University of BRISTOL

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The Pre-BRA (Pre-pectoral Breast Reconstruction Evaluation) Study

Patient Information Sheet

We would like to invite you to take part in a research study. Before you decide to take part you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask questions if anything you read is not clear or you would like more information. Take time to decide whether or not to take part.

What is the purpose of the study?

Breast cancer affects one in eight women in the UK and 40% of all women with breast cancer need to have a mastectomy as their surgical treatment. Losing a breast may affect women's self-esteem and body image and breast reconstruction is offered to improve their quality of life.

Breast reconstruction using implants is the most commonly performed procedure in the UK. You have opted to have a ***pre-pectoral breast reconstruction. This is a fairly new type of implant reconstruction in which the implant is placed on top of the muscle with the aim of reducing post-operative pain and avoiding implant 'animation' the movement of the implant seen when the chest wall muscles contract.***

The main aim of the study is to determine whether this form of implant reconstruction is safe, which types of patients should be offered the procedure, and the best way of performing the technique. The study will collect information about women having pre-pectoral breast reconstruction**,** what happens to them around the time of surgery and if they are satisfied with the results afterwards. This research study is also part of an educational project.

Why have I been invited?

You have been asked to take part in this study because you are having a mastectomy and have opted to have a pre-pectoral, implant-based breast reconstruction.

We hope to recruit approximately 350 women having this form of reconstruction from 30 to 40 UK centres.

Do I have to take part?

No. It is up to you to decide whether or not to take part.

This information sheet will go through the study and what taking part means for you.

Before you take part, you will be asked to sign a consent form to show you have agreed to do so. You are free to withdraw at any time, without giving a reason. It will not affect the standard of care that you receive if you take part or not, or if you withdraw.

ABS ASSOCIATION OF BREAST SURGERY

RCS BRISTOL SURGICAL TRIALS CENTRE

NHS National Institute for Health Research

Pre-BRA

What will I have to do if I take part in The Pre-Bra Study?

You will be asked to complete questionnaires before and after your surgery. You will have your operation and see your surgeon and their team as normal following your surgery. You will not be required to make any additional hospital visits to participate in the study. We will ask you to complete post-operative pain scores at 24 hours, 1 week, 2 weeks and 3 months following surgery. This may be by telephone or email depending on your preference. We will also ask you to complete questionnaires before surgery and at 3 and 18 months after surgery, to assess how satisfied you are with the outcomes of surgery and whether you have experienced any problems.

We will ask you for specific consent to store your name, date of birth, address and NHS number because we would like your permission to contact you in future. This may be for a follow on study to look at the long-term outcomes of this type of reconstruction and we may ask you to complete another questionnaire.

We would also like your permission to use your NHS number so we can follow you up via your medical records without contacting you in person. You can agree to take part in the initial study without giving consent to be contacted about future studies.

If you have any doubts, concerns or questions about your operation you should talk to your consultant surgeon, before agreeing to the surgery or to take part in the research.

If this initial study is a success, we hope it will allow us to proceed to another, larger and UK-wide study which will directly compare different types of implant-based breast reconstruction.

What are the possible disadvantages and risks of taking part?

Your treatment will not be affected in any way by taking part in this observational study. The questionnaires will take approximately 20 minutes to complete. There are no specific risks of taking part in the study. Participation will allow researchers and surgeons to better understand the outcomes of this form of reconstruction to help design future research studies.

What are the possible benefits of taking part?

This study will not benefit you directly but the information that you provide will help to improve the future management of patients who undergo breast reconstructive surgery.

What if there is a problem?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the standard National Health Service complaints mechanisms will be available to you. Advice about making a complaint regarding NHS treatment is available on the Department of Health and Social Care's website:

https://www.gov.uk/government/publications/the-nhs-constitution-for-england/how-do-i-give-feedback-or-make-a-complaint-about-an-nhs-service

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

Any information that is collected about you during the study will be kept strictly confidential. Your name and address will be removed so that you cannot be recognised. If any images or data about you is presented at surgical meetings or conferences it will be completely anonymised so that you cannot be identified.

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

You are free to withdraw from the study at any point without giving reason and it will not impact upon your clinical care.

Your Data and the General Data Protection Regulations (GDPR)

The University of Bristol is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol will keep identifiable information about you for up to 10 years after the study has finished.

[Insert local NHS site name] will collect information from you and your medical records for this research study in accordance with our instructions.

[Insert local NHS site name] may use your name, NHS number, email or other 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. Individuals from The University of Bristol and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [Insert local NHS site name] will pass these details to The University of Bristol along with the information collected from you and your medical records. The only people in The University of Bristol who will have access to information that identifies you will be people who need to contact you to about the research study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, email or other contact details.

[Insert local NHS site name] may keep identifiable information about you from this study up to 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 use the minimum personally-identifiable information possible. You can find out more about how The University of Bristol will handle your data here:

http://www.bristol.ac.uk/secretary/data-protection/

What will happen to the results of the research study?

We hope that the information we obtain will allow us to better understand what happens to women who undergo pre-pectoral breast reconstruction. This will allow us to provide better information and support to women making decisions about breast reconstruction in future. We also hope that the results of this study will be presented at national conferences and published in medical journals to help other people researching breast reconstruction.

Who is organising or sponsoring the research?

The research is organised and sponsored by the University of Bristol and funded by the NHS National Institute for Health Research (NIHR), The Association of Breast Surgeons (ABS) and The Royal College of Surgeons of England (RCSE). It is being conducted by Miss Shelley Potter, Consultant Senior Lecturer at the Centre for Surgical Research University of Bristol.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by South Central - Oxford B Research Ethics Committee.

What if I have any concerns?

If you have any concerns about this study or the way it has been carried out, you should contact the investigator in the first instance. If your concerns remain unresolved then you should contact the University of Bristol, Department of Research Governance, your local hospital or primary care trust complaints department (details on www.nhs.uk).

Further information and contact details:

If you would like to participate in the study, please let your consultant surgeon know.

If you have any additional questions about the study or require any further information before deciding whether or not to take part, please do not hesitate to contact the research team by email or telephone.

Local Research Team Details:

Phone no: ……..

Email: ……