TO BE PRINTED ON HOSPITAL HEADED PAPER

Patient Information Sheet – IMPORT LOW

For Centres not taking part in sub-studies

Randomised Trial Testing Intensity Modulated and Partial Organ Radiotherapy following Breast Conservation Surgery for Early Breast Cancer

We are inviting you to take part in a clinical trial called IMPORT LOW. We have written this information sheet to explain why we are doing this research and what taking part involves. Before you make up your mind whether to take part please read it carefully and discuss it with your family and friends. You may also want to discuss it with your GP. Please ask your doctor or nurse if there is anything that you do not understand or if you would like more information. Take your time to decide.

This Trial is supported and funded by Cancer Research UK

CANCER RESEARCH UK

MREC Oxford Research Committee B 06/Q1605/128

Approved by MREC 12/10/2006 **ISRCTN12852634**

Part 1

Purpose of the trial

This trial aims to improve radiotherapy treatment for women with breast cancer. We want to see if we can do this by reducing the amount of radiotherapy we give to the whole breast whilst giving the standard amount of radiotherapy to the area close to where the tumour used to be. The trial will test whether doing this preserves the long term physical appearance of women's breasts whilst being just as effective as standard radiotherapy.

➢ Why am I being invited to take part?

You have been diagnosed with breast cancer and your doctor has recommended a course of radiotherapy as part of your treatment. About 2000 women like you from all over the UK will be taking part.

➢ Do I have to take part?

It is up to you to decide whether to take part or not. Deciding not to take part will not affect the standard of care you receive.

➢ What are the new treatments being tested?

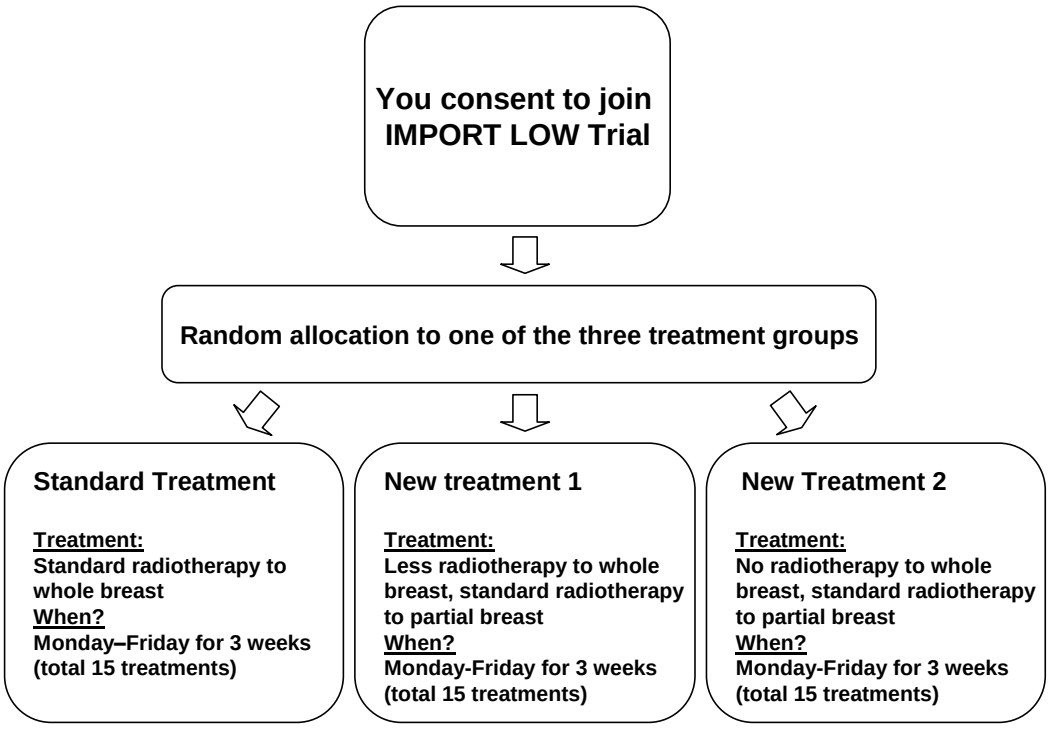
Below we have outlined the current standard radiotherapy treatment for your type of breast cancer and the two new treatments that we are going to be looking at in this trial:

Standard treatment –This is the standard dose of radiotherapy to the whole of your breast every weekday for 3 weeks. This makes 15 treatments altogether.

