To be printed on hospital headed notepaper

Version 4b, 8th August 2006
(For centres who routinely deliver 50Gy in 25 fractions as standard regimen)

FAST Trial

Faster radiotherapy for breast cancer patients

Prospective randomised clinical trial testing 5.7 Gy and 6.0 Gy doses of whole breast radiotherapy in terms of i) adverse effects of radiotherapy on normal breast tissue which emerge at a later date and ii) tumour control

Patient information sheet

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 and discuss it with others, including your GP, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Your doctor has advised you to have a course of radiotherapy as part of your treatment for breast cancer. Radiotherapy uses high-energy light waves called x-rays that have been used for many years to treat cancer patients. We know that cancer cells are sometimes left at the site of operation after removal of early breast cancer, despite the fact that the surgeon includes a margin of healthy tissue around the tumour and the pathologist sees no cancer cells at the edges of the surgical specimen. Radiotherapy is used to destroy any cancer cells left at the site of operation, even though we have no evidence that any cells remain in your case.

Standard schedules of radiotherapy were developed many decades ago. They deliver small doses (called fractions) of radiotherapy. Treatment regimens vary across the country. The standard treatment at this hospital is to have radiotherapy for 5 days per week for 5 weeks, 25 doses in all over a period of 35 days. Small doses are gentler than larger doses in their effects on normal tissues, but a large clinical trial has recently suggested that small doses are gentle on cancer cells as well. We think that a more effective approach to treatment may be to increase the size of individual doses and reduce the overall dose that is delivered, and this study has been designed to test the safety of this approach. We record the dose of radiotherapy in units of measurement called ‘gray’ (after a famous British scientist called Gray). So, instead of giving 25 doses of 2 gray (total dose 50 gray), we aim to test the effects of two new schedules: i) 5 doses of 6 gray (total dose 30 gray) and ii) 5 doses of 5.7 gray (total dose 28.5 gray).

Why am I being invited to take part?

The group of women to be tested in this study is those who have average or below average risk of local tumour recurrence and who fulfil the following criteria:

To be *suitable* for this study:

i) You should be at least 50 years old.
ii) You should be diagnosed with invasive cancer of the breast.
iii) You should have had breast conserving surgery (not mastectomy).
iv) The tumour you had removed should be less than 3 cm in diameter.
v) The tumour should have been completely removed.
vi) You should have had lymph glands removed from your armpit (axilla) and all of these should be free of cancer cells.

You are *not suitable* for this study:

i) If you have had a mastectomy (removal of the breast).
ii) If you require radiotherapy to your armpit (axilla).
iii) If you require a breast boost to the area where your tumour was as part of your radiotherapy.
iv) If you have had chemotherapy.

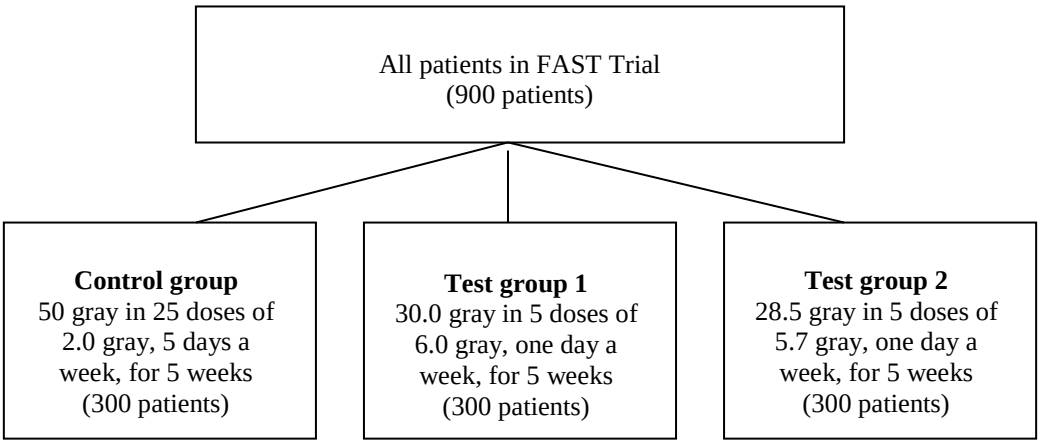
Your doctor has checked your suitability for this research carefully, and we are inviting you to take part because we feel that you could benefit from the schedules we are testing. We plan to recruit a total of 900 women from a number of hospitals in the UK over a period of 30 months.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. A copy may also be sent to your trials office. You will be given a copy of the consent form to keep, together with this information sheet. We will ask for your permission to inform your GP about the study and your participation in it.

