(To be presented on local headed paper)

A randomised trial of COnventional care versus Radioablation (stereotactic body radiotherapy) for Extracranial oligometastases

CORE Study

IRAS number: 182152
Sponsor reference number: CCR 4323

PROSTATE

Patient Information Sheet

ICR The Institute of Cancer Research

CANCER RESEARCH UK

The ROYAL MARSDEN NHS Foundation Trust

INVITATION TO TAKE PART IN A RESEARCH STUDY

- Before you decide whether to take part in this study, it is important for you to understand why the research is being done and what it will involve.
- Please read the information in this sheet carefully. Discuss it with friends and family if you wish. Take time to decide if you would like to take part.
- Please ask your study doctor or nurse if there is anything that you do not understand or want to find out about more.
- It is your decision whether to take part or not. If you choose not to take part, this will not affect the care you get from your doctors.

IMPORTANT THINGS YOU SHOULD KNOW ABOUT

- We are investigating if the addition of stereotatic body radiotherapy (SBRT) to standard therapy benefits patients whose cancer has spread to only a limited area.
- SBRT is also known as stereotactic ablative radiotherapy (SABR) and is a way of giving targeted radiotherapy to a tumour.
- You have been given this information sheet as you have prostate cancer which has spread to no more than 3 small areas in your body, and so may be eligible to participate in this study.
- If you decide to take part in the study you may need to provide extra blood samples and will have to visit the hospital more often for check ups.
- As with all treatments, SBRT may cause side effects.
- If you join the study, you can stop taking part at any time.

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HOW TO CONTACT US

If you have any questions about this study, please talk to your doctor:
[*name*] at
Hospital Department
Hospital
Address
Address
Tel: 01234 XXX XXX

Research nurse: [*name and contact number]*
Out of hours contact tel:

1. Why are we doing this study?

The CORE study aims to understand whether there is a benefit for patients with your type of disease in receiving a type of radiotherapy called stereotactic body radiotherapy (SBRT) in addition to standard treatment. The study is also investigating this in patients with metastatic breast or non-small cell lung cancer.

2. Why am I being invited to take part?

You have been invited to take part in this study because your cancer has spread beyond its original site but this spread is confined to a limited area, in 3 or fewer sites. This is called oligometastatic disease. The usual treatment for oligometastatic prostate cancer depends on a number of factors and could include; monitoring or surveillance, chemotherapy, endocrine therapy, or palliative radiotherapy.

SBRT is an advanced radiotherapy approach which delivers high dose radiation to a targeted area within the body. The purpose of this study is to see if SBRT is a suitable treatment for the type of oligometastatic prostate cancer you currently have.

Do I have to take part?

No, it is up to you to decide whether to take part or not. If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. You are free to change your mind and withdraw from the study at any time without giving a reason. If you do choose to withdraw, your doctor will discuss with you the best treatment option available for you at that time.

This will not affect the standard of care that you receive.

3. What is radiotherapy treatment?

Radiotherapy uses targeted beams of high strength x-rays to kill cancer cells. Because radiotherapy can also cause damage to normal, non-cancer cells, the treatment is carefully planned by doctors and physicists at your hospital so that only your cancer and a small border surrounding it is exposed to the highest radiotherapy dose. Radiotherapy has been used to treat cancer for many years and is given in doses known as 'fractions'. You get one fraction at each visit. The amount of radiotherapy you get is measured in units called 'Gray' (Gy for short).

Standard radiotherapy is delivered using equipment similar to a large x-ray machine, called a linear accelerator (linac). It delivers beams of radiation to the targeted area. This type of radiotherapy is usually given daily over a period of weeks.

What is stereotactic body radiotherapy (SBRT)?

SBRT uses many beams of radiation directed from different angles that meet at the tumour. This means that the tumour itself receives a high dose of radiation from multiple beams, while the individual beams that travel through the surrounding healthy tissues are of a lower dose. This reduces the risk of damage to normal cells. SBRT can therefore be given with fewer treatments than standard radiotherapy.

