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Version: 3.0
Date: 1st July 2020
Protocol Version number and date: V2.0 14May2020
Sponsor reference number: 123874

Study Title: ReIMAGINE Prostate cancer screening – inviting men for a prostate cancer assessment using MRI

This is the Participant Information Sheet for a Heath Research Study called ReIMAGINE Prostate Cancer Screening

We are approaching you to take part in this study because you have been randomly selected from a list of men between the ages of 50 – 75 at the general practitioner (GP) surgery you are currently registered with. Your GP surgery is one of several GP practices collaborating on this screening study.

Before you decide whether or not to take part in this study, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Talk with your GP, family or other people about the study if you wish.

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

If you agree to participate we will ask you to attend University College London Hospital (UCLH) for a single study visit where you will be asked to:

- Provide information on your medical history / status.
- Provide a blood sample so we can measure the amount of prostate specific antigen (PSA) in your blood *(see section 4 for details).*
- Have a Magnetic resonance imaging (MRI) scan. This scan uses strong magnetic fields and radio waves to produce detailed images of the inside of the body. *(20 minute scan as detailed in section 5*)

In total the study visit should last approximately one hour. A letter will be sent to you and your GP with the results of the tests within 3 weeks of your visit. We will also ask for permission to collect some further healthcare data on you from your GP or other healthcare professional.

Please ask questions if there is anything that is not clear or if you would like any more information.

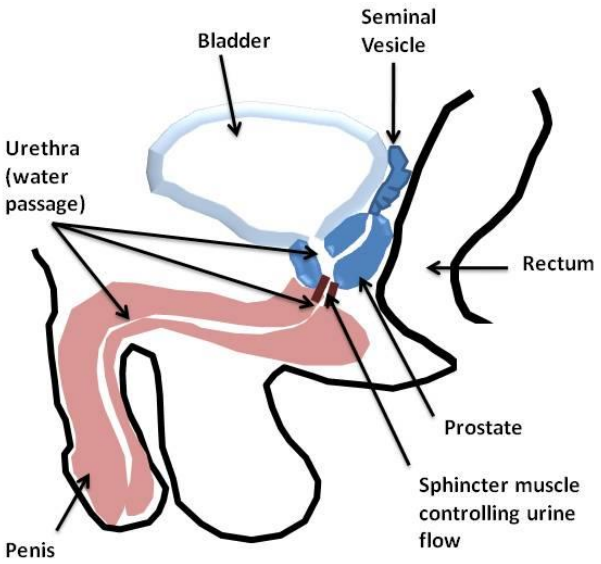
You are free to decide whether or not to take part in this research; your involvement in the study will not affect your medical care.

PART 1

1. What is the prostate?

The prostate is a male gland that sits just below the bladder (See Figure 1). The prostate produces fluid that forms part of the semen and may help nourish sperm. When you empty your bladder, urine flows through a tube (the urethra) that passes through the prostate before reaching the penis.

Figure 1: Location of the prostate



2. What is the purpose of the study?

This is a feasibility/preliminary study to investigate how common abnormal MRI scans (the presence of a lesion in the prostate) are in men over the age of 50, who have been randomly selected for a scan (i.e. a screening population). We will assess the relationship between PSA and the presence of a lesion (if there is one) and how acceptable MRI is to men as a method of screening for prostate cancer.

The National Institute for Health and Care Excellence (NICE) in the UK recommend MRI as one of the first investigations to be performed when a man is referred to hospital with a suspicion of prostate cancer. The recommended MRI normally done on the NHS takes approximately 40 minutes, uses several different methods to obtain images and requires men to be injected with a chemical element (called a contrast agent). The MRI then enables the medical team to recommend whether or not it is necessary to take tissue samples from the prostate (called a biopsy), and if a biopsy is being done what area they should target.

In this study, however, the MRI we are investigating will not require an injection and take about a quarter of the time, and hence a quarter of the cost and burden to both the NHS and patients. Additional research images will however be collected meaning the scan will take up to 20 minutes. The additional images will separately assess whether the data within the images can help predict the presence of abnormalities, without the requirement for interpretation by a doctor who specialises in reporting scans of this nature (a radiologist).

This is the first part of a future study involving a much greater number of patients which will look at whether there might be a benefit from using MRI as a screening method for prostate cancer.

3. Why have we invited you to take part in this study?

Your GP surgery is participating in this research project. If we have sent you an invitation letter this means your name has been randomly selected from a list of men aged between 50 – 75 years of age currently registered at that particular GP surgery.

4. What is a PSA test?

A PSA test is a blood test that measures the amount of prostate specific antigen (PSA) in your blood. PSA is a protein produced by cells within the prostate. It's normal to have a small amount of PSA in your blood, and the amount rises slightly as you get older and your prostate gets bigger. A raised PSA level may suggest you have a problem with your prostate, but not necessarily cancer.

