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cohesive

Core Outcomes for early pHasE Surgical Innovation and deVicEs study

Participant Information Leaflet

Patient Support and Complaints Team
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Introducing new surgical devices into clinical practice

We are undertaking a research study, called the COHESIVE (Core Outcomes for early pHasE Surgical Innovation and deVicEs) Study to improve how new medical devices (such as implantable surgical devices) and procedures are introduced into clinical practice. You have been sent this information because you expressed an interest in taking part, or you may have previously taken part in a surgical research study and we would now like to invite you to take part in this study.

Taking part in research is voluntary. You do not have to take part. If you choose to take part, you are free to withdraw at any time. You do not have to give any reason for your decision. The standard of care you receive will not be affected.

Before you decide whether you would like to take part or not, we would like you to understand why the study is being done and what it would involve. Please read the following information carefully. Talk to others, such as friends or relatives, if you wish and take time to decide. If anything is not clear or you would like more information, please contact us using the contact details on the back of this leaflet.

What is the purpose of the study?

Before new medicines or drugs can be introduced into clinical practice, they undergo rigorous testing and this process is highly regulated. In contrast, new surgical devices may be introduced without firm evidence that they are safe and effective. This can compromise patient safety and health. This problem is caused, in part, by uncertainty and inconsistency around the selection and reporting of health-related outcomes (results or endpoints) of new surgeries and surgical

devices, such as their such as benefits and harms.

A solution to this problem is to develop a core outcome set, which is an agreed minimum set of outcomes that should be measured and reported in all uses of a new surgical device in clinical practice, research studies or audits. We hope that a core outcome set would improve the quality of information available to patients and health professionals for decision-making and for monitoring the safety and effectiveness of new surgical devices.

To develop the core outcome set, we want to know which outcomes are most important to patients. In this study, we will be asking patients like yourself to complete a series of survey questionnaires in which you will be asked to prioritise outcomes for inclusion in the core outcome set. We hope to enrol approximately 50 patients into the 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. You can speak to the research study team who will answer any questions you may have. If you decide to take part, please complete and return the enclosed study participation reply slip in the pre-paid envelope provided.

Survey questionnaires

If you agree to participate, you will be asked to complete a series of up to three online survey questionnaires over a period of several months. You will receive the link to the secure online questionnaire in an email. However, if you are unable to receive emails or complete the questionnaire online, please indicate in the reply slip that you wish for the questionnaire to be sent to you in the post (you will also be sent a prepaid envelope to return the questionnaire). In each questionnaire, you will be asked to rate the importance of including a list of outcomes in the core outcome set. The questionnaire shouldn't take more than approximately 20 minutes to complete each time over the period of approximately a year.

Face-to-face meeting

After completing the questionnaires, you may also be invited to a meeting with other study participants to discuss the survey results and to agree on the final set of outcomes to be included in the core outcome set. The meeting will be organised and run by members of the research study team.

What alternatives are there to taking part?

Taking part in research is voluntary. You do not have to take part. The standard of care you receive will not be affected.

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 improve the care of future patients.

What are the possible disadvantages and risks of taking part?

There are very few risks of taking part in this study. If you agree to take part in the study, the disadvantages may include possible anxiety caused by being asked to think about outcomes (e.g. benefits and risks/harms) of having surgery. You will have the opportunity to discuss any queries, anxieties or issues with a study researcher, for whom we will provide contact details.

What if there is a problem?

If you have any concerns or questions about this study, please contact the research study team listed on the back of this leaflet.

If you have concerns about the way you have been treated during the study or wish to make a formal complaint, you may wish to contact the Patient Support and Complaints Team. Please see their details on Page 1 of this information leaflet. Participants will have the opportunity to discuss any queries, anxieties or issues related to their surgery or the research with the study researcher and/or a qualified medic who is also part of the study team (Potter, Consultant Senior Lecturer in Oncoplastic Breast Surgery) at any point during the study.

This study is sponsored by the University of Bristol. The University has Public Liability insurance to cover the liability of the University to research participants.

Will my taking part in the study be kept confidential?

University of Bristol is the Sponsor for this study and where the research study team is based. Sponsor means the organisation responsible for running of the study. University of Bristol will use information the research study team collect from you to undertake this study and will act as the controller for this study. This means that they are responsible for looking after your information and using it properly. Any information collected about you and any data collected from you during the study will be stored securely at the University of Bristol. The research study team at the University of Bristol will keep identifiable information about you for 20 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. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The University of Bristol will use your name and contact details to contact you about the research study, make sure that relevant information about the study is recorded and oversee the quality of the study. The confidentiality of any data they hold about you will be respected at all times. All the information collected will be stored in a purpose built and secure database. Individuals from the Sponsor and regulatory organisations may look at your research records to check the accuracy of the research study. The University of Bristol will keep your name and contact details confidential. The only people in the study team who will have access to information that identifies you will be people who need to contact you as part of the COHESIVE Study or audit the data collection process.

Any information about you will only be used for the purposes of this research unless you give permission for it to be used in future ethically approved studies. If you agree, we may contact you in the future for other research studies. You can still take part in the COHESIVE Study if you do not want your data to be used for other studies.

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

You are free to withdraw from the study at any time without giving a reason and this decision will not affect your rights.

You can withdraw in writing, via the telephone, or in person by contacting the study team (details below).

What will happen to the results of this research study?

The main results of the study will take up to 2-3 years to become available. We will publish relevant results in scientific journals, as well as present regular reports at various local, national and international level scientific meetings. You will not be identified in any report/publication. We will also present the results to the local patient support group.

Who is organising and reviewing the study?

This study has been reviewed by an independent NHS Research Ethics Committee (Newcastle and North Tynside), who protect your safety, rights, wellbeing and dignity. The study is managed by the University of Bristol, who also has overall responsibility for the study.

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 obtain general information on clinical research from the UK Clinical Research Collaboration who produce information resources on clinical research, 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/

Contact details

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Thank you for reading this leaflet and considering taking part in our study

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