There are different machines that can be used to give SBRT. The linear accelerator (Linac) that delivers standard radiotherapy can also be used to give SBRT and there are specially designed machines for SBRT which are known by their brand name. One example is CyberKnife™. Your radiographer will tell you which machine will be used for your treatment.

4. What will taking part in the study involve?

If you agree to take part in the CORE study you will be given this information sheet to keep and asked to sign a consent form.

Screening/Baseline assessments

Before you are able to take part you will also need to undergo some tests. Most of these will be carried out as part of your routine care but others are needed to check that it is safe for you to participate and that you are suitable for the study. These additional assessments will only be performed after you have consented to take part. They may all be performed in one visit or over a number of visits, but your doctor will discuss this with you in more detail. The assessments and tests that you will need include:

- General medical history, oncology history and physical examination including blood pressure, weight and height.
- List of medications you are taking including prescription and over-the-counter vitamins and alternative medications.
- You will be asked to provide a blood sample for measuring your full blood count, kidney function and blood salts (biochemistry). You will also have your Prostate Specific Antigen (PSA) and testosterone levels measured.
- You will be asked about any disease-related symptoms you are experiencing
- Quality of life questionnaires (optional).

You will also need to have scans taken to allow the doctors to see your cancer. The type of scan you have will depend on where in the body it is. It is possible you will have one or more of the scans listed below but this will depend on what is normally performed at your hospital:

- A CT scan (computerised tomography) uses X-rays and a computer to create detailed images of the inside of the body. A bone scan gives more detailed information about the inside of your bones than a CT scan. During a bone scan, a small amount of radioactive material is injected into your veins.
- Some patients may undergo a PET scan (Positron Emission Tomography) which is used to produce a detailed three-dimensional image of the inside of the body. PET scans are often combined with CT scans to produce even more detailed images.
- Some patients may also have a magnetic resonance imaging (MRI) scan which is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body and does not use X-rays. A diffusion weighted MRI (dwMRI) may help to show up areas of cancer more clearly than a normal MRI scan and may be used in some patients. MRI will however be performed at the screening visit if you have spinal metastases.

Who decides which treatment group I will be in?

Once assessments and tests confirm you are suitable to join the study, you will be put into

one of the two possible treatment groups: standard care or SBRT followed by standard care. Half of the patients will receive the standard treatment alone and half will receive SBRT followed by the standard treatment.

It is important that each group of patients are as similar to each other as possible. This is because we need to be sure that if one group does better than the other group it is because of the treatment and the way the treatment was given and not because the patients in the two groups are different from each other in some way. The only way to make sure that the groups are as similar as possible is to allocate patients to a group at random. This process is called 'randomisation' and it is done by a computer.

What are the two treatment groups?

If you are in the standard care group, you will receive standard treatments as you would in normal clinical care (except for some extra hospital visits).

If you are in the SBRT group, you will receive SBRT before the standard treatment and like the standard care group you will be required to attend some extra hospital visits.

Standard care

Standard care is what you would normally receive at your hospital trust. This could be any of the following treatments:

- Monitoring or surveillance.
- Chemotherapy.
- Endocrine therapy.
- Palliative radiotherapy.

Monitoring or Surveillance

In this situation, your doctor has decided to closely observe and monitor your condition. You will need to have follow up appointments at regular intervals. You may also be asked to have additional scans depending on your condition so your doctor can investigate symptoms that may develop during your follow up. This will be decided by your doctor.

Chemotherapy

Chemotherapy uses anti-cancer (cytotoxic) drugs to destroy cancer cells. Cytotoxic means toxic to cells. Chemotherapy drugs disrupt the way cancer cells grow and divide but they also affect normal cells. Research that has already been done will help your cancer specialist decide the most effective drugs to treat your cancer. You may have one drug or a combination of different drugs. The drugs are carried in the blood so they can reach cancer cells anywhere in the body. Different drugs damage cancer cells in different ways. When a combination of drugs is used each drug is chosen for its different effects. Chemotherapy drugs are also taken up by some healthy cells. These healthy cells can usually repair damage caused by chemotherapy but cancer cells cannot do this and eventually die.