New treatment 1 – We give less radiotherapy to the whole of your breast and standard radiotherapy to the area of your breast around where the tumour was (partial breast). We give these different doses of radiotherapy together every weekday for 3 weeks. This makes 15 treatments.

New treatment 2 – We give the standard dose of radiotherapy only to the area of your breast around where the tumour was (partial breast), every weekday for 3 weeks. This makes 15 treatments.

These three treatments are summarised in the diagram below:



- **How will you decide which treatment to give me?**

We will allocate you to one of the three treatment groups at random. We do this to make sure that there cannot be any bias to the allocation. Then if one of the groups does better than the others we know it is because of the treatment and not because the groups were different to each other in some way. You will have an equal chance of being in each of the groups. A computer programme will be used to make sure that this is done properly.

- **What are the alternatives for treatment?**

If you decide not to take part in the trial you will get the standard radiotherapy treatment used in your hospital. Your doctor will explain what this involves.

- **Does the treatment have any side effects?**

All treatments involving radiotherapy have potential side effects. Your doctor will give you a leaflet explaining any side effects that you may experience during the course of your treatment. A few women may experience long term side effects which are caused because we have to expose the breast and the underlying area of your body to the radiation. These are breast shrinkage, hardening and tenderness in the breast and stiffness in the chest muscles. More rarely there may be cracked ribs and scarring to the lung. Also rarely, if your tumour was in the left breast, there may be some injury to the heart.

- **Pregnancy and treatment**

Radiotherapy can be harmful to a developing baby. If you are of childbearing age and think you may be pregnant, please tell the radiographers or your doctor. For the same reason you must guard against becoming pregnant whilst you are having treatment.

- **Are there any advantages to taking part?**

If you are in one of the groups receiving the new treatments the larger area of your breast away from where the tumour used to be will be exposed to less or no radiation.

- **Are there any disadvantages to taking part?**

If you are in one of the groups receiving the new treatments there is the possibility that you will have a slightly higher risk of your tumour coming back although we do not think that this will happen. We would not expect this to affect more than one or two women in every hundred treated over a ten year period.

- **What do I have to do if I take part?**

We will ask you to sign a consent form to say you agree to take part.

We will allocate you to one of the treatments described above and your doctor will let you know when your treatment starts.

- **Understanding the side effects of radiotherapy**

Your doctor will give you a physical examination of your breasts at 1, 2, 5 and 10 years after your radiotherapy treatment. This will be carried out at your hospital

during your follow up visits to the clinic. This will help us to assess any changes in your treated breast tissue during the years following radiotherapy.

We will ask you to donate a single blood sample which will be sent to the Cancer Research UK/MRC Tissue Bank at Ninewells Hospital, Dundee. Your blood will be stored here in accordance with the Human Tissue Act 2004. This will be up to 20ml of blood, the equivalent to 4 teaspoons full, which will be put into blood tubes. Your blood sample will be given a unique identification number and may be used in future years for analyses which may include genetic analysis. This aims to find out if inherited differences between individuals explains why some patients are more sensitive to the effects of radiotherapy than others. The results will only be used for epidemiological research purposes. It will not be possible to release the results of these blood tests to you or your doctor and they will not form part of your medical records. We will ask you to complete a family history questionnaire. If you agree, please give as much information as you can about your immediate (blood) relatives, whether or not they have had cancer. With this information we may be able to see if there is a connection between how individuals react to radiotherapy and a history of cancer in the family. This may help us to improve radiotherapy treatment for breast cancer in the future. This is an additional part of the IMPORT LOW trial and you can still take part in the main part of the trial even if you do not want to donate a blood sample.

- **Understanding why cancer sometimes grows back again**

We want to learn more about why breast cancer grows back again in a small number of women. When you had your surgery the breast cancer was removed and stored in a laboratory. We would like you to donate some of this stored tissue for future research into breast cancer. It is unlikely that you will get another breast tumour, but if you did we would like you to donate a small part of any new tumour, from either breast, in the same way. By comparing the characteristics of the two samples we can build up information about breast cancer recurrence to further improve treatment in the future. Your hospital will send your surgical tissue to Guy's and St. Thomas' Hospital in London where a small amount will be taken and stored in accordance with the Human Tissue Act 2004. This tissue will be used for future analysis which will include removing DNA from the tissue to look for genetic changes in the tumour. Your original surgical tissue will be returned to your hospital's own pathology laboratory. If you

have agreed to donate a blood sample we would like to compare the DNA removed from your blood with the DNA removed from your tumour. This will help us to understand the changes that happen when a cancer is formed. As with the blood tests it will not be possible to release the results of these tests to you or your doctor and they will not form part of your medical records. This is an additional part of the IMPORT LOW trial and you can still take part in the main part of the trial even if you do not want to donate your stored tissue.

