Patient Information Sheet

Effectiveness of total knee replacement with PAtellar Resurfacing compared to selective patellar resurfacing Trial with blinding (PART)

PART 1: INFORMATION ABOUT TAKING PART IN OUR STUDY

Why have I been asked?

We are a team of researchers who are conducting a study looking at whether during total knee replacement surgery it is also necessary to resurface the kneecap (resurfacing is replacing the back of the kneecap). You have been sent this information sheet because you may be having surgery and we would like to invite you to take part in our research study. We may contact you about this before or during one of your routine hospital appointments, or we will talk to you when you come to the hospital for your operation. The research is sponsored by the NHS and will be carried out jointly by the University of Bristol and the North Bristol NHS Trust. The National Institute for Health and Care Research (NIHR) have provided the funding for the study.

Before you decide if you would like to take part, we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish, such as friends, relatives or your doctor and take time to decide. A member of our team will go through this information sheet with you to explain the study in more detail and answer any questions you have.

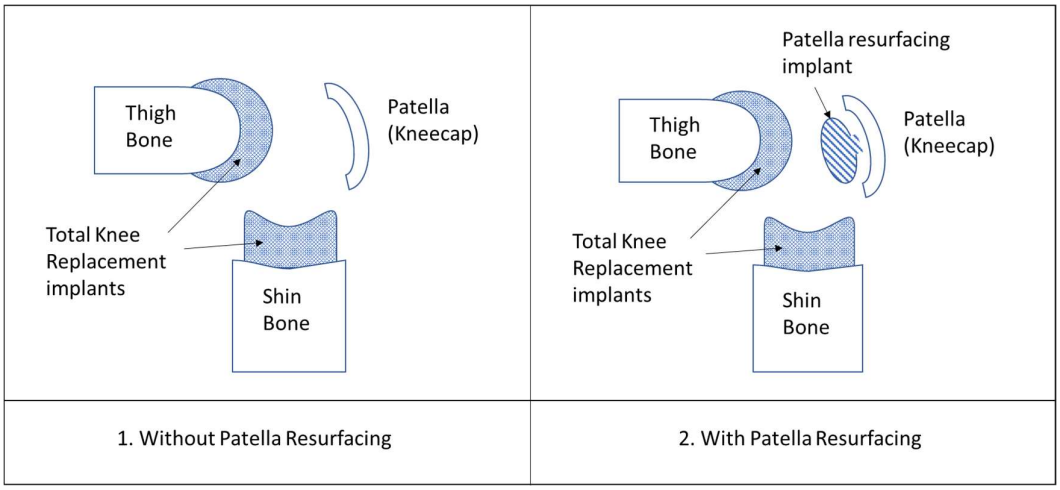
Taking part in research is voluntary; it is up to you to decide whether or not you would like to join the study. You are free to stop taking part at any time, and you do not have to give any reason for your decision. The standard of care you receive will not be affected if you decide not to take part.

What is the purpose of the study?

Controlling pain and improving mobility in the long-term after total knee replacement surgery has been highlighted as a research priority by patients. Knee replacement is a common operation, with 109,000 carried out every year in the UK. It is performed to help patients with pain from disabling arthritis.

Knee replacement involves replacing the bottom of the thighbone (femur) and the top of the leg bone (tibia) with artificial implants. After this is done, surgeons can decide on one of two options for treating the kneecap:

1) The kneecap (patella) is unaltered during the operation.
2) The surgeon attaches a separate artificial implant to the back of the kneecap, which may help reduce further wear or pain. This is known as resurfacing the kneecap.



Total Knee Replacement surgery 1. Without kneecap resurfacing and 2. With kneecap resurfacing.

Resurfacing is an extra step in the operation, which takes about 5 to 10 minutes more time during surgery. It can sometimes cause problems, such as breakage of the kneecap or tears in the nearby tendons. By contrast, not resurfacing may cause long-term knee pain, and more surgery may be needed to resurface or replace the kneecap in the future.

Recent national guidelines recommend that resurfacing the kneecap in all patients is better than never resurfacing the kneecap. However, many surgeons make an individual choice about whether or not to resurface the kneecap for each patient, based on pre-operative factors such as pain (discussed with patients before surgery) and intra-operative factors such as the condition of the kneecap (reviewed by the surgeon during surgery). We call this selective resurfacing of the kneecap.

In this study we will compare whether it is better if surgeons resurface every patient's kneecap during knee replacement or, if surgeons only resurface the kneecap when they believe it will lead to a better outcome for that patient. We hope to enrol 520 patients into this study.

What will I have to do if I take part?

Consent

You will need to take the time to read and understand what the study would involve for you. You can speak to the research nurses or clinicians who will answer any questions you may have. If you decide you would like to take part in the study you will be asked to provide your written agreement to do so, which we call your 'informed consent'.