Endocrine therapy

Hormones are substances that occur naturally in the body. They act as chemical messengers, which influence the growth and activity of cells. Hormones are produced by a number of different organs or glands which together are known as the endocrine system. Hormone therapy, also called endocrine therapy, works by altering the production or activity of particular hormones in the body.

As prostate cancer cells usually need testosterone to grow, this therapy works by either stopping your body from making the hormone testosterone, or by stopping testosterone from reaching the prostate

cancer cells. Androgen deprivation therapy is a type of endocrine therapy that works by reducing the levels of androgen hormones (the main one being testosterone) to prevent the prostate cancer cells from growing.

Palliative radiotherapy

Palliative radiotherapy is used to provide relief from pain caused by cancer or to prevent further spread of the disease. Palliative radiotherapy will also be carefully planned so that it avoids as much healthy tissue as possible. However, there will always be some healthy tissue that is affected by the treatment and this may cause side effects.

If you are allocated to the standard care group, you will receive palliative radiotherapy that will target areas of oligometastatic disease. If you are allocated to the SBRT followed by standard care group, then the areas of oligometastases will be treated with SBRT and you will not receive palliative radiotherapy to those areas as well.

The above information on the different standard care treatments has been taken from the Macmillan Cancer Support website and further information on specific treatment or agents may be obtained from there: http://www.macmillan.org.uk/Home.aspx

These standard treatments will be different depending on the site of your oligometastatic disease and can also depend on current practice in your hospital. Information about your standard treatment can be provided by your hospital.

SBRT followed by standard care

If you are randomised to receive SBRT followed by standard care there are some additional visits you would have to make to the hospital for the SBRT treatment. Standard care treatment will be started after you have completed your SBRT, although if you are going to receive endocrine therapy this may start before your SBRT. You will have the same standard care treatment as you would have if you had been allocated to the standard care alone group. The exception is if you would have received palliative radiotherapy as part of your standard care. If you have had SBRT you will not receive additional palliative radiotherapy.

5. More information about the SBRT

What do I have to do before my SBRT treatment?

To ensure that your treatment is as effective as possible, it has to be carefully planned by your Cancer Specialist and other specialised staff (radiographers, physicists). Some patients will need markers to be implanted into, or around the tumour, in a procedure similar to a biopsy. This helps us to target the tumour. Your doctor will tell you if your treatment needs this procedure. See page 12 for more information about fiducial markers and their side-effects.

If your SBRT treatment area is close to your kidneys, you may need to have a dimercaptosuccinic acid (DMSA) scan. During a DMSA scan, a small amount of radioactive material is injected into a vein and is used to check kidney function. The scan will tell the doctor whether it is safe to do the SBRT treatment or not.

You will have one planning session of about 30 minutes at the radiotherapy department. A planning CT scan taken of the area to be treated will take place and you may also need

a MRI scan. You will have measurements taken that are needed for treatment planning.

What do I have to do during my SBRT treatment?

The number of treatment(s) you need will be dependent on where your disease is. You will usually receive treatment on alternate days. The average treatment will be 3 treatments over 5 days. However, you could receive up to 8 treatments over 21 days. You will discuss your final treatment programme with your doctor.

Your radiotherapy treatment is similar to having an x-ray and you will not feel anything. The duration of radiotherapy treatment will vary depending on the type of machine that is used. If a Linac is used, the treatment will take a few minutes, but you will need to lie still for about 20 minutes while the machine moves around to deliver the radiotherapy from different angles. If the Cyberknife machine is used, the treatment will take longer, maybe 30-45 minutes. In some cases the treatment may take more than an hour. Support devices, for example for your head, may be used for your comfort and stability during treatment.

How many times will I need to visit the hospital during and after my standard care or SBRT followed by standard care treatment?

After your treatment, whether you are in the standard care group or the SBRT plus standard care group, you will be seen by your doctor and/or nurse every 3 months for the first 2 years and 6 monthly therafter for up to 5 years. At these visits any side effects you may have will be recorded and treated. The doctors will also check how well the treatment has controlled your cancer. If your cancer is found to have returned your doctor will discuss available treatment options with you.

Will I be asked to do anything else?

