(To be printed on local headed paper)



STAR-TRAP: Phase II clinical trial of using stereotactic body radiotherapy (SBRT) on first line androgen receptor pathway inhibitor for metastatic prostate cancer

**PATIENT INFORMATION SHEET**

**For patients with Oligoprogressive disease**

Version3.0 12.08.2024



**INVITATION TO TAKE PART IN A CLINICAL TRIAL**

We would like to invite you to take part in a clinical trial called STAR-TRAP.

Before you decide if you would like to take part, it is important that you understand why the research is being done and what it will involve for you if you do take part. One of your doctors or nurses will go through this information sheet with you and answer any questions you may have or explain anything you don’t understand.

Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide if you want to take part.

You are free to decide if you want to take part in this research study. **If you choose not to take part, this will not affect the care you get from your own doctors in any way.**

STAR-TRAP is a clinical trial to assess whether a precise radiotherapy technique called stereotactic body radiotherapy (SBRT) can delay progression of cancer in patients whose cancer has spread away from the prostate.

If you decide to take part, you will be asked to sign the consent form at the end of this information sheet. You will be given a copy of this information sheet and a signed consent form.

**You can decide to stop taking part in the study at any time without giving a reason.**

**CONTENTS**

**Part 1**

1. What is the purpose of the trial?
2. What is Stereotactic Body Radiotherapy (SBRT)?
3. Why am I being invited to take part?
4. Do I have to take part?
5. What treatment might I have if I decide to take part?
6. What happens during the trial?
7. What do I need to know about the treatment used in this study?
8. How to decide whether to take part in the trial?

**Part 2**

1. Quality of Life study
2. Confidentiality
3. General information about STAR-TRAP
4. Useful contact information
5. Glossary – list of definitions

**Terms listed in the glossary are indicated with asterisks when they first appear in this leaflet.**

**HOW TO CONTACT US**

If you have any questions about this clinical trial, please talk to your medical team. Their details are given on page x of the information sheet.

This study is coordinated by the research centre at The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU).

**Part 1**

1. **What is the purpose of this study?**

In STAR-TRAP is we will treat some patients with a precise radiotherapy technique called stereotactic body radiotherapy (SBRT)\*. We want to find out if SBRT can delay progression of cancer where the disease has spread outside of the prostate. This spread is known as metastases\*.

SBRT has been shown to be safe and effective in other groups of cancer patients who have a small number of metastases. The treatment is now widely available within the UK and we want to test if it is effective in patients with more advanced prostate cancer. We will also look for links between imaging findings and outcomes to see if these findings predict which patients benefit most from the addition of SBRT.

1. **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. However, 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. There are also specially designed machines for SBRT which are known by their brand name. One example is CyberKnifeTM. Your radiographer will tell you which machine will be used for your treatment.

1. **Why am I being invited to take part?**

You have been invited to take part in this study because:

Your doctors have confirmed that your prostate cancer is progressing with less than 5 ‘active’ metastases and/or there is active disease within the prostate

This study is hoping to recruit participants in a number of hospitals across the UK. Approximately 236 participants will be invited to take part. You have been approached because your hospital doctor feels that you are suitable to take part.

1. **Do I have to take part?**

No, you do not have to take part. It is up to you to decide. If you do want to take part, you will be asked to sign a consent form. You will be free to withdraw at any time without giving a reason if you do not want to. This will not affect the standard of care you receive. Your doctor will discuss alternative treatment with you and offer you the most suitable treatment available.

Provided you agree, your GP will be informed about your participation in this trial.

1. **What happens during the trial?**

Before treatment
After the initial discussion with your medical team, you will have as long as you need to decide if you would like to take part in STAR-TRAP. You can take this opportunity to speak to someone to make sure that you fully understand what will happen in this study. If you agree to take part in STAR-TRAP, you will be asked to sign a consent form.

All patients in both treatment groups will need to have a number of routine examinations before you can enter the study. You would have these examinations whether you are on the trial or not, to help determine the extent of your prostate cancer.

These assessments will include:

* Testosterone and Prostate-Specific Antigen (PSA) blood tests

The treatment you receive in STAR-TRAP will not be decided by you or your doctor or any other person. You will be allocated into one of the groups by a process called randomisation. This is where a computer randomly assigns you to one of the groups. Randomisation ensures that if one group does better than the other, it is because of the treatment and not because of the patients in the two groups are different from each other in some way. Randomisation ensures that the treatments can be compared fully and fairly. You will have an equal chance of being in group one or group two.

