(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 Induced oligo-metastatic disease**

**TRIAL REGISTRATION for imaging**

Version 3.0 12.08.2024



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

We would like to invite you to have a scan that will determine if you are eligible 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.

At this stage you are being approached to have a scan to determine if you would be eligible to take part in STAR-TRAP. If you are eligible, you will be given a separate information sheet and consent form to discuss this part of the trial.

**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. What will I need to do if I take part in the registration part of STAR-TRAP?
5. What treatment might I have if I am eligible to go into the treatment part of STAR-TRAP?
6. What treatment might I have if I am not eligible to go into the treatment part of STAR-TRAP?
7. How to decide whether to have this registration scan?

**Part 2**

1. Confidentiality
2. 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 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. 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, 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.

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

You have been invited to join the registration part of STAR-TRAP and have a scan because:

* You have been diagnosed with prostate cancer which has spread outside of prostate, and
* You have been taking first line hormone treatment for metastatic prostate cancer for at least 6 months and no more than 12 months

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. **What will I need to do if I take part in the registration part of STAR-TRAP?**

If you decide to take part, you will be asked to sign a consent form. After you have signed the consent form, your doctor will arrange a PSMA PET-CT (Prostate-specific membrane antigen ligand positron emission tomography-computed tomography) scan for you. You would not normally be having this scan as standard care outside of the trial. The images will then be reviewed to see how you are responding to the first line hormone treatment you are receiving. If the results of the PSMA PET-CT scan\* show that your cancer is responding well and you now have five or fewer visible metastases, you will be invited to take part in the treatment part of the STAR-TRAP trial. Cancer where the patient has five or fewer metastases is called induced oligometastatic disease.

Depending on the availability at your hospital, you may be asked to take part in an imaging sub-study which will involve having a whole-body MRI (WBMRI) scan. This imaging sub-study is entirely optional, you do not have to consent to this and it will not affect your consent to the registration scan (PSMA PET-CT) for STAR-TRAP. The organisers of this sub-study want to compare the number of metastases shown on PSMA PET-CT compared to WBMRI.

1. **What treatment might I have if I am eligible to go into the treatment part of STAR-TRAP?**

Everyone who agrees and are eligible to join this research study will be included in one of the following two treatment groups:

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

If you’re in this group, you will continue to receive the treatment you have already been receiving for prostate cancer in the same way.

**Group 2: Continue on 1st line therapy with SBRT**

If you’re in this group, you’ll continue to receive the treatment you have already been receiving for prostate cancer. You will also receive SBRT to your prostate and also the areas to which your cancer has spread.

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.

SBRT will be given for five alternate days. 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.

A diagram to explain the design of the study is below.

Patients with metastatic prostate cancer receiving 1st line therapy

Consent for registration part of STAR-TRAP

PSMA PET-CT scan

Patients with induced oligometastatic prostate cancer

Group 1:
Continue on1st line therapy

Group 2:
Continue on 1st line therapy with SBRT

Regular check-ups by your hospital

Regular check-ups by your hospital

1. **What treatment might I have if I am not eligible to go into the treatment part of STAR-TRAP?**

After the PSMA PET-CT scan, if you are not eligible for STAR-TRAP, your hospital clinical team will offer you the standard of care treatment at your hospital.

1. **How to decide whether to have this registration scan?**

Possible benefits of taking part
There is no guarantee that you will benefit directly from taking part in this part of the imaging 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
PSMA PET-CT scans are images that detect prostate cancer and its spread in the body. It uses a radioactive medication called a radiotracer that attaches to a protein on the surface prostate cancer cells.

The whole procedure will take about 2 hours. During the assessment, this radiotracer will be injected into your body through a small tube or needle inserted into a vein in your body, normally in the arm. After this injection, you will be asked to avoid contact with small children and pregnant people for the rest of the day. PET-CT is a series of X-ray pictures to produce detailed images of the inside of your body.

PSMA PET-CT scan is safe for most people. Some people may experience headache, taste changes or fatigue after the scan but these symptoms will go away. Rarely, there may be allergic reaction. As people having PSMA PET-CT will be exposed to radiation, this adds a very small risk (17 in 10,000 people) of potential tissue damage that could cause cancer in the future.

If you consent to have a whole body MRI (WB-MRI) scan too, this will take about 40 minutes. This scan does not involve x-rays and is very safe. While inside the scanner you will hear a loud drilling noise. This is due to the magnetic field being switched on and off at a high frequency. You will be given earplugs and possibly music in the background to make you feel more relaxed.

If you have any questions about this study or your participation in this imaging.

Your hospital study doctor is: xxx

Your hospital study nurse is: xxxx

Contact phone numbers: xxxx

Out of hours number: xxxx

**This completes Part 1 of the Information Sheet. Part 2 containing information about how the data collected as part of registration for imaging will be stored.**

**Part 2**

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, the Medicines and Healthcare products Regulatory Agency (MHRA) 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.

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.

A copy of your PSMA PET-CT and WB-MRI (if you consent to have one) will be sent to the designated central review team for review. The data is sent electronically by a secure file transfer system and encrypted during transit from the hospital acquiring the data to the ICR. Your name will not be included in any of the files sent. The organisers of this study may use the information and images for future research, but the information stored for future research will not contain your name.

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 if you are eligible and consent to take part in the STAR-TRAP study.

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 | Metastasis | Cancer that has spread outside of the prostate |
| 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-Computerised 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) |