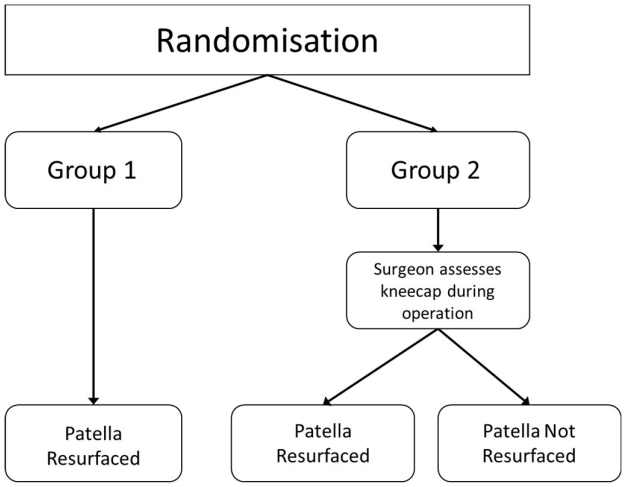
If consenting via e-consent, a process where you can consent remotely through a pre-designed database, your email address will be collected ***before*** consent. Please note that your email address will be held as per the GDPR guidance on a University of Bristol database. This database will also be used for sending 3-, 6- and 12-month follow-up questionnaires.

Due to the design of the database, the email address cannot be deleted so will be held indefinitely. The email address will be used for no other purpose than sending links to the consent process. It will not be shared to any other party or used for any other purpose.

Randomisation

We will put everyone who takes part in the study into one of two groups. To try to make sure the groups are the same to start with, people will be put into a group randomly, so that each person has an equal chance of being in each group. People will be allocated to groups during the operation.

One group will always have patellar resurfacing and the other will have selective patellar resurfacing. If you are part of the selective resurfacing group, then your surgeon will assess your kneecap during the surgery to decide if it should be resurfaced.



Every other aspect of surgery and care will stay the same for all patients. The clinical care team (apart from those involved in the surgery) will not know which surgery you have, and nobody will be able to choose which type you will receive. You will not know which type of surgery you have received until after the research is completed. This could be at least 1 year after you join the study. This is to ensure that the results are not influenced by knowing what treatment you receive.

If you agree to enter the study, it will not affect any future treatment you are offered.

Hospital visits and Questionnaires

There are no additional hospital visits for this study. However, you may be asked to attend the hospital for clinical follow up at 3 months, 6 months, and 1 year after your surgery. These hospital visits are part of routine care for patients following this surgery, but exact timings vary depending on which hospital you have your surgery at.

We will ask you to complete a questionnaire at your first assessment and then at each follow up visit. If you are unable to attend or if there is no hospital follow-up visit when we would

normally ask you to complete a questionnaire (i.e. 3, 6, and 12 months), we will post the questionnaire to you, complete it with you over the phone or you can completely the questionnaire electronically using email. This will give us information about your general health status; for example, how you are feeling, what activities you are able to perform and how much pain (if any) you are feeling. You will also be asked some questions about any visits to hospital you have had, other healthcare you have received in the community, or any expenses and burden you may have experienced because of your surgery. We may call/email/text you when a questionnaire is due or if we do not receive a questionnaire back from you. If you would prefer to complete the questionnaires over the telephone with a researcher, we can offer this option.

We expect you to be in the study for approximately a year from your date of surgery. You may be in the study longer than this if there is a delay between you giving consent and your surgery date. Everyone that takes part in the study will be asked to complete the same questionnaires and provide the same data regardless of any unexpected delays.

What alternatives are there to taking part in the study?

If you decide not to take part in the research study, or if you are not suitable for the study, then you will receive the normal method of treatment at this hospital and by your surgeon.

What are the possible benefits of taking part?

We cannot promise that the study will help you, but we hope that the results from this study may help the NHS and improve the management of future patients.

What are the possible disadvantages and risks of taking part?

There should be no additional risk if you agree to take part in this study as both operations are in common use already in the NHS and neither is new or experimental. Your doctor will explain the risks and benefits of the procedures.

What will happen if I do not want to carry on with the study?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected. If you decide to stop being part of the study before your surgery, you will receive the normal method of treatment at your hospital or by your surgeon. Following surgery, you can decide that you no longer want to take part in active follow up e.g., receiving questionnaires.

You can also stop taking part in any optional part of the study at any time, for example if you no longer want us to store your information for use in future research.

You can request these changes in writing, by telephone, by email, or in person by contacting your local research team or the study coordinating centre using the contact details on page 9. You can find out more about how we store and use your information in part 2 on page 7.

What will happen to the results of the research study?

The results of the research will not be known until sometime after the last patient has entered the study. The results may be reported in medical journals or presented at meetings, but your identity will never be disclosed. During the study, we will ask you if you would like to receive a summary of the results by post/email after the research has finished; this will include details of which operation you received.

Expenses

There are no additional expenses expected for participants in this trial as all visits are part of normal practice or conversations will take place over the telephone/via email.