**RANDOMISATION**

**Group 2: Continue on first line therapy with SBRT**

**Group 1: Continue on first line therapy**

Gray (Gy) is the unit used to measure the total about of radiation. The radiation dose prescribed in radiotherapy is delivered as a series of small daily doses, called fractions.

Group 1: Continue on first line therapy
If you are allocated to group 1, you will continue to receive the treatment you have already been receiving for prostate cancer in the same way.

Group 2: Continue on first line therapy with SBRT
If you are allocated to group 2, you will continue to receive the treatment you have already been receiving for prostate cancer in the same way. You will also have SBRT to your prostate and also to the areas to which your cancer has spread.

The radiotherapy will be given over three to five alternate days. The site(s) where your cancer has spread will receive a radiation dose of up to 30 Gray split over 3-5 treatments. If you are having radiotherapy to the prostate, your prostate will receive a radiation dose of 33 Gray split over 5 treatments. Treatments to the prostate and treatments to the other sites will be given on the same treatment days, or on different days and this will be discussed with you. You would not normally receive SBRT as standard treatment outside of the trial.

SBRT planning and treatment
To ensure that your treatment is 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. 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. Your SBRT treatment will typically start within 8 weeks after randomisation.

You will receive treatment over 3 to 5 alternate days. SBRT treatment is similar to having an x-ray and you will not feel anything. The duration of the treatment session depends on the type of machine that is used at your hospital. A Linac machine will deliver the treatment over a few minutes but you will need to lie still for about 20-30 minutes whilst the machine moves around the body to deliver the radiotherapy. A CyberknifeTM machine will take longer, usually 45-60 minutes, but in some cases may take up to 90 minutes.

Follow up visits
You will be seen regularly by your doctor and/or another member of the clinical team after treatment and within the study for up to 3 years (36 months). For whichever group you are allocated, you will be seen as per standard of care schedule for your hospital.

At each follow up visit, the clinical team will manage and record any side effects you have and check on your progress. You will have routine PSA test at a regular interval. The interval of this test depends on your hospital’s standard practice. For STAR-TRAP, we recommended this to be done at least once every 12 weeks. The test will be done at your hospital. You will also have regular scans to monitor the status of your disease. The intervals and types of scans you have will depend on your hospital’s standard practice.

Quality of Life questionnaire
We will ask you to complete Quality of Life (QoL) questionnaires before randomisation and at specific time points. More information about the Quality of Life questionnaires can be found in Part 2, Section 1 on page xx.

The table below summarises the time for questionnaire completion:

|  |  |  |
| --- | --- | --- |
| Follow up visit | Group 1 (from date of randomisation) | Group 2 (from start date of SBRT) |
| 1 | Before randomisation | Before randomisation |
| 2 | Week 10 | End of SBRT |
| 3 | Week 20 | Week 12 |
| 4+ | Around month 6, 9, 12 and then every 4 months up to 36 months | Around month 6, 9, 12 and then every 4 months up to 36 months (from date of randomisation) |

1. **What do I need to know about the treatments used in this study?**

Side effects

All treatments may cause side effects.

Your hospital doctor will have already discussed with you the side effects of the treatment you have had so far. Therefore, in this information sheet we will discuss the possible side effects of SBRT.

Radiotherapy treatment can cause side effects because the healthy tissues in the pelvis, mostly the bladder and bowel, are exposed to the radiation. Radiotherapy can occasionally cause you to feel more tired than normal. Most patients experience some side effects but nearly all of these are temporary. At two years after radiotherapy, around 1 in 20 (5%) of patients have ongoing noticeable side effects; in total around 1 in 8 (12%) may be affected at some point.

It is important that you tell your study doctor or nurse about any problems you have at each hospital visit, so that appropriate action can be taken. You can contact your doctor or nurse between visits if you are concerned. Their numbers are on page xxxxx of this information sheet.