- **What should I do if I get another breast tumour?**

It is unlikely that you will get another breast tumour, but if you do it would be helpful if you could mention that you are taking part in this trial when you contact your doctor for an appointment. If the new tumour is in the same breast as the first one your doctor will tell the radiotherapy department and we may ask you to have an additional scan so that we know exactly where the new tumour is in your breast. The risk to you from this extra scan is minimal.

- **What happens if something goes wrong?**

It is unlikely that anything will go wrong with your treatment or care, but if you have any complaints about the way that you have been treated during the course of the study you are free to use the usual NHS complaints procedure. Your hospital will be able to advise you how to proceed with this. There are more details about this in part 2.

- **Confidentiality**

We will follow ethical and legal guidance and handle all the information that we have in confidence. More details about this are given in part 2.

Part 2

- **What will happen to the results of the study?**

We will publish the results in a respected medical journal, but this will not be for several years since we are looking at the long term side effects of radiotherapy treatment. A committee of independent experts will review the results before this happens. You will not be identified in any report or publication. The results will help us to decide the best way to give radiotherapy treatment to patients with breast cancer in the future.

- **What happens if something goes wrong?**

If taking part in this trial were to harm you in any way, there are no special compensation arrangements. However your hospital would be liable for any harm caused by negligence on the part of the hospital staff.

We will monitor your progress very carefully both during and after your treatment and we will offer you any available treatment to help with any side effects that you may experience.

Your legal rights will not be affected by your agreeing to take part in this trial.

- **What if I agree and then change my mind?**

If you change your mind about taking part in the trial you are free to withdraw at any time. You do not have to give a reason. We would however like to ask your permission for your hospital to send information about your progress to the Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU). This is information that is routinely taken and you will not need to do anything extra. This will ensure that the quality of the research study is not impaired. If you do not want us to collect this information or if you want us to destroy any samples that we may have collected from you please tell your doctor or nurse.

If you withdraw from the trial your doctor will advise you about your treatment.

- **Who is organising and funding the research?**

The research will be co-ordinated by the ICR-CTSU. Several hospitals throughout the United Kingdom will be joining. It is being funded by Cancer Research UK. Your doctor will not receive any payment for entering patients into this study.

- **Who has reviewed the design of this trial?**

The trial has been reviewed by experts in the field and approved by a NHS Research Ethics Committee as well as the local ethics committee at your hospital.

- **Confidentiality**

Your medical records will need to be seen by authorised members of the research team at your hospital in order to collect the information needed for the study and also check that it is correct. When you join the trial your name, date of birth hospital number and NHS number will be passed to the ICR-CTSU so that they can find you again if you lose touch with your hospital in the future. We will give you a unique registration number which will be used together with your initials and date of birth on any subsequent forms that are sent to the ICR-CTSU. We will be contacting your hospital over the years to find out how you are getting on.

Information from your medical records about your treatment and disease will also be sent to the ICR-CTSU. Representatives from this organisation and/or government regulatory bodies may need to see these to check that this information is correct and that the study is being conducted to nationally agreed standards.

A copy of the treatment plan made for you before your radiotherapy starts will be sent to the IMPORT LOW Quality Assurance team at Mount Vernon Hospital, Northwood, Middlesex. This includes copies of your CT and treatment images associated with this plan. These will be monitored and stored by the Quality Assurance team.

We will treat all information that we have about you as strictly confidential. Nothing that might identify you will be released to any third party.

With your permission we will tell your GP that you are taking part.

- **What happens now?**

Your doctor or nurse will be happy to answer any questions that you have. You can ask when you next visit the hospital or you can telephone. Once you have reached your decision let your doctor or nurse know.

- **Further Information**

Cancerbackup is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. Amongst their booklets are ones about breast cancer, radiotherapy and clinical trials in general. You can contact one of their specialist cancer nurses on their freephone number, 0800 800 1234.

Breast Cancer Care has a message board on their internet website where you can read or add messages about deciding to take part and your experiences of treatment. To use it go to www.breastcancercare.org.uk .

Thank you for your interest in our research

Contact information:

Local treatment centre details including trial personnel

Centre number:

Study number:

Patient identification: