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Participant Information Sheet

MISSION–Prostate (Molecular Imaging and Spectroscopy with Stable Isotopes in Oncology and Neurology – Imaging metabolism in the prostate)

We would like to invite you to take part in a clinical research study. Before you decide whether or not to take part, it is important for you to know why the research is being undertaken and what it will involve for you. Please take time to read the following information carefully before making your decision and discuss it with others if you wish. Please ask us if there is anything that is unclear or if you would like more information.

If you are satisfied with the information provided and would like to take part in this study, you will be asked to sign a consent form; the supervising doctor will also sign it. You are still free to change your mind about taking part even after you have signed the consent form.

This information sheet is in two parts:

- Part 1 tells you why the study is being carried out and what will happen if you take part
- Part 2 gives more detailed information about how the study is carried out

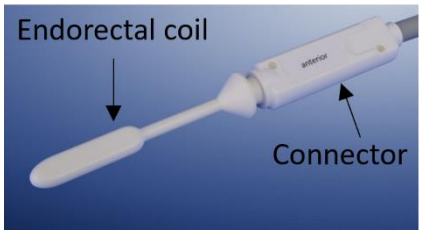
Part 1

What is the purpose of this study?

Medical imaging helps find and track prostate cancer. At Addenbrooke's Hospital, we are trying new ways to use Magnetic Resonance Imaging (MRI) to see changes in tumours. Some tumours use more sugar and have more sodium than normal tissue. We can spot these differences with new imaging methods like Hyperpolarised Carbon MRI, Proton MRI and Sodium MRI. The information we collect could make MRI scans better and help doctors choose the right treatment for each person later on.

An MRI machine makes detailed pictures of your insides using magnets and radio waves, without harmful radiation. We might use special coils (such as endorectal coil) to get better tumour data, and a trained Radiographer will guide you in adjusting or repositioning if needed. An example of a coil is shown in the picture below.

MRI scanner



Who is organising the study?
The study is being conducted by the Department of Radiology, University of Cambridge and Cambridge University Hospitals NHS Foundation Trust.

Why have I been invited?
We are asking patients with prostate cancer who might have a standard of care surgery, biopsy, or other treatment to join our study. Your medical team thinks you might be a good fit based on the criteria we are considering.

Do I have to take part?
No, it is up to you. We will talk about the study and discuss it with you. You will get a copy of the details and time to decide if you want to join. If you do, we ask you to sign a form to show you agree. You can leave the study whenever you want, and it will not change the care you get from your medical team.

What will happen if I take part*?*
If you choose to participate, some extra steps will be taken, in addition to your regular procedures for your prostate cancer. Although these extra steps may not directly benefit you, they could help future prostate cancer patients. Here's what will happen if you decide to join:

1. You will meet a researcher who will explain the study and answer your questions.
2. You may have some simple blood tests and a check-up to make sure you are fit for the study.
3. We will do MRI scans (for example conventional MRI, proton MRI, Hyperpolarised MRI, and sodium scans, not all scans may be performed) to find the cancer. These scans take about an hour and need a small plastic tube in your arm for the necessary blood samples and injections to improve the quality of scans.
   The scans will take place either at Addenbrooke's MRIS Unit or at the Wolfson Brain Imaging Centre which is part of the Department of Clinical Neurosciences of the University of Cambridge and located on Addenbrooke's site.

4. For some scans the research may need to place an endorectal coil into the rectum – a short tube of 2 cm in diameter. These are regularly used in prostate MRI at many hospitals worldwide and are essential for this study. A cover will be put over the coil, and a rectal exam will be done before placing it. Although it might be uncomfortable initially, most people tolerate it well with only a little pressure. An experienced doctor in the research team will place and remove the coil during the scan. In some cases, we may need to re-site or reinsert the coil after a time period has passed. If you were not comfortable with the first placement, you do not have to do the second one. The researcher will ask you before putting in the second coil.