One of the reasons we are carrying out the CORE study is to look at the side effects of the SBRT treatment and how these affect your daily life. This is called the Quality of Life (QoL) study. If you decide to take part in CORE, we would like you to complete Quality of Life (QoL) questionnaires to describe any side effects that you may experience. This is an optional part of the study but these QoL questionnaires will help us to understand more about the side effects of treatment. The questionnaires should take less than 10 minutes to complete and will be given to you by a research nurse whilst you are waiting to see your doctor. The research nurse will explain how to fill out the questionnaire and will be available to answer any of your questions. There are no 'right' or 'wrong' answers.

The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) is the research centre coordinating the CORE study. Researchers from the ICR-CTSU will send you further QoL questionnaires to your home address at 3, 6, 12, 18 and 24 months after the end of your treatment. You may opt out of completing them at any time.

6. What will happen next if I decide to take part?

Once you have read this information sheet, if you agree to take part in this study, you will be asked to sign a consent form before any study related procedures are performed.

If you agree to take part, your doctor or nurse will contact the ICR-CTSU who will record your details and tell your specialist which treatment you are to receive as part of the study. Whichever group you are in, you will be treated with the best possible care and will be monitored closely.

If you join the study you will be one of about 230 patients taking part.

Study schedule

In addition to the screening assessments described on page 4, the following assessments will be carried out at various visits during the study:

Before you start treatment:

- Full blood count, urea and electrolytes, liver function tests.
- Re-assessment of symptoms you are experiencing.

At the end of treatment:

The following assessments will be carried out within 7 days of the last SBRT treatment visit or 6 weeks after randomisation for patients randomised to standard of care alone.

- Physical examination, weight and height.
- List of medications you are taking (including prescription and over-the-counter vitamins and alternative medications).
- Quality of life questionnaire.

Follow up:

The research team would like to follow your progress after receiving the standard care or the SBRT plus standard care. This will involve regular clinic visits every 3 months for the first 2 years and 6 monthly thereafter for up to 5 years.

At each visit:

- You will receive a clinical examination (physical exam including performance status, height and weight).
- Your PSA will be assessed, and your testosterone will also be assessed yearly.
- You will be asked about any side effects.
- You will be asked about any disease-related symptoms you are experiencing.