If you agree to join you are still free to withdraw at any time without giving a reason. If you withdraw from the study this will not affect the standard of care you receive. However, if this were to happen, we would like permission for your hospital to send information on your progress to the trials office in the Section of Clinical Trials at the Institute of Cancer Research who are co-ordinating the study. The information needed is routinely recorded in your medical records and you would not need to do anything. Collecting this information ensures that the overall quality of the research study is not impaired.

What will happen to me if I take part?
If you decide to take part in this trial, you will be allocated to one of the following treatment schedules:
Control group: 50.0 gray in 25 doses, 5 days a week for 5 weeks (standard radiotherapy dose).
Test group 1: 30.0 gray in 5 doses, 1 day a week for 5 weeks.
Test group 2: 28.5 gray in 5 doses, 1 day a week for 5 weeks.



The treatment you are allocated will be decided by a process called randomisation, and not chosen by you or your doctor. Randomisation is performed using a computer and allocates treatment rather like the toss of a coin. Randomisation is the only way that we obtain unbiased and trustworthy results.

Before you start your radiotherapy, we will ask you to attend the hospital for an appointment in the radiotherapy planning department. At this visit your radiotherapy will be planned. Detailed information about the area of your breast due to be treated will be entered onto a computer, and this information will be used to deliver your radiotherapy accurately and safely. The planning normally takes between 30 and 60 minutes.

Depending on which treatment you are allocated, you will then attend the hospital for radiotherapy either once a week or five times a week for five weeks. Each treatment session normally takes 10-15 minutes.

You will be asked to have a photograph of your breast taken before you start your radiotherapy and when you attend for follow-up appointments 2 years and 5 years after you finish your treatment. The photographs will help us assess any changes that may happen to your treated breast over a period of years. Only authorised researchers will have access to the photographs, which will be coded and stored in a safe manner at the Institute of Cancer Research.

What are the alternatives for treatment?
If you choose not to participate in this trial, you will be given radiotherapy treatment according to the current standard practice of your cancer centre.

What are the possible side effects?
As well as benefits, there are side effects associated with all radiotherapy schedules. During your radiotherapy treatment, you may experience a skin reaction, confined to the area being treated. It will start about two weeks in to treatment, reaching a peak at the end, or within a week of finishing. The severity varies from person to person, but you may experience: dryness, reddening, itching/irritation, slight swelling or tenderness, increased pigmentation, like a suntan, skin breakdown, in areas of friction e.g. under the breast. If any of these skin reactions need medical attention, the radiographers will refer you to a specialist nurse in the department.

Long-term side effects in the breast area may develop many years after treatment and are usually permanent. Mild effects are common but don't usually interfere with everyday activities or lifestyle. A small proportion (less than 10%) of women develops more marked effects, which may interfere with some aspects of everyday life. These include change in the appearance of the skin, shrinkage of the breast, firmness of the breast, breast pain and tenderness, damage to lung tissue (less than 5%), damage to the bones (less than 5%) and damage of the heart tissue (left sided breast cancer only, less than 1%). We do not expect that these side effects will be any higher after the test schedules than after the schedule used in the Control arm.