In the UK men over 50 have the right to a PSA test if they have talked through the possible advantages and disadvantages with their GP or practice nurse. However, this is usually only recommended if you have family history of prostate cancer, have symptoms related to your waterworks (e.g. difficulty starting to urinate or emptying your bladder) or are at greater risk of Prostate cancer due to your ethnicity/race (black males are more likely to get prostate cancer at some point in their lives).

In this study we will do a PSA test regardless of whether or not any of these are present. We will assess the PSA value itself, and in relation to the size of the prostate (i.e. its density).

Further information can be found at:
https://prostatecanceruk.org/prostate-information/prostate-tests/psa-test

5. What is an MRI?

Magnetic resonance imaging (MRI) is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body.

You will lie on a flat bed and be moved into the scanner head first. The scan will last no more than 20 minutes, where images will be taken throughout your pelvic area, including your prostate. The scan itself can be noisy so you will be offered earplugs or headphones to wear during the scan. It's important you remain still throughout the scan so high-quality images can be taken. An MRI is a painless and a safe procedure.

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

The invitation letter attached to this information sheet provides details of the study team at UCLH. If you are willing to be involved the first step is to telephone a member of the team (using the

details on this invitation letter or below on pages 8 & 9) who will run you through a checklist to confirm you are eligible to participate.

To be eligible you **must**:

- Be between the age of 50 - 75
- Had no prior prostate cancer diagnosis or treatment.
- Have the capacity to fully consent (men with dementia or similar neurological conditions may not be able to participate).

You **must not**:

- Suffer from claustrophobia.
- Have any metal implantable devices e.g. pacemaker, cardioverter-defibrillator, brain aneurysm clips, hip replacement or other implant.

If you are eligible we will schedule a date for you to visit the hospital. On the day you will be given the opportunity to ask any additional questions you may have and asked to sign the consent form. This will be witnessed and countersigned by a member of the research team.

At this visit we will:

- Collect information on you and your medical history.
  Either directly from you or via your GP or another hospital, with your consent.
- Ask you to provide a blood sample for PSA testing. No other testing will be processed on the donated blood sample.
- Undertake the MRI scan.

Free return taxi travel can be arranged for you by the research staff, or reasonable travel reimbursement is available for this visit on presentation of valid travel receipts e.g. train receipt, parking receipt, personal taxi receipts.

The MRI scan will be reported by two doctors who specialise in this type of reporting (radiologists). The result of the reviews will be made available to your study doctor within 2 weeks. The study doctor will assess the result of this scan alongside the PSA value recorded by the blood test.

A recommendation letter will then be sent to you and your GP detailing the results. This letter will advise whether you are deemed to be ‘at risk’ or ‘not at risk’.

1. **Men not at risk**: No further action is required.
2. **Men at risk:** We will recommend your GP refers you to an NHS institution where you will be advised to have a more detailed MRI as described previously.

It’s important to note that given the ReIMAGINE MRI is performed within a research setting any results will need to be further investigated using existing NHS approved investigations.

For those men advised to have additional tests on the NHS we will ask for your permission to collect reports related to these tests and enter the data from them into our study database. We will also request anonymised images from the detailed MRI you may have. For this you will not be required to attend hospital, we will request this directly from your GP or other healthcare professional e.g. NHS hospital. The study team will contact you or your GP to make sure this happens.

7. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part we will ask you to sign the consent form, and we will give you a copy of the information sheet to keep. You will have at least 24 hours to decide to take part and you are free to withdraw at any time without giving a reason and without affecting the care you receive in the future.

8. What are the alternatives?

If you choose not to take part in the study no further action is required. You care with your GP will in no way be affected.

9. Can I change my mind?

Yes, you can decide not to have any of the procedures at any time.

10. What are the possible disadvantages and unwanted side effects of the study?

The main risks of blood tests are discomfort and bruising at the site where the needle goes in. These complications are usually minor and go away shortly after the tests are done.

MRI is a safe technique that has no harmful side effects with the magnets used in routine clinical practice. There are certain precautions that we undertake to ensure that the individuals having the MRI scan can do so safely, for example making sure that you do not have any metal in the body. We will ask you a set of routine questions before you are allowed to enter the MRI scanner room.

Some people may experience symptoms of claustrophobia from lying in a confined 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.

11. What are the possible benefits to me and for others of me taking part?

We cannot guarantee or promise that you will receive any benefits from this research. However, the information we obtain from this study could, in time, improve the pathway by which prostate cancer is identified. This could introduce future improvements to the care of men with prostate cancer.

12. What data will be collected and use of data?

University College London (UCL) is the sponsor for this study based in the UK. 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. UCL will keep identifiable information about you until the end of the study.

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.

UCL will work in partnership with Philips Electronics Nederland BV to create a data warehouse to collect, store and process pseudonymised data (data with patient details removed) for research purposes specific to the study. The data warehouse, which is hosted and managed securely in the EU will be protected against unauthorised access with established security procedures. Philips or other ReIMAGINE partners will not have access to any identifiable information about you, this will be stored and managed by UCL only.

Anonymised images from your MRI scan(s) will be shared with both academic and industry partners within the ReIMAGINE consortium. Strict procedures are implemented to ensure you cannot be identified.