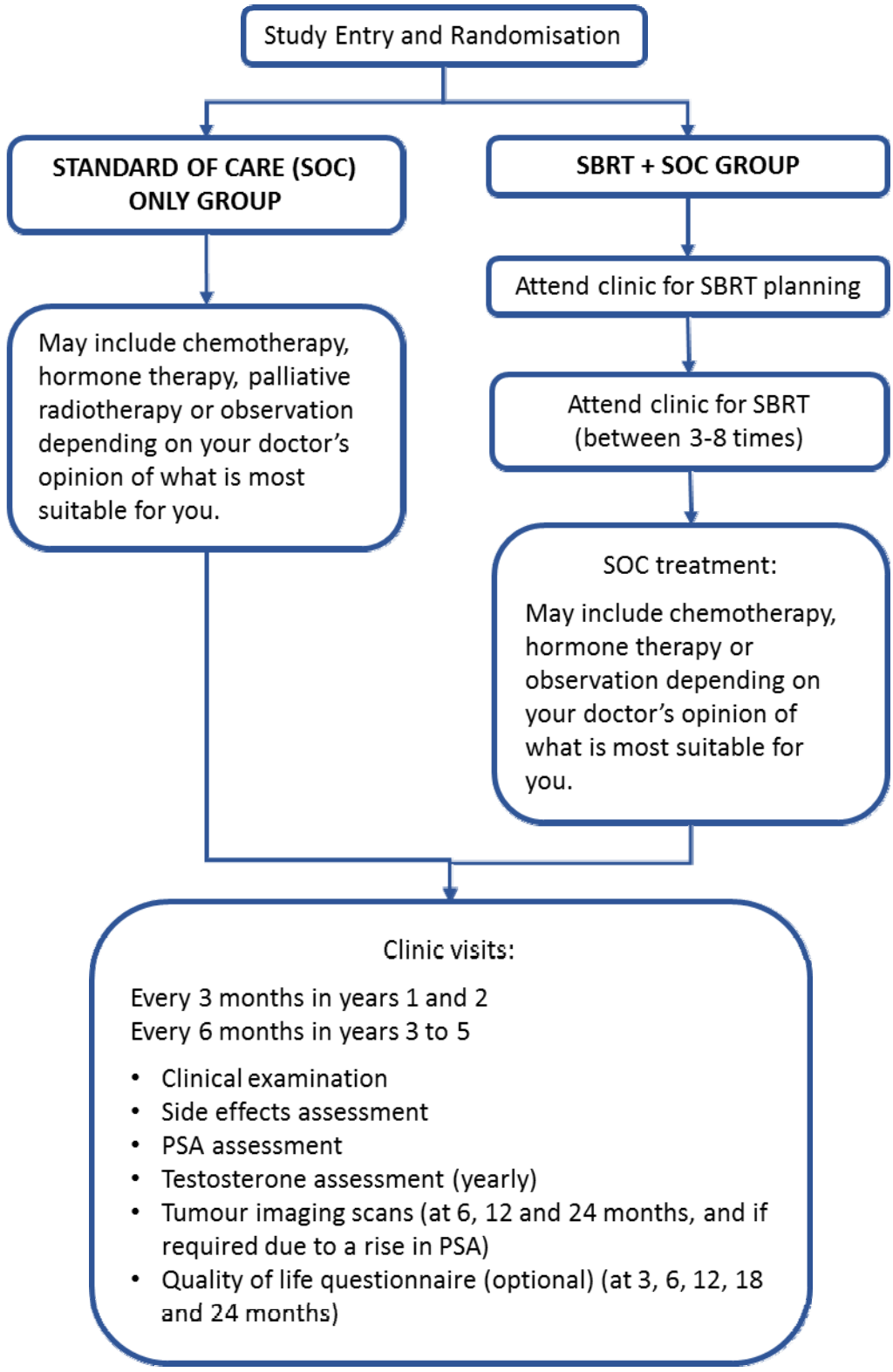
Quality of Life questionnaires will be completed at 3, 6, 12, 18 and 24 months.

Imaging assessments will also be performed:

- A CT scan and a bone scan will be performed at 6, 12 and 24 months. A raised PSA will trigger additional imaging (CT) between these visits.

If you are in the SBRT plus standard care group and your cancer then spreads to another site, it may be possible to have further SBRT treatment. Your doctor will discuss this possibility with you.

This flow diagram shows the visit time points and assessments to be conducted for prostate cancer patients as part of the CORE study.



Stopping treatment

You can choose to stop your treatment at any time. Your doctor may also take you off treatment if they believe it is making you too unwell or not working.

You will be given a card, which will provide details about the CORE study and what treatment you are receiving. Please carry it with you at all times while you are taking part in this study.

7. What are the possible benefits and disadvantages of taking part?

What are the possible benefits of taking part in the study?

There is no guarantee that you as an individual will benefit directly from taking part in this study. The aim of CORE is to find out whether there is benefit in patients receiving SBRT in addition to standard treatment. SBRT may provide benefit, but we do not currently know this. It is hoped that potential benefits may include improving disease related symptoms and decreasing the size of your tumour. The information gained from this study may help in the treatment of future patients with cancer similar to yours.

What are the possible disadvantages of taking part in the study?

The effects of the SBRT treatment are not completely known. You may have more side effects as a result of receiving SBRT in addition to your standard treatment.

You may experience some side effects that are not listed on the following page. There is no way of predicting if you will experience any, or how severe they will be. You must contact your study doctor if you experience any side effects even if you are not sure that any problems you may have are related to your cancer treatment.

Taking part in this research study will involve several additional visits to the hospital as detailed earlier in this information sheet. Being involved in any research study requires a degree of commitment, such as regular clinic visits and additional tests. If randomised to receive SBRT you will also need to make extra trips to the hospital in order to receive this SBRT treatment.

Before participating you should consider if this will affect any medical insurance you have and seek advice if necessary.