What are the possible disadvantages and risks of taking part?
About 5 women per 100 treated develop marked breast shrinkage and/or discomfort several years after current standard radiotherapy. We do not expect the test schedules to be any different, but if we are wrong, this number could rise to 6 or 7 women per 100. We do not expect any reduction in the effectiveness of the treatment against cancer recurrence in the breast, although this will take several thousand research volunteers to demonstrate. If the new treatment is less effective than standard treatment in eradicating cancer cells in this respect, it is likely that this would affect, at worst, 1 patient out of every 100 treated.

What are the possible benefits of taking part?
There are practical benefits of a treatment that involves fewer visits to hospital. We think the treatment will cause the same level of early and late (years later) side effects as standard treatment, or even milder effects. Any cancer cells remaining in the breast are likely to be eradicated at least as effectively as current treatment.

What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

What is the expense of volunteering?
None.

Will I be paid for taking part in this study?
No. Neither you nor your doctor will be paid for taking part.

Are there any restrictions on what I might eat or do?
If you are of childbearing age, it is important to avoid pregnancy whilst on treatment, so contraceptive measures must be used.

What if something goes wrong?
Your progress will be watched closely during and after treatments and you will be offered whatever treatment is available to help with any side effects. We do not believe you will suffer any injury from participating in this study. You should however know that 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 have grounds for legal action. Regardless of this, if you have any cause to complain about any aspect of the way you have been approached or treated, the normal NHS complaints mechanism is open to you. Your hospital will have a formal complaints procedure that is available to you.

Will my taking part in this study be kept confidential?
Your medical records will need to be seen by authorised members of the research team at your hospital, so that they can collect information needed for this research study and also to check that it is correct. Your name, date of birth and NHS number will be passed to the trials office at the Institute of Cancer Research when you join the study so that they can find you again if you lose touch with your hospital in the future. You will be given a unique registration number, which will be used together with your initials and hospital number on forms that the research staff sends to the trials office. Information from your medical records about your treatment and disease will be sent to the trials office at the Institute of Cancer Research. Representatives from this organisation and/or regulatory bodies may wish to see your hospital or clinic records to make sure the information sent was correct. All information which is collected about you during the course of the research will be kept strictly confidential and nothing that might identify you will be revealed to any third party.

We will be contacting your hospital over the years to find out how you are getting on. Ideally we would like to do this for life, but patients often change address and/or GP or lose touch with their hospital. If this happens we would like to use national records which are kept on everyone's health status to find out how you are. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This is usually your name, date of birth and NHS number (or Community Health Index and/or hospital number in Scotland). Any details we receive from any source are confidential and will only be used for the purposes of the FAST trial. Please initial the consent form to show that we have your permission to do this.

GP notification
Your GP will be informed of your participation in the trial with your permission. If you withdraw from the study, we will ask your GP to provide authorised researchers with basic clinical information that would routinely be collected and written in your medical records.

What will happen to the results of the research study?
Independent experts will review the progress of the research, and the results will be published in a respected medical journal as soon as there is enough information to be sure the results are reliable. You will not be identified in any report or publication. The results will help to decide how best to deliver radiotherapy to patients with breast cancer in the future.
Your hospital will write to you when the results are known to ask if you would like to see them. The letter will explain how to get a copy.

Who is organising the study?
This research is being organised by Professor John Yarnold, Consultant Clinical Oncologist at the Royal Marsden Hospital in Sutton in collaboration with other cancer specialists at centres throughout the UK. The trials office co-ordinating the study is based in the Section of Clinical Trials at the Institute of Cancer Research, Sutton, Surrey.

If you are a private patient, please inform your insurance company that you are participating in this study, in order to ensure that your medical expenses will be covered. This applies to all research studies, not just this one.

Who has reviewed the study?
We have approval for the study from an NHS Research Ethics Committee and the local research ethics committees at the institutions involved in the research. All research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be approved by a NHS Research Ethics Committee before it goes ahead. Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision to take part or not.

Contact for the Further Information
[Add local treatment centre details including trial personnel as well as availability of language line or other facility for translation.]

Thank you very much for your help.

Date given to patient:_____