.** This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Your NHS site will keep identifiable information about you for this study for a minimum of 10 years after the study has finished.

Access to these data will be restricted to authorised personnel only.
All of your data will be handled with full data security measures and will not be shared outside of the study team.

Data sharing between organisations, including universities, NHS organisations, or medical companies, is important and helps improve the care we give to patients. It allows us to improve technology and care for the future along with stopping unnecessary repetition of studies. We are, however, very careful with the data we hold about you and will only share fully anonymised data, that does not identify you in any way, unless we have your full permission otherwise.

If you agree to take part, your GP and other doctors who may treat you, but are not part of this study, may be notified that you are taking part

in this study. If we are not able to keep in touch with you, we may contact your GP in the future to collect your health records, so we know if you have had any problems related to the operation

What happens if something goes wrong?

In the event that something goes wrong and you are harmed during the study due to someone's negligence, then you may have grounds for legal action for compensation against the University of Warwick (contact the Head of Research Governance, Impact Services, University House, University of Warwick, Coventry, CV4 8UW or by email researchgovernance@warwick.ac.uk or telephone 02476 522746)

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a Senior University of Warwick Official, entirely independent of this study:

Head of Research Governance
Research & Impact Services
University House

University of Warwick
Coventry
CV4 8UW
Email: researchgovernance@warwick.ac.uk
Tel: 02476 575733

For independent advice contact the PALS service (Patient Advice Liaison Service) on <<local PALS or patient liaison contact number>> or follow the NHS complaints procedure in your country.

What will happen to the results of the research study?

At the end of the main RACER study we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications resulting from the study. If you would like to obtain a copy of the published results, please contact the study manager by emailing: RACER@warwick.ac.uk

Who has reviewed this study?

This study has been reviewed and approved by the East Midlands - Nottingham 2 Research Ethics Committee and the Health Research Authority. It has been reviewed by numerous experts throughout the United Kingdom and by the National Institute of Health Research (NIHR). It has also been reviewed by an independent steering committee who oversee this study.

Who is organising and funding the research?

This research has been organised by University Hospitals Coventry and Warwickshire and the University of Warwick. It has been funded by the UK NHS research body, the National Institute for Health Research, through its Health Technology Assessment Programme.

Stryker, the manufacturers of the robotic system have agreed to meet the additional costs of robotic surgery within this study. They will have not be involved in the analysis or interpretation of the study findings.

Contacts for further information

If, at any time, you would like further information about this research project (HTA Project: NIHR128768) you may contact your local Research Team on <<local research contact details>> or email the study coordination team via: RACER@warwick.ac.uk

Thank you for considering participation in this learning sub-study and for taking the time to read this information sheet.

RACER - OPTIONAL DATA SHARING INFORMATION

The data we collect in the RACER study include your CT scans, as well as data collected by the robot during surgery and questionnaires about your health. If you agree, the University Hospitals Coventry and Warwickshire and the University of Warwick may share these data with the company that makes the robots (Stryker Orthopaedics), who may pay the hospital and university for providing this data. Stryker will only use your data for future research and development purposes (e.g. developing new and existing instruments, knee replacement products and software), outcome studies and related publications aimed at improving patient care, this will provide commercial benefits for them. They will not use your information to contact you or sell you their products or services.

There are clear legal agreements between Stryker, the University Hospital of Coventry and Warwickshire and the University of Warwick to protect your identity and your personal information will always be held confidentially in accordance with GDP, these protections will remain even if data is transferred outside the EU, such as to the USA. Whilst they will already have received your CT scans for the purposes of planning the surgery (and could theoretically link the scans to your information) we will have strict contracts in place to ensure this does not happen.

On the Consent Form, there is a specific question about whether you are happy for additional details to be shared with Stryker Orthopaedics. This is optional, and you may still participate in the RACER study if you do not agree to the sharing of your data.