During this study, blood samples will be drawn to perform a variety of tests. The number of blood tests required in this study is more than if you were receiving treatment outside of a research study. Full blood counts will be taken prior to the treatment and 6 months after. You will also have further tests for PSA at each visit and for testosterone at 12 month intervals during your participation within the trial. Risks linked with blood sampling include pain from the needle being inserted, light headedness, possible fainting and (rarely) infection.

You may also have a dwMRI scan during this study as part of your clinical care. When having an dwMRI scan you will be made as comfortable as possible before you start. You will be asked to remain still during the entire procedure. People who are afraid of being in

enclosed spaces may feel anxious or nervous while in the scanner. Also, some people find it difficult or painful to hold one position for more than a few minutes.

Occasionally during the course of a study you may be found to have a previously undiagnosed medical condition. In this situation your doctor will take the necessary steps to ensure you receive appropriate treatment.

Are there any radiation risks associated with CT scans, X-rays or radioactive tracers?

By taking part in this study, you may have more CT, PET-CT or bone scans to monitor your treatment than you would under standard of care. If you have a DMSA scan, this would be part of normal care. Having a CT scan will expose you to an amount of radiation comparable to 8 years' worth of normal background radiation in the UK. Having a bone scan will expose you to an amount of radiation which is roughly the same as 1 year's worth of normal background radiation. Having a PET-CT scan will expose you to an amount of radiation which is roughly the same as 14 years' worth of normal background radiation.

If you undergo radiotherapy to treat your cancer, you will be exposed to much higher levels of radiation than described above. If you undergo palliative radiotherapy, the exposure will be the same as you would receive as standard of care. If you undergo SBRT, the exposure will be additional to standard of care as this is a new type of radiotherapy treatment.

Radiation can cause cell damage which may, after many years or decades, turn cancerous. In light of your current clinical condition, the chance of this happening to you is extremely small.

In rare cases, you may have an allergic reaction to the contrast material "dye" given for CT scans. If you have had allergic reactions to X-ray dyes in the past, you should let your doctor know.

8. More information about taking part

What are the possible side effects of SBRT treatment?

Patients who have SBRT can experience some side effects. No one can predict who will have these or how severe they may be. They are usually mild but can sometimes be more serious. Possible side effects will depend on where your disease is being treated so it is unlikely you will experience anything outside the area that was treated with SBRT. A list of possible effects of SBRT is provided on the next page:

Potential side effects of SBRT:

Acute side effects (first few weeks)	Late Side effects (months to years)
• Tiredness • Nausea and/or vomiting • Temporary worsening of original symptoms • Skin changes at treated sites • Hair loss (temporary/permanent) • Diarrhoea • Swallowing problems/ pain on swallowing • Spinal cord damage	• Skin changes at treated sites • Bone fracture • Small risk of serious damage to gut • Chest wall pain/fracture • Temporary worsening of original symptoms • Liver damage • Kidney damage • Small risk of nerve damage • Liver damage
Acute side effects for patients with Lung metastases	**Late side effects for patients with Lung metastases**
• Dry cough • Breathlessness	• Reduction in breathing capacity • Spinal cord damage • Rib fracture • Cardiac damage • Swallowing problems

Potency and fertility side effects

Men may be infertile after radiotherapy, depending on the area treated. If you are still intending have children, please discuss this with your doctor at this point. It is important to ensure that contraception is used at all times as radiation may cause abnormalities in sperm.

Fiducial marker side-effects

Gold markers, known as fiducial markers, may be used as a method of guiding the SBRT treatment. The procedure takes approximately 10-15 minutes, and is very similar to a biopsy and can be uncomfortable. If you had a lot of discomfort with a previous biopsy, your doctors may offer you sedation for this procedure (or if necessary a general anaesthetic). The markers are inserted through the skin under local anaesthetic with a needle into or near the location of disease. You can go home after the procedure and you will be given antibiotics to prevent infection. For a few days afterwards you may also notice a small amount of discomfort or blood.

Please let your doctor or nurse know about any side effects that you are concerned about so they can advise you what to do. Their telephone numbers are at the end of this information sheet. There is also 24 hour support available from your hospital, to provide access to immediate medical care in the event of any serious problems.

What alternative treatments are there?

