PATIENT INFORMATION SHEET

Surgical and large bore pleural procedures in Malignant pleural Mesothelioma And Radiotherapy Trial (SMART trial)

A Randomised Controlled Trial evaluating whether prophylactic radiotherapy reduces the incidence of procedure tract metastases.

1. Study Title
This is a research study examining the role of radiation treatment (radiotherapy) after chest wall procedures (such as surgery, thoracoscopy or chest drain insertion), in patients with cancer of the lining of the lung (mesothelioma). It will try to identify the best timing for radiotherapy to be given in order to minimise the risk of the cancer spreading during the procedure.

‘Randomised Controlled Trial’ means that patients who take part will be randomly allocated to either receive radiotherapy immediately after the procedure or radiotherapy later on, if a lump is discovered near the procedure site.

2. Invitation
You have been invited to take part in this research study. However before you decide to take part, it is important for you to understand why the research is being done and what it will involve, therefore please take time to read the following information carefully. It is a good idea to discuss taking part in the trial with your family and/or GP before making a decision. If you would like to take time to do this please let us know and a further appointment will be made to see you in due course. Please feel free to ask us if there is anything that is not clear or if you would like more information.

3. What is the purpose of the trial?
Radiotherapy is not able to change the course of mesothelioma but may prevent or suppress the spread of the cancer through the chest wall following surgery. It is often given to patients soon after a chest wall procedure to reduce the risk of this happening. The radiotherapy involves attending hospital on 3 consecutive days soon after the diagnosis and may also be associated with mild side effects (as described below).

Recent research suggests that cancer spreading through the chest wall in mesothelioma may not be as common as previously thought and some studies suggest that radiotherapy soon after the procedure may not actually reduce the chances of this happening.

Hence it is important that we know when it is best to give radiotherapy in this situation. This trial will endeavour to answer this question.
4. Why have I been chosen?
You have been chosen to consider taking part in this trial because you have mesothelioma and have recently had a procedure to your chest. We would like to know whether immediate radiotherapy is useful for patients in exactly your situation.

This study is taking place across many centres in the United Kingdom and 203 patients will be asked to participate.

5. 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 asked to sign a consent form and you will be given a copy for your records along with this information sheet.

If you decide to take part, you are free to withdraw at any time without giving a reason. A decision to withdraw or a decision not to take part will not affect your future medical care.

6. What will happen to me if I take part?
Your doctor will perform an initial assessment, including finding out about your current health and medications and examining the area of your chest where you had the procedure done. You will also be asked to complete questionnaires about your current level of pain and how your illness is affecting your life, which will take about 10 minutes.

You will then be randomly allocated to receive either immediate radiotherapy or deferred radiotherapy in the event that you develop a lump near the procedure site.

If you are allocated to the immediate radiotherapy group, an appointment will be arranged with an oncologist to plan the treatment you will receive. This will take about 30 minutes. After this you will need to attend the hospital on 3 consecutive days to receive the treatment. Each visit takes about 30 minutes.

All patients will be seen in clinic at 1, 3, 6, 9, 12 months after entry into the trial. Again details of your current health and medications will be recorded. Your chest will be examined to look for any lumps near the procedure site and you will be asked to fill in some more questionnaires on quality of life and pain.

When you are not seen in clinic, you will receive a phone call once a month from a nurse who will ask if anything has changed around the procedure site on your chest. They will explain what to look out for and if necessary, a clinic appointment will be arranged for you to see the doctor. Each month you will also be asked to complete a score sheet about your current pain levels, which you will then post back to the hospital.
Should a lump be felt near the site of the procedure you will be seen by the doctor and if necessary, radiotherapy will be arranged shortly afterwards and given over 3 working days. If you were in the immediate radiotherapy group, you will be able to discuss with the doctor whether further radiotherapy is necessary.

Patients who have been involved in the study at Oxford and Bristol may also be invited to undertake an additional short interview at the 6 month follow up visit to discuss their experiences of the trial and treatment so far with a trial nurse. This is an extra part of the study which is entirely voluntary and we are hoping to interview about 20 people in total. These interviews will be recorded but any information used from these interviews will not be identifiable to you.

7. If I take part, which aspects of my treatment will be ‘experimental’ or ‘extra’?
As immediate radiotherapy is already commonly given in centres across the UK, the treatment itself is not experimental. This study is trying to work out the best time for it to be given to patients to maximise its benefit without causing undue inconvenience.

The first trial visit will be extra to your normal clinical care in order to enrol you into the study. The other follow up visits in the trial are what you would receive as part of your normal clinical care, so these visits will not be extra, however the questionnaires and pain scores are an addition for the trial only.

As part of the trial, a nurse will contact you once a month to ensure we respond quickly to any changes you notice around the procedure site.

8. About the radiotherapy
Regardless of whether you receive radiotherapy at the beginning of the trial or later on should you develop a lump, the radiotherapy you will be given is the same.

It will be given every day for 3 days and you will be able to go home after each dose.