**Common side effects during and immediately after radiotherapy treatment**

(Most patients (>50%) will experience one or more of these):

* Tiredness
* Loose bowel motions or diarrhoea
* Discomfort in the back passage
* Needing to pass water more frequently
* Needing to pass water more urgently
* Discomfort on passing water

**Rare side effects during and immediately after radiotherapy treatment**

(Likely to affect less than 1 in 10 patients)

* Skin redness
* Temporary loss of pubic hair
* Small risk of needing a urinary catheter (1-2% risk)

**Common side effects in the long term** (occurring in the months and years after radiotherapy treatment):

* Impotence or change in sexual experience (about 50% risk)
* Infertility (almost 100% risk)
* Minor change in bowel habit (around 30% risk)
* Minor change in urinary function (about 50% risk)

**Rare side effects in the long term**

(Likely to affect less than 1 in 10 patients; occurring in the months and years after radiotherapy treatment):

* Narrowing of the urethra (tube to the bladder) causing problems passing water (<5%)
* Moderately bothersome change in bowel habit (up to 10 % patients over 5 years)
* Bleeding from the back passage needing surgical treatment (<5%)
* Bowel or bladder incontinence (<1%)
* Severe bleeding upon urination (<1%)
* Possible very small increase in the risk of rectal (bowel) or bladder cancer (<0.5%)
* Risk of damage to the bones of the pelvis (<0.5%)
* Risk of damage to the nerves of the pelvis (<0.5%)

**Bowel side effects:**During radiotherapy there may be an increase in the frequency and urgency of bowel movements with passing of mucus. After treatment, symptoms are expected to substantially settle within 4-8 weeks but some degree of urgency and looseness may persist. Rectal bleeding is usually slight but may occur in approximately one out of 10 patients treated. The majority of patients do not need any treatment for bleeding. However it may be necessary to investigate this, in case it is due to a different problem. In addition, rectal discomfort may occur in fewer than 2 out of 10 patients during and after radiotherapy treatment.

**Bladder side effects:** It is quite common for patients to urinate more frequently and/or urgently during radiotherapy, sometimes with discomfort. These side effects usually subside within 4-8 weeks of treatment finishing, and commonly any remaining symptoms are less than those reported before radiotherapy started. However, a small proportion will continue to have increased frequency or urgency. Urinary incontinence is rare. In addition, fewer than 2 out of 10 patients will experience slight blood loss whilst urinating during and after radiotherapy. This should be investigated in case it is due to a different problem. Rarely, patients develop a narrowing (stricture) of the water tube (urethra) inside the prostate. This leads to a poor urine stream which might require a stretching procedure.

**Sexual impotence and fertility:** Sexual activity is likely to be significantly impaired during hormone and radiotherapy treatment but may recover in about 30-50% of cases after radiotherapy. Patients treated with over 6 months of hormonal therapy, as in this trial, will take longer to recover sexual function. Those with difficulties before treatment have more difficulties after radiotherapy. If you would like to maintain sexual function it is important to try to do this as soon as possible after your hormone treatments have worn off, using Viagra or Cialis if needed. We expect patients to become infertile after radiotherapy treatment but please see guidance below regarding contraception*.* If there is a possibility of you fathering a child, your medical team will discuss with you and you will be advised to use barrier protection and avoid conception for 12 months after SBRT treatment.

**Long-term risks:** If you take part in this study, you may undergo SBRT radiotherapy treatment, which you would not have if you chose not to participate. The radiotherapy that you may have is used as standard for patients with other similar clinical conditions.

You could also have PET-CT scans, bone scans, CT scans and radiotherapy verification imaging. Some of these will be extra to those you would have if you did not take part. These procedures use ionising radiation to form images of your body or provide treatment and provide your doctor with other clinical information.

The radiation dose from the PET-CT scans, bone scans and CT scans will be very small compared to the dose from the radiotherapy. Ionising radiation may cause cancer many years or decades after the exposure. Taking part in this study will not significantly alter the chances of this happening to you.

|  |  |
| --- | --- |
| **Side effects during or immediately after radiotherapy if you are having radiotherapy for lung metastasis** | **Side effects in the long term if you are having radiotherapy for lung metastasis** |
| * Dry cough
* Shortness of breath
* Chest wall pain
* Pneumonitis
* Nausea
* Inflammation of the oesophagus
 | * Chest wall pain
* Rib fracture
* Reduction in breathing capacity
* Pneumonitis
* Damage to the heart (risk of heart failure/heart attack)
* Swallowing problems
* Damage to the spinal cord
 |
| **Side effects during or immediately after radiotherapy if you are having radiotherapy for bone metastasis** | **Side effects in the long term if you are having radiotherapy for bone metastasis** |
| * Pain flare
* Swallowing problems
 | * Bone fracture
* Vertebral compression fractures
* Spinal cord damage
 |
| **Side effects during or immediately after radiotherapy if you are having radiotherapy for liver metastasis** | **Side effects in the long term if you are having radiotherapy for liver metastasis** |
| * Nausea
* Increase of liver enzymes
* Abdominal pain
* Decrease in white blood cells
 | * Liver failure
* Ascites
 |

The side effects of SBRT depend on the area where you are treated. Your medical team will discuss any other potential side effects with you.