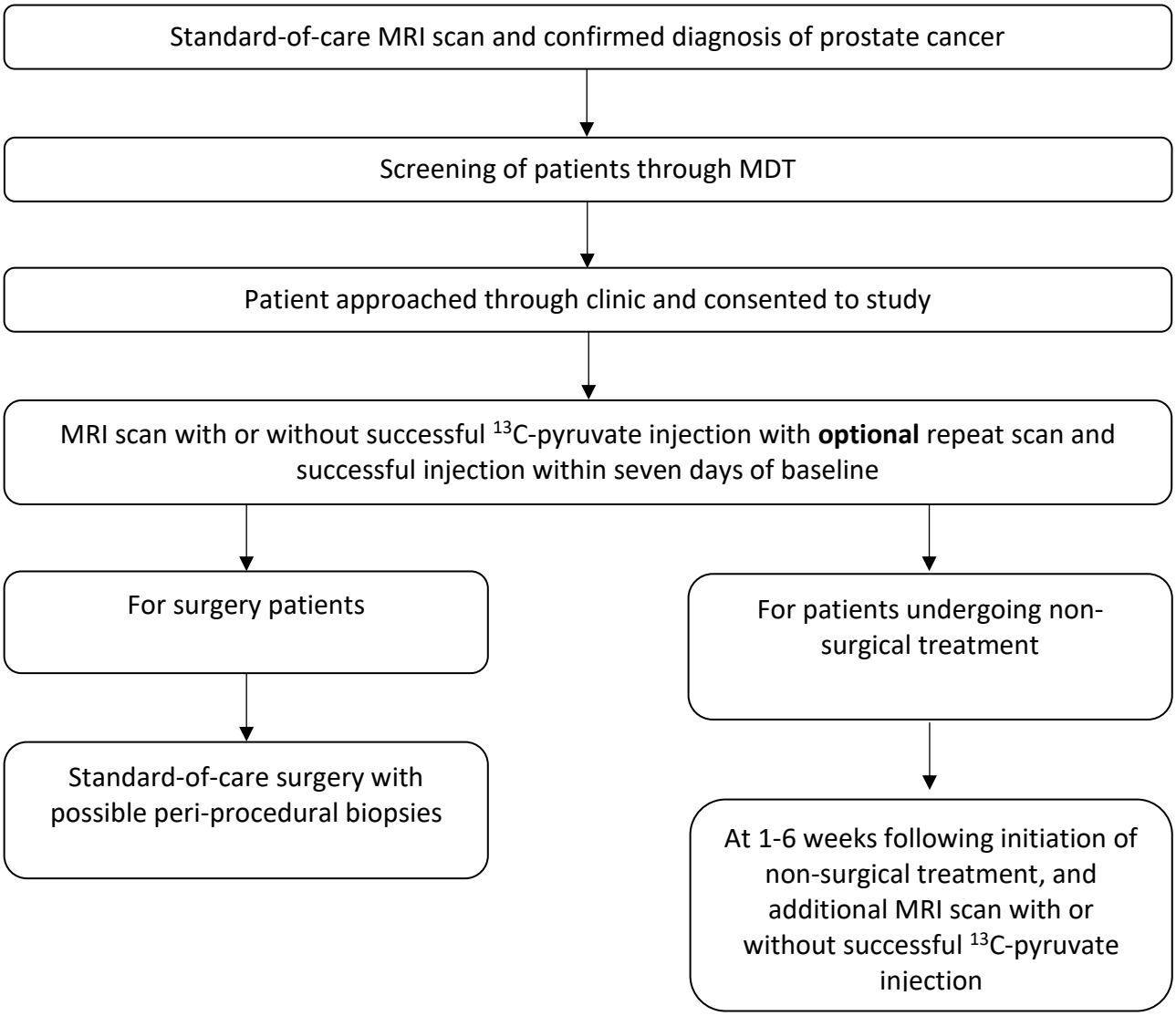
5. We may ask you to repeat the MRI scans within seven days to check for consistency. You can choose not to take part in this part of the study if you prefer.

6. If you are having non-surgical treatments (for example drugs such as hormone therapy), we may ask you to have another MRI scan between one to six weeks after starting the treatment.