You can find out more about how we use your information by contacting the ReIMAGINE trial coordinator on situ.reimagine@ucl.ac.uk. Our Data Protection Officer is [insert name here] and you can contact them at data-protection@ucl.ac.uk.

To be acquainted with what data is actually shared with ReIMAGINE partners please consult the privacy notice which can be accessed via our website, [Insert URL here]. If you would prefer a paper copy please contact the study team using the details listed in Part 2, section 9.

Your local NHS Trust will collect information from you and your medical records for this research study in accordance with our instructions.

Your local NHS trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from UCL and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your local NHS trust will pass these details to UCL along with the information collected from you and your medical records. The only people in UCL who will have access to information that identifies you will be people who process or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Your local NHS trust will keep identifiable information about you from this study for 25 years after the study has finished.

This completes Part 1 of the information sheet. If you are considering participating in the study, please continue to read the additional information in Part 2 before making your decision.

PART 2

1. What happens if relevant new information becomes available?

Sometimes, during the course of a research project, new information becomes available about the procedures that are being studied. If you are in the study and this happens, your study doctor will tell you about it and discuss with you whether you want to, or should, continue in the study. If the study is stopped for any other reason, you will be told why and your doctor will arrange for your continuing care. If any relevant new information becomes available after you have had all of your procedures, it will not affect you as you will no longer be in the study.

As described earlier, you can stop taking part in the study at any time without giving a reason and without your rights or care being affected in any way. If you do decide to withdraw then you should inform your doctor of your decision so that appropriate follow up can be arranged.

We expect this study to run for three years.

2. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Their contact details can be found at the end of the document. If you remain unhappy and wish to complain formally, you can do this via the hospital's Patient Advisory Liaison Service (PALS).

Site/Hospital to insert local details

Tel: Site/Hospital to insert local details

http://www.nhs.uk/chq/pages/1082.aspx?CategoryID=68

Every care will be taken in the course of 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 discussing with your research doctor, please make the claim in writing to Professor Caroline Moore, who is the Chief Investigator for the research and based at Division or Surgery and Interventional Science, 3rd Floor, Charles Bell House, 43 – 45 Foley Street, London W1W 7JN. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

3. Will my taking part in this study be kept confidential?

Yes. All personal information we collect is strictly confidential and is covered by the Data Protection Act 2018 and General Data Protection Regulations and any subsequent legislation.

4. Involvement of your General Practitioner (GP)/family doctor

Your GP has provided initial support for this study, by helping us to approach you. If you agree to participate, we will write to him/her to let them know of your decision and we may ask them for medical information about you in the future.

5. What happens when the study stops?

After your participation in the ReIMAGINE Prostate cancer screening study is complete, the routine standard of care will continue as normal. After the study itself is complete, we aim to analyse the results, write them up in medical journals and hopefully change the way we assess Prostate cancer.

6. What will happen to the results of the research study?

The results of this study will be published in scientific or medical journals and may be presented at scientific or medical meetings. Please be assured it will not be possible to identify you in any report or publication. Results from the study will also be published on the study website at, https://www.reimagine-pca.org and the Surgical & Interventional Trials Unit (SITU) website at, www.ucl.ac.uk/surgery/research/surgical-interventional-trials-unit-situ

7. Who is organising and funding the research?

ReIMAGINE is conducted by University College London (UCL) (Chief Investigator(s): Prof Caroline Moore & Prof Mark Emberton) and co-ordinated by the Surgical & Interventional Trials Unit (SITU). The study is funded by the Medical Research Council (UK) and Cancer Research UK. Both of these organisations are charities and are supported only by public donations and invested funds.

8. Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a UK National Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. The study has been reviewed and approved by the London-Stanmore Research Ethics Committee). It has also been reviewed by patient representatives.

The study has also been reviewed by independent international experts for the funders.

9. Contacts for further information

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

Re-IMAGINE study contact details:

Professor Caroline Moore *(via research team)*
Chief Investigator
UCLH NHS Foundation Trust and University College London
Tel: *insert number here*
E-mail: *insert email here*

[Insert team details here]

You can also view the study website at https://www.reimagine-pca.org/ where you can find videos from both patients and researchers discussing the ReIMAGINE consortium and its goals.

If you would like some independent advice, you can contact either of the following:
Macmillan Cancer Support, which is a useful source for further information. They can provide information on prostate health care and clinical trials. You can find this at www.macmillan.org.uk Alternatively, you can call them on 0808 808 0000 (Freephone), and they will send you information leaflets in the post free of charge.

If you would like to know more about how patients help initiate, design, support and monitor research, you will find information on the websites for the National Institute for Health Research (NIHR) (www.crncc.nihr.ac.uk), the National Cancer Research Institute (NCRI) (https://www.ncri.org.uk/patient-and-public-involvement/) or the NHS (www.invo.org.uk)

We will give you a copy of this information and a copy of the signed consent form to keep.

Thank you for taking the time to read the information about the study.