Not all patients will have these side effects, and they can often be treated to make them less serious or uncomfortable. Your progress will be closely monitored and your medical team will offer whatever help is available to cope with any side effects you are having. Occasionally, some people need a short stay in hospital for side effects to be treated. If any health-related or incidental findings are found during your participation in STAR-TRAP, your medical team will discuss these with you and will offer whatever help is available.

1. **How to decide whether to take part in the trial?**

Possible benefits of taking part
There is no guarantee that you will benefit directly from taking part in this study. The aim of STAR-TRAP is to find out whether SBRT can delay progression of cancer in metastatic prostate cancer patients. We do not currently know whether this is the case. The information we get from this study may help in treating people with cancer like yours in the future.

Possible disadvantages and risks of taking part
*Side effects*

You may have side effects from the study treatment. 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 in Section 6. 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.

*Additional hospital visits and travel*

You may need to attend hospital more frequently than you would if you decided to participant in this study. Your medical team will explain if this is the case for you. If randomised to receive SBRT, you will also need to make extra trips to the hospital in order to receive this SBRT treatment. This may cause some disruption to your normal activities and home life and this should be discussed with your family and friends if it will impact on them.

*Private medical insurance*

If you have private medical insurance, you should check with your insurance company before agreeing to take part in this study to ensure that your participation will not affect your cover.

Alternatives for treatment

Your medical team should discuss with you all available treatment options before you decide if you want to take part in this study. Participation in this study will not affect the usual standard of care you receive.

What if there is a problem?

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2, Section 4of this leaflet.

What if new information relating to the study 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 medical team will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Also, on receiving new information your medical team might consider it to be in your best interests to withdraw you from the study. If this happens, they will explain the reasons and arrange for your care to continue.

**This completes Part 1 of the Information Sheet.**

**If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**

**Part 2**

1. **Quality of Life study**

If you decide to take part in the STAR-TRAP study, we would like to ask you some questions about the way you feel, both physically and emotionally. These are called quality of life questionnaires. These will help us to understand about how the trial treatments affect you and the impact of any side effects you might experience from your point of view.

You will be asked to fill in some short questionnaires asking about your quality of life and general health. We will ask you to fill in a questionnaire 11 times, following the below schedule:

Group 1

* before you find out which treatment group you are randomised to
* at 10 weeks after randomisation
* at 20 weeks after randomisation
* at 6, 9, 12 months after randomisation
* and every 4 months afterwards, up to 36 months.

Group 2

* before you find out which treatment group you are allocated to
* at the end of your SBRT treatment
* at 12 weeks from the start date of your SBRT treatment
* at 6, 9, 12 months after randomisation
* and every 4 months afterwards, up to 36 months.

You will be given your first questionnaires in clinic. Subsequent questionnaires will be sent to you at your home address. We will check with your GP and/or hospital medical team beforehand that you are well. The questionnaire should take about 20 minutes to complete. The information you provide in the Quality of Life study will be treated in strictest confidence.

A member of your medical team will explain the questionnaire and answer any questions that you have. Some of the questions may seem to be a bit repetitive but these are standard questionnaires and we would ask you to answer them as best you can.

1. **Confidentiality**

Who will have access to my data?

The Institute of Cancer Research is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for at least 5 years after the study has finished.

The Institute of Cancer Research’s lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the United Kingdom General Data Protection Regulation (UK GDPR).

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.

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

[Insert appropriate name for NHS site] will collect information from you and your medical records for this research study in accordance with our instructions.

[Insert appropriate name for NHS site] will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) 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.

Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential. When you join the trial, your full name, hospital number, date of birth, postcode and NHS/CHI number will be passed to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU\*) where the study is being coordinated. You will be given a unique trial ID 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 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 trial ID number to be linked to you.

From time to time, we would like to know how you are getting on. Ideally, we would like to do this for life, and we would like to use national records, which are kept on everyone’s health status to find this out. 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 postcode and NHS number (or Community Health Index (CHI) 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 trial. Please initial the consent form to show that we have your permission to do this.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research, and ethics committee approving the trial, and third parties approved by ICR-CTSU may need to see your hospital or clinic records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

[Insert appropriate name for NHS site] will keep identifiable information about you from this study for at least 5 years after the study has finished.

As you will be receiving radiotherapy in this study a copy of the imaging (such as CT, MRI and PSMA PET-CT\*) used to design your treatment plan will be sent to the Radiotherapy Quality Assurance team. The data is sent electronically by an NHS secure file transfer system and your name will not be included in any of the files sent. We need to send this information to the Quality Assurance team to make sure that radiotherapy given to patients is consistent across the different hospitals taking part. The organisers of this study may use the information and images (including any future imaging) for future research into radiotherapy treatment, but the information stored for future research will not contain your name.

Will information about me be shared with other researchers?

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 in this organisation and in other organisations now or in the future. 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.

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.

Our main privacy policy can be found at <https://www.icr.ac.uk/legal/privacy>. If you have any questions about your rights under the UK GDPR or how we use your information, please contact our Data Protection Officer at dataprotectionofficer@icr.ac.uk.

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 in case of any side effects and/or drug interactions.

1. **General information about STAR-TRAP**

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

You are free to withdraw from the STAR-TRAP study at any time. You do not have to give a reason and your future treatment and care will not be affected. Your medical team 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 keep the information we have already collected from you, and to continue to collect information on your progress that is routinely recorded in your medical records.

What if something goes wrong?

If you have any concerns about any aspects of the trial, you should ask to speak with your medical team, who will do their best to answer your questions. Their contact details can be found in Part 2 Section 4 of this leaflet. If you are still not happy and wish to complain formally about the care and treatment received during the study, you may do so under the standard NHS complaints procedure, which is available to you at your hospital.

Healthcare professionals working on Clinical Trials are covered by NHS Indemnity and if you are harmed by taking part in this study you may have grounds for a legal action but you may have to pay for it. The Sponsor of this trial holds a clinical trials insurance policy.

If you do 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. 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), or equivalent in devolved nations, delete/complete as appropriate] which has been established in every NHS Trust and Primary Care Trust (PCT).

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 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 people with the same type of cancer 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 study.

A written results will be provided to your medical team and they will decide when and how to convey the results to you and/or your next of kin. Results will also be available to the public through peer reviewed publication(s), ICR website trial page and ICR-CTSU’s social media accounts.

Who is organising and funding the research?

STAR-TRAP is being carried out by a network of doctors across the UK. The trial is coordinated by The Institute of Cancer Research and funded by Prostate Cancer UK. Your doctor will not receive any personal payments for including you in this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. The study has been approved by xxx Ethics Committee. The study has also been reviewed and approved by the Health Research Authority (HRA) and by the Committee for Clinical Research (CCR).

What happens now?

Your medical team will be happy to answer any questions. Once you have decided, please let your medical team know. If you choose to join the STAR-TRAP trial, you will be asked to sign the consent form and will be given a copy to keep together with this information sheet.

1. **Useful contact information**

You have the right to ask questions about this study at any time are encouraged to do so. You can call your medical team if you feel that you are developing any side effects or if you have any questions about this study or your participation in this study.

Your hospital study doctor is: xxx

Your hospital study nurse is: xxxx

Contact phone numbers: xxxx

Out of hours number: xxxx

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 clinical trials on the Cancer Research UK patient website [www.cancerhelp.org.uk](http://www.cancerhelp.org.uk) and [www.cancerresearchuk.org/about-cancer/find-a-clinicaltrial](http://www.cancerresearchuk.org/about-cancer/find-a-clinicaltrial).

**Thank you for your interest in our research.**

1. **Glossary**

|  |  |  |
| --- | --- | --- |
| **Abbreviation** | **Full Name** | **What it means** |
| CT scan | Computerised Tomography scan | A CT scans 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 |
| ICR-CTSU | The Institute of Cancer Research Clinical Trials and Statistics Unit | The organisation carrying out the day to day work on the trial |
| N/A | Oligoprogression  | Cancer that has spread beyond its original site and its growth after anti-cancer therapy is confined to a limited area, in 5 or fewer sites |
| 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 tissue very clearly |
| PET-CT scan | Positron Emission Tomography scan | This type of scan can show how body tissues are working, as well as what they look like |
| 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) |