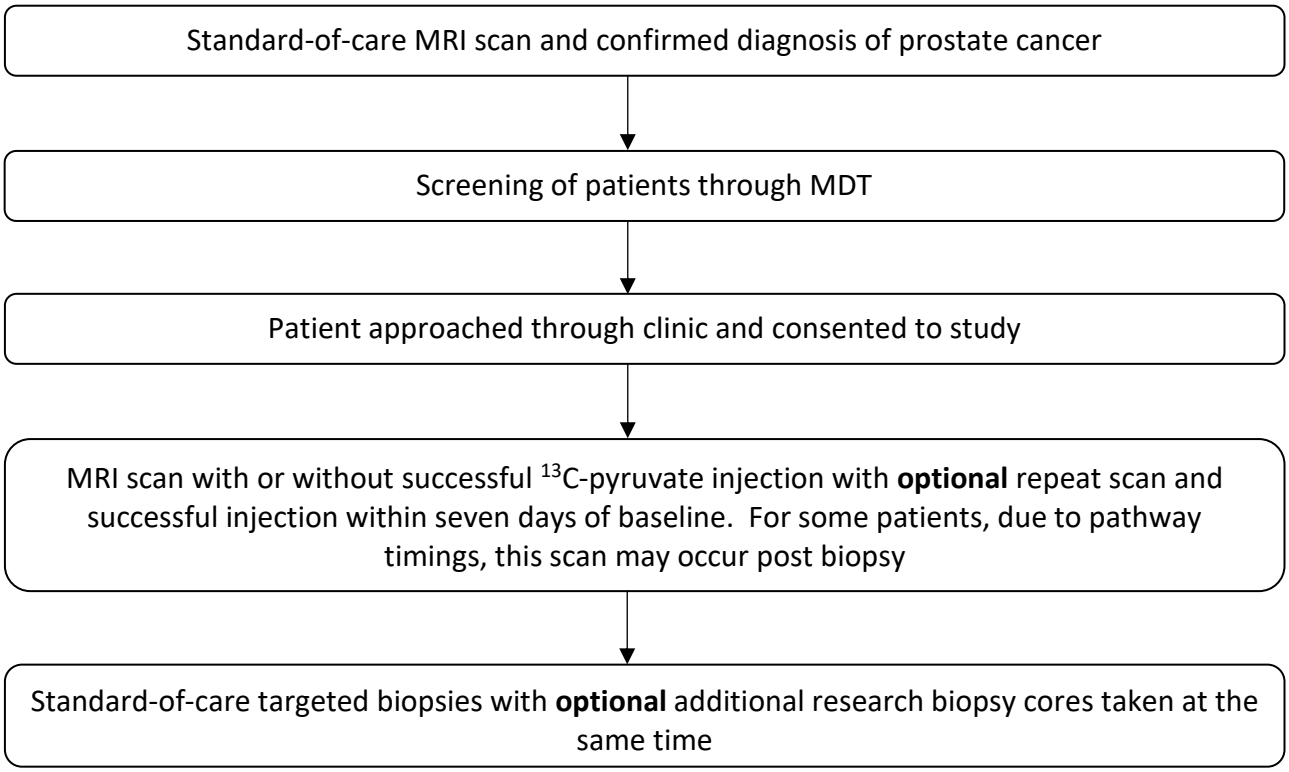
7. After the research scans, your treatment will follow the plan discussed with your medical team, just like it would if you were not in the study. We will ask if you agree to have a "biopsy" sample from the prostate for research purposes. These samples will be analysed for certain changes, including some genetic tests, but not for inherited genetic changes.

Study Flow chart for participants

For surgery and non-surgical treatment patients



For biopsy patients



Contra-indications
You cannot join the study if you have any known barriers to having an MRI scan, like a heart pacemaker, inner ear implant, or specific metal devices.

If you have a known allergy to MRI contrast (Gadolinium) or kidney problems that prevent MRI contrast injection, you won't be able to receive it.

Be sure to let the person discussing the study with you know if this applies to you.

What are the possible benefits of taking part?
Participating in this study is unlikely to directly benefit you. We hope it will benefit patients with prostate cancer in the future. You will not receive any payment for participating in this study. We can cover reasonable costs like travel and parking that you might have because of the study..

What are the possible risks/side effects of taking part?
Time
Participants will spend some time at the hospital for scans and blood samples. We'll try to be flexible with scheduling to make it more convenient for you. If you need transportation, we can consider providing a taxi.

MRI
MRI scans do not use X-rays or radiation and are very safe. A few people (less than 5%) might feel claustrophobic during the scan, but the radiographer will be there to talk to you and can stop the scan if needed. The machine makes noise, but you will get headphones or earplugs. You will also have a 'squeeze-ball' alarm if you feel uncomfortable.

Cannulation
Putting a small tube in your vein might be uncomfortable and rarely leads to infection, which is unlikely in the short time it is in place. Some bruising might occur, but this is a regular and safe procedure. The tube will go in just before the scan and come out right after.

Pyruvate Injection
Even though Hyperpolarised MRI is new, it has shown no major safety problems so far. Pyruvate is a natural substance in the body. Some people in previous studies reported a weird taste in the mouth, headaches, flushing, diarrhoea, or dizziness after the pyruvate injection, but these effects were mild and brief.

Gadolinium Injection
Gadolinium contrast will be used, which is a normal part of a prostate MRI. A small amount of Gadolinium might stay in the brain after the scan, but there is no proof that it causes harm. Gadolinium is crucial for detecting serious diseases and is widely used. In research scans, we will use the lowest necessary dose for a clear image. If you have any questions about your scan, talk to your doctor.

Biopsy (if needed)
Some discomfort and bruising might happen during and after the biopsy, but most people manage well. If you feel more severe discomfort, we can give you pain relief. The most important side effects that you need to be aware of are:

- Bleeding at the biopsy site, which happens to 2 in 100 people (2%).
- Skin infection under the skin, which happens to 1 in 100 people (1%).
- Skin infection where the needle goes through the skin, which happens to 2 in 100 people (2%).

Sometimes, the biopsy might not give a clear result because the tumour is very small or the sample does not

represent the whole tumour. This happens to 5 in 100 people (5%).

If any of these issues happen, we will take the right medical steps, like giving antibiotics for infections or stopping bleeding.

Investigations

There is a small but important chance of finding new health issues during the MRI scans, blood tests, and tissue samples. If we find something, your medical team will discuss it with you and decide if you should keep doing the study or have more tests. Because of this risk, think carefully if you are getting life insurance or a loan, like a mortgage, as your health information might affect your application. If you have private medical insurance, check with the company before joining the study to make sure it won't affect your insurance.

Blood Sampling

During the study, we will take some blood samples. This might cause bruising or discomfort at the needle site, and some people might feel dizzy. To make this better, a trained professional will take the samples while you are sitting or lying down.

Other studies

Joining this study might affect ones you are already in or want to join later. Other studies might also change your participation here. Let us know about any other studies you are in or want to be in, and we will talk about how it might relate to this one. It is important to think about the time and commitments needed for multiple studies at once, and we can discuss this with you if you want. You might also want to talk to your family about it.

What happens at the end of the study?

We will study the images and tissue samples to learn more about prostate cancer and new imaging techniques. We will ask you if it is okay for research staff to look at your medical records, but your identity will be kept private.

What if there is a problem?

If you have any concerns about how you've been treated or any potential harm, you can contact the Patient Advice and Liaison Service (PALS) at your hospital, as explained in Part 2.

Who will have access to the scans and results?

All information and images collected in the study will follow the regular rules for keeping medical information private. The imaging data will be stored at the NHS or University of Cambridge in a way that keeps your identity hidden, and only the study team will see the scans and data. A certified radiologist will review the images.

Will my taking part in the study be kept confidential?

Yes, we will not inform anyone of your participation in the study without your consent, as explained in Part 2.

Will my consultant be informed?

Your consultant will be aware of your participation in the study.

Will my GP be informed?

We will not tell anyone you are in the study unless you say it is okay, but we suggest telling your General Practitioner (GP). If you agree, we might contact your GP for an update on how you are doing 12 months after your last research scan.

If the information in Part 1 has interested you, and you are considering taking part, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to continue with the study?
If you decide you want to stop being in the study, you can do so at any time without having to explain why. This won't change any tests or check-ups you have in the future for your regular healthcare. We'd like to use the data (without your personal details) collected up to when you leave, but we'll need your permission for this.

What if there is a problem?
If you are worried about anything in this study, you can talk to the researchers, and they will try their best to help (check the contact info at the end of this sheet).

If you are still not satisfied and want to make a formal complaint, you can follow the NHS Complaints Procedure.

You can reach the Patient Advice and Liaison Service (PALS) at (01223) 216756 or via email at **cuh.pals@nhs.net** .

Are there compensation arrangements if something goes wrong?
If something goes wrong during the examination and you are harmed, the NHS and professional indemnity insurance will cover it, while study design issues are covered by insurance from the University of Cambridge.

Will my taking part in the study be kept confidential?
All information which will be collected about you during the course of the research will be kept strictly confidential. We may share the images we collect with researchers at other institutions for use in other ethically approved research, but any information which leaves the MRI unit at Addenbrooke's Hospital will be anonymised. In addition, anonymised data will be made available to the Trust Research and Development Department for audit and monitoring purposes. There may be occasions where anonymised versions of the data may be transferred outside the NHS to other research partners for use in other ethically approved research; this may include commercial organisations, and may involve data transfer outside the EEA. This will only be undertaken with the written consent of the participant.

In accordance with NHS guidance, your data will be stored securely for 10 years following the conclusion of the study. Data will then be disposed of securely. All data handling will be in compliance with the General Data Protection Regulation.

How will we use information about you?
We will need to use information from you, your GP and your medical records for this research project.
This information will include your initials, NHS number, name, contact details and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Cambridge University Hospitals NHS Foundation Trust and The University of Cambridge are the sponsor of this research and is responsible for looking after your information. We will share your information related to this

research project with the following types of organisations:

- NHS trusts and healthcare providers involved in your care
- Research collaborators (anonymised data only), this may include commercial companies some of which based outside of the EEA for use in ethically approved research
- Auditors/inspectors appointed by regulatory bodies, if requested
- Academic publishers (anonymised data only)

We will keep all information about you safe and secure by:

- We will keep all information about you safe using secured files or transfers and treating it in the strictest confidence.
- Data will be stored securely on encrypted servers during the course of the study.
- Only authorised researchers involved in the study will have access to view data that can identify you. Study researchers analysing the samples will not be able to identify you, as these samples will have no personal information attached.
- The patient research data will be pseudoanonymised and linked to a unique study number on all study related documentation throughout the course of the trial and data analysis process. Only the direct clinical care team will have access to the personal identifiable data.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Access the necessary skills or facilities to analyse specific data may be located outside the UK,
- involve global teams to improve research quality and findings.

If this happens, we will only share the data that is needed. We will also make sure you can not be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be shared with the following sorts of organisation:

- academic collaborators
- industrial collaborators

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having

appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website:
  https://ico.org.uk/for-organisations/report-a-breach .

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to cuh.gdpr@nhs.net, or

by ringing us on 01223 746438

What will happen to my samples?

Each sample from a participant will get a code to connect it to that person, but the code will keep you anonymous to most people, except the main research team.

Tissue samples from biopsies or surgery will be studied for 15 years and then disposed of, while blood samples will be looked at right away and then thrown out.

A few samples might be sent to companies or charities for testing, possibly even outside the country.

What will happen to the results of the study?

The research findings will be studied for publishing in medical journals and may be shared at national and international scientific meetings while keeping patient identities confidential.

If you would like, we can send you a summary of the study results in writing, but we will not be able to share individual results.

Who is organising and funding the research?
Researchers from the Department of Radiology are organising the study. The University of Cambridge and Cambridge University Hospitals NHS Foundation Trust are funding this research. The project has received additional charitable funding from Prostate Cancer UK, the Evelyn Trust and Cancer Research UK.

Who has reviewed the study?
All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed, and given a favourable opinion, by the Cambridge South Research Ethics Committee.

Contact details for further information

If you have any questions, you can contact the study team during office hours (9am to 5pm).

Please also contact the study team in the event of the following occurring:

- If you suffer an illness or a possible study related injury
- If you feel different in any way
- If you are admitted to hospital for any reason
- If you are seen at a casualty (accident/emergency department) for any reason.

Contact details are given below for the research team who can provide further information regarding the study:

During office hours (9am-5pm): 01223 767926

Team email: cuh.radiologyresearch@nhs.net

If you decide to participate in this study, in the event of an emergency outside of office hours, please contact:

Out of Hours:

On-call Urologist
01223 274224

Failing to contact one of the above numbers, please contact:

A&E department
01223 217118

PALS (Patient Advice and Liaison Service):
01223 216756
Email: cuh.pals@nhs.net

Thank you for considering taking part in this study. If you require any further information, please do not hesitate to contact us, we will be pleased to help you in any way we can. A copy of the consent form will be provided for you.