What if there is a problem?

If you have any concerns or questions about this study, please contact the research team listed at the end of this document.

If you have concerns about the way you have been treated during the study or wish to make a formal complaint, you can contact the Patient Advice and Liaison Service (PALS).

You can find your nearest PALS office on the NHS website (https://www.nhs.uk/service-search/other-services/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363).

We have no reason to believe that you will be placed at any greater risk to your health by taking part in this study. However, if something goes wrong and you are harmed during the study there are no special compensation arrangements.

If anything goes wrong because of taking part in the study due to negligence, the NHS trust responsible will compensate you. Negligence includes, for example, if injury was caused by a deviation from the study protocol by a researcher. The normal NHS complaints mechanisms will still be available to you.

Who is organising, reviewing, and funding the research?

The PART study team includes researchers at the University of Bristol, North Bristol NHS Trust and clinical staff at your local hospital. North Bristol NHS Trust has overall responsibility for conduct of the study. The research is funded by the National Institute for Health and Care Research - Health Technology Assessment Programme.

The research is being organised and run by the Bristol Trials Centre, University of Bristol on behalf of the North Bristol NHS Trust.

This study has been reviewed by the Wales 2 Research Ethics Committee.

Further information

It is unlikely that any insurance would be affected by taking part in this study, but you should consider this before consenting and seek advice if necessary.

You can find out general advice on surgery from:
http://www.nhs.uk/conditions/surgery/Pages/Introduction.aspx

You can find out general information on clinical research from the UK Clinical Research Collaboration who produce a booklet called 'Understanding Clinical Trials' which can be requested by email: crncc.info@nihr.ac.uk or online: http://www.ukcrc.org/public-awareness-of-clinical-research/information-resources-on-clinical-research/

Overview of key participant study milestones and questionnaires

	Initial visit	Operation day	3-month follow up	6-month follow up	1 year follow up
Consent	**X**				
Personal data collection	**X**				
Randomisation		**X**			
Health Questionnaires (OKS, KOOS, EQ5D5L)	**X**		**X**	**X**	**X**

PART 2: INFORMATION ABOUT HOW WE WILL USE YOUR DATA

What information will you collect about me and how will it be used?

North Bristol NHS Trust is the sponsor for this study based in the United Kingdom and the study coordination team is based at the Bristol Trials Centre, University of Bristol. Together we will use information from you and your medical records to undertake this study and will act as joint data controllers for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol and North Bristol Trust will process your personal data on behalf of the data controllers, in their role as data processors.

We will need to use information from you and your medical records for this research study. Your local hospital site will collect this information in accordance with our instructions.

Before consent we will ask for a copy of your email address (for contact purposes and only if via e-consent) and your postcode. Your postcode will be used to determine if the study is being inclusive to participants of all backgrounds.

This information may include your:

- Initials
- NHS number
- Name
- Contact details (including postcode, email address and contact number)
- Date of birth
- Email address (if available)

This information will be used to allow us to keep in touch with you during the study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Research staff will use this information to do the research or 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. Paper copies will be stored in secure storage during the conduct of the study and for 5 years after the end of the study.

Your medical records and study files may be inspected by individuals from the regulatory authorities, the sponsor organisation or other NHS Trusts as required to ensure the study is being conducted to all legal standards and to check the accuracy of the research study.

With your consent, your GP will also be informed that you are taking part in the study. Your GP may be asked to provide information from your records which is required for the research.

What are my choices about how my information is used?

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your central NHS records. If you do not want this to happen, tell us and we will stop. To safeguard your rights, we will use the minimum personally identifiable information possible.

We need to manage your information in specific ways for the research to be reliable and accurate. This means that we will not be able to let you see or change the data we hold about you. If you stop taking part in the study, we will keep and use the information about you that we have already obtained.

If you agree to take part in this study, you will have the option for your data to be saved for potential use for future research being run in this organisation and in other organisations. This data will be stored in a University of Bristol secure repository (called RedCAP) under controlled access and made available only to researchers who meet the criteria for access to confidential data.

You will also have the option for your data to be shared with the National Joint Registry. The National Joint Registry collects information about joint operations, to monitor their performance and effectiveness. Your data will be shared with the National Joint Registry to allow us to get longer term follow up. For more information, you can visit their website: **http://www.njrcentre.org.uk/**

Where can I find out more about how my 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
- our leaflet available from www.nbt.nhs.uk/PatientResearchdata
- by sending an email to part-trial@bristol.ac.uk, or
- By contacting Helen Williamson (Head of Information Governance) at helen.williamson2@nbt.nhs.uk or by ringing 0117 41 44767.

Contact details

Coordinating centre

PART Study Coordinating Centre

Bristol Trials Centre (BTC)

University of Bristol

1-5 Whiteladies Road, Bristol, BS8 1NU

Email: part-trial@bristol.ac.uk

Thank you for reading this information sheet and considering taking part in our study.

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