If you do not want to take part in the study there may be other treatment options available. Participation in this study will not affect the usual standard of care you receive.
Your clinical care team will be able to discuss these alternative treatments and the associated risks and benefits with you before you decide whether to take part in this study.

9. Confidentiality

The Royal Marsden NHS Foundation Trust is the sponsor for this study based in the United Kingdom. The Institute of Cancer Research Clinical Trials & Statistics Unit (ICR-CTSU) is the coordinating trials unit working on this study with The Royal Marsden NHS Foundation Trust. The ICR-CTSU will be using information from you and your medical records in order to undertake this study and so will act on the sponsor's behalf as the data controller for this study. This means that ICR-CTSU are responsible for looking after your information and using it properly.

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.

[NHS site] will collect information from you and your medical records for this research study in accordance with instructions from the ICR-CTSU.

[NHS site] will use your name, NHS number and 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 ICR-CTSU and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS site] will pass these details to the ICR-CTSU along with the information collected from you and your medical records. The only people in the ICR-CTSU who will have access to information that identifies you will be people who need to contact you to send Quality of Life booklets or audit the data collection process.

[NHS site] will keep identifiable information about you from this study for 20 years after the study has finished.

When you join the study, your name, date of birth, postcode, hospital number and NHS or Community Health Index (CHI) number will be passed to ICR-CTSU. You will be given a unique study number, which will be used together with your initials and date of birth on forms that the research staff at your hospital will send to ICR-CTSU. All information about you will be coded with the study number and will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams at your hospital and the ICR-CTSU will have access to the information that could allow this study number to be linked to you.

We will be contacting your hospital from time to time to find out how you are getting on. Patients sometimes change address and/or GP or lose touch with their hospital. If this happens we would like to use national records including the National Cancer Registry and the General Register Office (GRO), to find out how you are and to collect basic information about your health. Any details we receive from any source are confidential and will only be used for the purposes of the study. Please initial the consent form to show that we have your permission to do this.

The ICR-CTSU will keep identifiable information about you for 20 years after the study has finished.

By signing the attached consent form you agree for us to access your original medical records as outlined above.

Will my General Practitioner (GP) be told I am taking part?

Yes, your GP will be notified about your participation in this study. By signing the consent form you are agreeing to this. It is routine practice for your GP to be told that you are taking part in a research project.

Data Sharing

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies at the ICR and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified, your data will only be used in research that has been independently reviewed by an ethics committee.

You can find out more about how we use your information at www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency

10. General information about CORE

What happens if I don't want to carry on with the study?

You are free to withdraw from the CORE study at any time. You do not have to give a reason and your future treatment and care will not be affected. Your doctor will discuss your treatment options with you and will offer the most suitable treatment available.

If you were to withdraw we would like your permission to continue to collect information on your progress that is routinely recorded in your medical records.

What if something goes wrong?

Every care will be taken in the course of this clinical trial. Your progress will be watched closely and you will be offered whatever help is available to cope with any side effects. Occasionally some patients need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious. If this were to happen, full details of what has happened will be reviewed carefully by the doctor who has overall responsibility for the CORE study.

If you are not happy with the general care and treatment you receive during the study, please speak first to your study doctor, who will try to resolve the problem. If you have any concern about any aspects of the study you should ask to speak with your study doctor or research nurse who will do their best to answer your questions (contact details at front of sheet).

If you remain unhappy and wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you. We recommend that you obtain a copy of your hospitals complaints procedure or policy if you intend to make a complaint. Concerns should be raised by speaking to a member of staff at your hospital or by talking to the local Patient Advice and Liaison Service (PALS), which has been established in every NHS Trust and Primary Care Trust (PCT).

In the unlikely event that you are injured by taking part, compensation may be available.

If you are harmed due to the negligence of someone treating you, then you may have grounds for legal action for compensation. NHS Trusts are responsible for clinical negligence and other negligent harm to individuals who are under their care and covered under the NHS Indemnity Scheme.

What if I have private medical insurance?

If you hold private medical insurance, you should check with the company issuing the insurance before agreeing to take part in this clinical study, as you will need to ensure that your taking part in the study will not affect the insurance.

What will happen to the results of the clinical study?

