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PARTICIPANT INFORMATION SHEET

Comparison of diagnostic accuracy of **L**uminal **I**ndex and **M**ulti-parametric MRI for **A**ccelerated de**TE**ction of significant prostate cancer
CLIMATE

Site Principal Investigator: [insert name of PI]

You are being invited to take part in this research study because your doctor advised you to undergo a Magnetic Resonance Imaging scan (MRI) to check for prostate cancer. CLIMATE is a research study looking at a new type of quick MRI scan called Luminal Index MRI (LI-MRI) to see if it is as effective, or perhaps better than, the current standard scan used today. If you choose to participate, you will have a LI-MRI scan in addition to the standard scan. This will mean that you would need to stay for an additional 5-10 minutes for the LI-MRI scan.

Before you decide whether you wish to participate, please take time to read the following information carefully. We would like you to understand why the research is being done and what it would involve for you.

This information sheet describes the study we are running. Our study team will go through the information sheet with you to explain the study and answer any questions you may have. Please ask the study team if there is anything that is not clear; if you would like to receive further information our contact details are also included.

Part 1 tells you the purpose of this study and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the study.

You can take your time to decide whether to take part or not. Please talk to your family, friends or your doctor about the study if you wish, to help you make your decision.

If you would like to take part, you will be asked to sign a consent form to confirm that you agree. You will be given a copy of the signed consent form to keep. Even after you give consent, you can of course change your mind and leave the study at any time without giving a reason and this will not affect the care that you receive.

PART 1

What is the purpose of the study?

We think a new scanning method called Luminal Index MRI (LI-MRI) might be able to be as good as the Multi-Parametric MRI (mpMRI) that is currently used as standard. A LI-MRI scan takes only 5-10 minutes compared to 30-45 minutes needed for an mpMRI scan and it does not require the injection of dye to improve images.

To know this, we need to compare the two types of scan, which we are plan to do by enrolling about 700 people from hospitals in the UK into the CLIMATE study over a 3-year period. If this study confirms that the new scanning method is at least as good as mpMRI, it could make undergoing an MRI faster and more comfortable for patients in the future and reduce the cost of diagnosing prostate cancer.

Most people that enter the study will have had a PSA (Prostate Specific Antigen) blood test with a higher-than-normal reading. Routinely, the next step would be to have a mpMRI scan of the prostate to investigate. The purpose of the MRI is to produce an image that your doctor examines to look for anything of concern that needs to be investigated further. If there is, the doctor would usually take samples of prostate tissue (biopsies) using a needle that would then be examined under a microscope to see if what was seen on the MRI image was cancer or caused by something else.

The usual mpMRI scan takes 30-45 minutes and in most cases involves injecting a special dye into a vein in your arm. Although this is the best type of scan currently available to look for prostate cancer, we know that it is not perfect. Around half of the people that go on to have biopsy after they have something found on mpMRI actually have no cancer found at biopsy, or 'low grade' cancer that does not require treatment.

Additionally, mpMRI images can be distorted if there is air in the bowel next to your prostate at the time of the scan, making it more difficult to spot potential cancer. The injection of a special dye into a vein in your arm improves mpMRI imaging and helps to see things in the prostate that might be cancer, but some parts of the dye can remain in your body for a long period of time and we are not sure about the long-term effects of this.

The new scan we are trying out in this study, is called the Luminal Index MRI (LI-MRI). This scan allows us to look at the microstructure of the prostate using a single 5–10-minute scan. It does not require the injection of dye, and it may be better at identifying prostate cancer than mpMRI.

What will happen to me if I take part in the study?

We will ask you about your medical history to ensure that you can take part in this study. If you can, we will book a date for you to visit the hospital. We will do our best to make sure this appointment is on the same day as other hospital appointments. Both your normal mpMRI scan and your LI-MRI will be booked to happen on the same day. On the visit day, you will be given the opportunity to ask any questions you may have and you will be asked to sign a consent form, to participate in the study.

If you agree to the optional CLIMATE blood sub-study, prior to the scan, up to 30ml of blood (five teaspoons) will be collected. This blood will be used for laboratory work within this study to see if tests can show whether markers in blood can tell us if prostate cancer will grow big and spread quickly.

You will have both the usual mpMRI plus the new LI-MRI in the same scan session. The usual mpMRI scan will last approximately 30-45 minutes, and the LI-MRI scan will not last more than 10 minutes.

The LI-MRI images will then be processed to produce an overall map of microstructures within the prostate that our group of expert doctors will use to produce a report. These doctors are based at different sites in the UK and are working together as part of this study so we use a company that specialises in secure online image sharing (Biotronics 3; https://www.3dnetmedical.com/public/) and the microstructure map will be processed by our commercial medical imaging partner within this project (iCAD, https://www.icadmed.com/), who prepared the code for processing these images online.

The LI-MRI images will then be reported by our specialised doctors in this field (research radiologists) whilst the usual mpMRI will be reviewed in the normal way by the radiologists at your hospital. Once both scans have been reported, a research radiologist will combine both of their findings and let your urologist doctor know if any lesions have been found within your prostate. You will then be contacted by your urologist doctor with your scan results. You may have:

- **A Negative scan** which means there is no suspicion of prostate cancer from both usual mpMRI and new LI-MRI. Therefore, no further action is required.
- **A Positive scan** which means an abnormality has been found within the prostate either on the mpMRI and/or on the new LI-MRI. At this stage your urologist doctor will not know which of the two scans found this abnormality. To find out whether this abnormality is or is not cancer your urologist doctor will likely ask you to undergo a **prostate biopsy.** A biopsy is when small samples of tissue are taken out of the prostate by inserting a needle into it. The samples are then looked at under a microscope to see if cancer is present. Because we are performing our new LI-MRI technique in addition to the usual mpMRI, you may undergo a biopsy that you would not have otherwise had as part of routine care (for example if the mpMRI was negative and the LI-MRI positive; or if the LI-MRI finds more lesions that need to be biopsied than the mpMRI).

  All prostate biopsies taken in the study will be used as part of your usual NHS care, this includes biopsies needed because of the new scan technique. You will be given the option to consent to donating any tissue surplus to NHS requirements for research to improve the detection of prostate cancer and identify which cancers are more likely to grow and spread.

A summary of your hospital visits

Visit 1a: Your consent and screen visit. At this visit you will be asked about your medical history, the research team would have checked whether you are eligible to join the study, you will be consented and enrolled.

Visit 1b: Your baseline data and scan visit. Some demographic data, a list of all the medicines you take and information about how you feel will be collected. You will have your MRI scans and if you consented to giving blood, this will be taken.

Visit 1a and 1b may happen on the same day or on separate days. Visits will as much as possible be aligned with your standard of care visits

Visit 2: Your biopsy visit. You will come to the hospital for your prostate biopsy, information on the medicines you take will be reviewed and you will be asked how you feel.

Visit 3: Your results visit. Your doctor will give you the results of your prostate biopsy, information on the medicines you take will be reviewed and you will be asked how you feel. This visit marks the end of your

involvement in the CLIMATE study; usual medical care will continue as normal. The total time you will spend in the study is approximately 12 weeks.

What are the possible benefits of taking part?

We cannot guarantee that you will receive any direct benefits from this research. However, it is possible that the new technique LI-MRI picks up a cancer that the usual mpMRI scan did not.

You will also be contributing to medical research that may improve prostate cancer diagnosis for patients in the future, which may include family members.

What are the possible disadvantages of taking part?

There are no known additional safety issues associated with taking the new LI-MRI scan compared to the usual mpMRI.

MRI is known as a safe technique that has no harmful risks and is used in routine clinical practice. MRI does not involve any ionizing radiation such as x-rays, so no additional exposure to radiation. However, there are certain precautions that we undertake to ensure that patients having MRI scans can do so safely, for example making sure that you do not have any metal implantable devices in the body. We will ask you a set of routine questions before you can enter the MRI scanner room.

The LI-MRI scan will increase the length of time you spend in a scanner by up to 10 minutes. Some people may feel claustrophobic lying in a small space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a buzzer and can communicate with them through the headphones provided. The exam will be stopped immediately on your request. Symptoms will go away once you are outside the scanner. If you know that you are claustrophobic, you may wish to discuss this with your research doctor beforehand.

You may undergo a biopsy that you would not have otherwise had as part of routine care (for example if the mpMRI was negative and the LI-MRI positive; or if the LI-MRI finds more lesions that need to be biopsied than the mpMRI). Patients do not have many problems after a prostate biopsy. All biopsies are performed by trained urologists or radiologists following their hospital's approved procedures. After a prostate biopsy, you may have some discomfort, and there may be traces of blood in your urine or semen. Both of these get better with time and do not need medical treatment. Some patients have bruising due to the needle used for the blood test, for a short period of time. 1 in 100 patients might need to be admitted to hospital due to complications following a prostate biopsy.

Blood tests can result in pain, discomfort and/or bruising from the needle, although these are relatively uncommon. Taking blood samples is unlikely to cause any other side effects.

Expenses and Payments

You will not be paid for taking part in this study. All study visits will be planned to happen at the same time as your usual care visits to the hospital. If you are not able to have both scans on the same session and you need to attend for a separate visit for the research scan alone, we will be able to cover reasonable travel expenses. You will need to give your research team receipts or provide your mileage if you travel by car.

PART 2

What if relevant new information becomes available?

Sometimes during a study, new information becomes available about the treatment or procedure that is being studied that could affect your decision to continue. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue in the study, you may be asked to sign an updated consent form.

If the study is stopped for any reason, you will be told why, and your study doctor will arrange for your continuing care. If any relevant new information becomes available after you have had all your procedures, it will not affect you as you will no longer be in the study.

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

You are free to withdraw at any time without giving a reason and without your rights or care being affected in any way. If you decide to withdraw then you should inform your doctor of your decision so that appropriate follow up can be arranged.

In the event of loss of capacity during the study, the clinical data and study samples collected with consent would be retained and used in the study. No further data or sample would be collected, or any other research procedures carried out on you.

What if something goes wrong?

If you have concern about any aspect of this study, please contact a member of the study team: [insert local site team's contact details], who will do their best to answer your questions.

If you remain unhappy or wish to complain formally, you can do this through the NHS Complaints Procedure. If you wish to speak with someone who is independent of this research study, or if you have questions about your rights, you can contact the hospital Patient Advice and Liaison Service (PALS) on [insert local site contact details and email address as appropriate].

Every care will be taken during this study. However, in the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of the sponsor's (University College London) or the hospital's negligence, then you may be able to claim compensation. After discussion with your study doctor, please make the claim in writing to Professor Shonit Punwani who is the Chief Investigator for this study and is based at UCL. The Chief Investigator will then pass the claim to the sponsor's insurers, via the sponsor's office. You may need to bear the costs of the legal action initially, and you should consult a lawyer about this.

How will my information be kept confidential?

All information collected about you during the research will be kept strictly confidential and stored in password protected secure data repository facility. Your information will be identified by a unique participant study number known only to the research team at your hospital. Any information about you which leaves the hospital will have all personal identifiable data removed. Information would only be transferred to other researchers after all necessary approvals are in place. There is strict law which safeguard patients' privacy at every stage.

In order to monitor and audit the study we will ask your consent to access your medical records and data collected during the study, where it is relevant to taking part in this research. Only the researchers, study

monitors on behalf of the study sponsor and representatives of regulatory authorities and research ethics committees may have direct access to the study information.

Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data and can be contacted at data-protection@ucl.ac.uk. This 'local' privacy notice sets out the information that applies to this study. Further information on how UCL uses participant information can be found in our 'general' privacy notice. The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices. The lawful basis that will be used to process your personal data are: 'Public task' for personal data and' Research purposes' for special category data. Your personal data will be processed so long as it is required for the research project. We will pseudonymise the personal data you provide and will endeavour to minimise the processing of personal data wherever possible. If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

What will happen to the results of this study and when the study finishes?

The whole study is expected to take 3 years to complete. Shortly after this, we wish to publish the results of the study in a scientific paper, through medical publications and/or websites. Some of the data from this study may be used for the purpose of obtaining a research degree and qualification e.g. a doctoral degree. No participants will be identified in any published results.

Once the results of the study are available, we will publish them on www.ncita.org.uk. If you wish to have a copy of the results, we will provide you a summarised version of the main findings of the study. Please contact us.

After your participation in the study is complete, the usual medical care will continue as normal. You may discuss this with your study doctor at any time.

What will happen to the sample I give?

As part of the main study, your MRI images and other clinical data collected will be retained in a secured research facility in a pseudo-anonymised form for 25 years after the study has been completed. The consent form for the CLIMATE study gives you the option to donate samples for future research. If you have said yes to this on your consent form, whatever blood is not used for the analysis of this study will be donated for future prostate cancer research and may be shared with academic and commercial collaborators both in the UK and outside of the UK. Prostate tissues samples obtained can also be kept for 25 years after the study completes, this tissue can be used to support other ethically approved research in the future, but only if you consented to this. Your prostate tissue will also be stored in pseudo-anonymised digitalised data format. In principle no longer than 25 years from the end of the study before being destroyed.

You also have the option of giving permission to the research team to obtain information about your health status through the NHS Information Centre. In addition, the research team would also ask you to consent to being contacted up to ten years after participating in this study to find out whether participating in this study affected you in any way and also to learn about any changes in your condition relevant to this study.

Who has reviewed the study?

All research in UK hospitals is reviewed by an independent Research Ethics Committee, which is there to protect your safety, rights, and wellbeing. A favourable ethical opinion has been obtained from South Central-Hampshire B Research Ethics Committee and local NHS Research Ethics Committee as required.

This study has also been reviewed by a peer review group and independent experts for the funders and by Patient and Public Involvement (PPI) organisation.

Who is organising and funding this study?

University College London is sponsoring the study. This means that they are legally responsible for the study organisation and for overseeing the work of the researchers. Funding of this research is provided by The Urology Foundation, Cancer Research UK and John Black Charitable Foundation.

Involvement of your General Practitioner (GP)

If you consent to participate, we will write to your GP to inform them of your participation in this study.

Further Information and contact details:

If you would like further information or have any questions about this study, please discuss them with your study doctor or a member of the research team.

CLIMATE study team contact details:

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Principal Investigator at local site
Name:
Address:
Tel: / Email:
Research Team at local site
Point-of-contact (Job title)
Name:
Address:

Tel: / Email:

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

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team (please see contact details above)
- Looking on the UCL website: https://www.ucl.ac.uk/legal-services/privacy
- UCL Data Controller contact: data-protection@ucl.ac.uk

Thank you

Thank you for considering taking part and taking the time to read this information sheet.