COMICE: A study to compare the effectiveness of magnetic resonance imaging (MRI) in breast cancer

INFORMATION SHEET FOR STUDY PARTICIPANTS

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If anything is not clear, or you would like more information, please ask your consultant or one of the members of the team. Thank you for reading this.

What is the purpose of this study?

The usual investigations for women with breast disease are X-ray mammography, ultrasound and fine needle aspiration/ core biopsy. Occasionally, these tests may not detect the full extent of disease and some women require a second operation to ensure that all disease is removed. A new breast imaging method is now available: magnetic resonance imaging (MRI). The aim of this study is to see if MRI can provide additional information about the disease compared with X-ray mammography and ultrasound alone, and as a result reduce the number of women requiring a second operation. The full impact of this technique on the women's lives and on the NHS will be assessed.

Why have I been chosen?

You have been invited to take part in this study because you are scheduled to have an operation (a wide local excision) for breast cancer. The study will involve 1840 women from several hospitals in the UK.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. The standard of care you receive will not be affected if you withdraw from the study at any time, or decide not to take part.

What will happen to me if I agree to take part?

If you decide to take part, you will be randomised either to have an MR scan or to receive no extra investigations. This decision will be made randomly by a computer, i.e. by chance. Half of the women will have no MR scan, half will have an MR scan, and the groups will then be compared. The randomisation will be performed centrally by computer and not by your Breast Surgeon. If you are to have no further investigations, you will proceed as planned to surgery. If you are allocated to have an MRI scan, this will be carried out before your operation. The appointment will be organised so that your planned surgery is not delayed. MR scanning may detect abnormalities that are not detected by X-ray mammography or ultrasound. The results of the scan will be discussed at a multi-disciplinary team meeting. Any suspicious areas identified by the MR scan will be further investigated by needle biopsy. If the results of this are positive, your Consultant Surgeon will discuss this with you. However, it is possible that these abnormalities may subsequently be found to be of no importance, and you will have the operation originally planned.

What does the MR scan involve?

If you are allocated to have an MR scan, both breasts will be examined in addition to the tests that have already been performed. During the scan you will be asked to lie comfortably on your stomach on a special couch, which passes through the MR scanning machine. Throughout the scan you will be able to see out of the machine into the scanning room. You will be able to talk to a radiographer at all times via a two-way intercom system. Before the scan a small needle will be placed in a vein in the back of your hand or in your arm. A dye will be injected through the needle during the MR scan. This is routinely used for this type of examination and causes very few problems, mostly mild allergic type reactions. During the scan you will hear knocking noises as the pictures are taken. The MR scan takes between 30 and 45 minutes. **A relative or friend may come in to the scan room with you.**

What are the side-effects of the MR scan?

Our radiographers will check that you do not have any conditions such as pieces of metal in your body that may cause problems during an MR scan. The dye injected

during the scan is associated with very few problems, the most common being slight pain at the site of injection and mild allergic-type reaction, for example skin rash.

What are the possible disadvantages and risks of taking part?

It is possible that the MR scan may show abnormalities that are later found to be of no importance, and as a result you would have undergone unnecessary additional tests (needle biopsy). There is also a small chance that the MR findings will suggest that more extensive surgery should be performed than is actually necessary.

What are the possible benefits of taking part?

Your planned operation is a wide local excision. For some women, the pathology findings from this surgery show that a second operation is required. We hope that the MR scans will provide additional information to show which patients require more extensive surgery before the operation is carried out, to prevent a second operation.

What if something goes wrong?

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during this study, the normal National Health Service complaints mechanisms should be available to you. Information about patient rights, research-related questions and research-related injury can be obtained from the Local Patients Action Teams or the charity CancerBACUP.

Will the information obtained in the study be confidential?

All information collected about you for this study will be kept strictly confidential. This information will be securely stored at the COMICE Study Offices on paper and electronically under the provision of the 1998 Data Protection Act. Anything you say will be treated in confidence, no names will be mentioned in any report of the study, and care will be taken so that individuals cannot identify you from details in reports from the results of the study. Only appropriately qualified members of the COMICE research team may confidentially review your medical records. This is to ensure that the study is carried out to the highest possible scientific standards. In order to be able

to check your notes we will need to hold some information, such as your date of birth and hospital number, so that we can identify your notes accordingly. We will also hold a copy of your signed consent form.

What other information will be collected in the study?

With your agreement, information will be obtained about any medication you are currently taking, the findings from X-ray mammography and ultrasound, the type of operation carried out, the pathology findings from the tissue removed, and your post-operative recovery. If you agree to take part in the Quality of Life study, you will be asked to fill out four short questionnaires at baseline, 8 weeks after randomisation, and 6 months and 12 months after your operation to find out how you feel. In order to send these to you we will need to collect your full name and address. We may also contact you in 12 months' time to ask you if you would take part in a more detailed interview about your treatment and how you have been feeling. We would contact you nearer the time and give you a separate information sheet for this part of the study.

Can I withdraw from the study at any time?

You are free to refuse to join the study and may withdraw at any time or choose not to answer certain questions.

Will anyone else be told about my participation in this study?

We will inform your GP that you are helping with this study, unless you ask us not to. Your name will not be disclosed outside of the Study Offices or GP surgery.

What will happen to the results of the study?

The results of this study will be published in a medical journal approximately 12 months after the last patient has been entered. The results will also be available on the following web site: http://www.hta.nhsweb.nhs.uk.

Who is organising and funding the research?

This study is being conducted in co-operation with the Clinical Trials Research Unit at the University of Leeds, and the Centre for Health Economics at the University of York. It is funded by the National Health Service Research and Development Programme for Health Technology Assessment.

The study has been approved by the North-West Multicentre Research Ethics Committee.

Contact for further information

If you have problems or questions, please do not hesitate to get in touch. Please use one of the following contact numbers:

Thank you for considering this study.