Independent experts will review the progress of the research, and the results will be published in a scientific journal as soon as there is enough information to be sure the results are reliable. This will be in a few years time. The results will help to decide how to treat oligometastatic disease in the future. The results from this study may also contribute to reviews of worldwide evidence about this type of cancer and its treatment. You will not be identified in any report or publication relating to this research.

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied, which may affect your willingness to continue in the study. If this happens, your study doctor will tell you in a timely manner and discuss whether you should continue in the study. If you decide to continue in the study, you may be asked to sign an updated informed consent form. If you decide to discontinue, your doctor will make arrangements for your future care.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

Who is organising and funding the research?

CORE is organised by leading cancer specialists at the Royal Marsden Hospital in London and Sutton. It is being coordinated by The Institute of Cancer Research Clinical Trials and Statistics Unit and has been funded by Cancer Research UK. The funding helps to cover the cost of including you in the study and helps support the study staff. None of the researchers are personally benefiting from this grant.

Your doctor will not receive any payments for including you in this research study.

Who has reviewed the study?

Cancer Research UK has reviewed the CORE study and supports the aims of the study. CORE has also been approved by the London Fulham – Charing Cross Hospital Research Ethics Committee West London. Their approval means they are 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 the right information to decide whether to take part.

What do I have to do now?

You will have some time to think about the study and make your decision. You may wish to discuss it with your GP, family or friends. Please keep this information sheet and a copy of the signed consent form. If, at any time, you have any questions about the study you should contact your consultant.

11. Expenses and Payments

You will not receive any payment for your participation in the CORE study. We are unable to cover any expenses incurred as part of your participation in the study such as transport or parking charges.

12. Contacts for further information

Who else can I contact for further information?

You have the right to ask questions about this study at any time and are encouraged to do so. You can call the study doctor or hospital if you feel that you are developing any unwanted side effects, or if you believe you have been injured as a result of your receiving study treatment, or if you have any questions about this study or your participation in this study.

Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information Nurse Specialists on the Macmillan Support Line:

Freephone 0808 808 00 00
Monday to Friday, 9.00am to 8.00pm

In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns.

You can learn more about cancer treatment and clinical trials on the Cancer Research UK, Prostate Cancer Foundation and Prostate Cancer UK websites:

www.cancerhelp.org.uk

http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial

http://www.pcf.org

https://prostatecanceruk.org/

Thank you for your interest in our research.

13. Glossary

Abbreviation	Full Name	What it means
CT scan	Computerised Tomography scan	A CT scan uses x-rays to take detailed pictures of inside your body from different angles. A computer then puts them together to give a series of pictures.
dwMRI scan	Diffusion weighted Magnetic Resonance Imaging scan	A dwMRI scan may help to show up areas of cancer more clearly than a normal MRI scan.
ICR-CTSU	The Institute of Cancer Research Clinical Trials and Statistics Unit	The organisation carrying out the day to day work on the trial.
MRI scan	Magnetic Resonance Imaging scan	An MRI scan creates pictures using magnetism and radio waves. It produces pictures from angles all around the body and shows up soft tissues very clearly.
Oligometastatic disease	/	Cancer that has spread beyond its original site but this spread is confined to a limited area, in 3 or fewer sites.
PET scan	Positron Emission Tomography scan	This type of scan can show how body tissues are working, as well as what they look like.
PSA	Prostate Specific Antigen	PSA is a protein made in the prostate gland. Some of this PSA leaks into the blood and can be measured in a PSA test. PSA levels can be higher for a number of reasons. A raised level may be a sign of prostate cancer.
QoL	Quality of Life	QoL questionnaires are used to assess how a treatment is affecting your quality of life, for example what side effects you are having and how the treatment is making you feel.
SBRT	Stereotactic Body Radiotherapy	Radiotherapy delivered from many different positions around the body. The beams meet at the tumour so the tumour receives a high dose of radiation and the tissues around it only receive a low dose. This lowers the risk of side effects. It is also sometimes called Stereotactic Ablative Radiotherapy (SABR).
SOC treatment	Standard of Care treatment	This is the treatment you would receive if you were not participating in a study.