Prior to the first treatment you will meet a radiotherapy specialist to discuss and plan the treatment. Each radiotherapy appointment takes about 15 minutes and you will be free to go home once you have received the treatment. The procedure itself is not painful.
Possible Side effects

Most patients do not experience severe side effects from this type of radiotherapy. However some patients notice mild side effects such as:

- Feeling more tired than usual
- Skin reactions- these may occur in the area treated and may develop a few days or weeks after the radiotherapy. The skin may become pink and might feel sore or itchy.
- The skin is more sensitive than normal after radiotherapy. We advise against using perfumed creams and soaps on the treated area and keeping the area covered if you are in the sun.

At each clinic visit we will carefully assess and record any side effects you have noticed from the radiotherapy.

9. Will my medical information be kept confidential?

If you consent to join the study, your medical records may be looked at by:

- Key members of the research team (doctors and nurses who would usually be involved in your care as well as the doctors and nurses who are co-ordinating the trial)
- Representatives of the Sponsor (North Bristol NHS Trust) or the Regulatory Authorities to check the study is being carried out correctly.

All of these individuals will have a duty of confidentiality to you as a research participant. It is normal practice that if the radiotherapy is provided at a different hospital, personal and clinical information regarding your care will be shared between these sites.

Information about you will be collected for analysis by the Sponsor’s trial team and other collaborators involved in the study. This will include information about your health and other details such as your date of birth and gender. This information will be recorded and stored on a secure database, accessible only to the research team. You will be allocated a personal study number to identify you, so identifiable information (such as your name and contact details) will not be stored on the study database.

Some identifiable details, such as your name, address and NHS number, may be transferred to the Sponsor’s trial team on paper or electronic records. This will only be done where necessary for the purposes of monitoring and follow-up. In these instances, the information that identifies you will be kept completely secure and accessible only to authorised individuals within the Sponsor’s trial team.
Information held by the NHS and records maintained by the NHS Information Centre may be used by the Sponsor’s trial team to keep in touch with you and follow up your health status.

10. What are the possible disadvantages and risks of taking part?
As radiotherapy of this type is already administered in many centres across the UK, the side effect and safety profile is already well established. The main risk is experiencing a side effect to radiotherapy, but these are generally mild (as described above). You will need to attend hospital on four occasions for the planning and treatment.

We do not know if by having deferred radiotherapy, your chances of the cancer spreading at the procedure site are higher or not. This is what we are trying to find out from this study.

You will need to complete some questionnaires for the trial purposes, but these only take a few minutes and you will be provided with stamped addressed envelopes to return them in.

Radiotherapy is associated with some additional radiation exposure. However, in patients with mesothelioma, this does not result in an additional significant risk given the long time lag it would take for it to cause harm.

11. What are the possible benefits of participating in the trial?
Regardless of which treatment group you are allocated to, you will receive radiotherapy should it become necessary. You will have regular contact with the trial team and be followed up regularly.

Regardless of the trial results, you will be helping us find out how patients with mesothelioma should be treated in the future. You will be contributing to our understanding of the disease and helping us to develop better ways to treat your illness in the future.

12. What if new information becomes available?
The trial team will continue to review all new research data. If new information that influences the trial becomes available, alterations will be made accordingly. If this happens we will discuss whether you want to continue in the study and provide you with all the information you need to make this decision.

13. What if there is a problem?
If you have a concern about any aspect of this study you should ask to speak to the study doctor who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. The study doctor or the hospital switchboard can provide you with contact details for the complaints department.
If you are harmed as a result of your participation in the study due to someone’s negligence, North Bristol NHS trust will provide indemnity and/or compensation via the NHS indemnity scheme.

If you are harmed as a result of your participation in the study, not due to negligence, North Bristol NHS trust will sympathetically consider any claim for compensation.

14. Who is organising and funding the research?
North Bristol NHS Trust is sponsoring the research, which means that the trust has overall responsibility for the safe and appropriate conduction of the trial.

The trial has been funded by a grant from the National Institute of Health Research ‘Research for Patient Benefit’ scheme.

No payment will be made to trial doctors or nurses for including you in the trial.

15. Who has reviewed the trial?
This study has been reviewed and approved by a Research Ethics Committee, the Oxford Respiratory Trials Unit and the clinical trials team at North Bristol NHS Trust as well as the doctors and research department at your own hospital.

External experts have also reviewed the trial as part of organising funding for the study.

16. What will happen to the results of the trial?
When the study has finished and the results have been analysed, they will be published in a medical journal so that other doctors can read them. If you would like us to write to you personally, explaining the study findings, please indicate this on your consent form.

17. What do I need to do?
After reading this sheet, you will be invited to ask questions about the trial. If you would like to take part, we will ask you to sign a consent form. Your GP will be informed that you are taking part, with your consent.

If you wish to take a few days to consider whether to take part or would like to discuss the trial with your GP, please inform us.

If you decide not to participate, your routine care or legal rights will not be affected in any way. You can withdraw from the study at any time without giving a reason.

Thank you for taking the time to read this information and considering taking part in the trial.
Chief investigator:
Dr. N. Maskell (Consultant in Respiratory Medicine, North Bristol Lung Centre)

Contact details for local PI and recruiting centre here