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A feasibility study inviting men for prostate cancer screening using a new short scan, a usual practice scan and a blood test, to identify men at risk of cancer and to measure the acceptability of these methods

Submission date
27/01/2023

Recruitment status
No longer recruiting

Registration date
10/03/2023

Overall study status
Completed

Last Edited
10/09/2024

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The UK government is planning a national prostate cancer screening study, and this is a feasibility study which will provide data to feed into the national study. Researchers have developed a new MRI technique that can allow prostate cancer to be detected using a 5-minute scan as opposed to the current 35–40-minute MRI scan. As this novel scan is simple, cheap and has good performance, it can be delivered within the community setting even using an MRI scanner located in a travelling van. The researchers believe that providing scans in the community setting could allow men, who would otherwise not be scanned, the opportunity to have their cancer detected earlier.

Who can participate?
Men aged between 50 and 75 years old. Additionally, the researchers have looked at using a community strategy to recruit participants as they think this will encourage men from the Black, Asian and Minority Ethnic (BAME) groups to participate as they are at a higher risk of getting prostate cancer besides their age.

What does the study involve?
MRI is the best available test for the detection of prostate cancer, but at present this can only be provided in a hospital setting. Whilst MRI is being used, there are still many men (about 16%) that are being diagnosed with late-stage disease and almost 12,000 men dying per year from prostate cancer in the UK. Clearly, these men are not being scanned early enough in the time-course of their disease for treatment to make a difference. If we can detect their cancer earlier, we think we might be able to reduce deaths from prostate cancer. In this study, leading doctors and scientists from both hospital and GP settings are collaborating to establish the best pathway to deliver a community-based MRI scan. The community-based approach has been selected specially to attract and engage black men to have the opportunity to have their

prostate cancer detected early. The researchers will collect feasibility data and determine how acceptable a short MRI-based prostate cancer screening process is for participants, GPs, urologists and commissioners. They will explore screening invitations sent by GPs and within the community (via leaflets, social media, transport for London, barber shops, and influencers to name a few), hoping to attract more participants at risk due to their ethnicity. This first step will show whether a large national trial of the detection strategy using the new MRI technique is feasible. Should it be feasible, the results of this study will allow the researchers to plan the national trial.

What are the possible benefits and risks of participating?
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 although it can be noisy. Some people may experience symptoms of claustrophobia from lying in a confined space.
The study uses a short 5-minute MRI scan, based in the community, to detect men with prostate cancer, who would otherwise not be scanned. The information gathered on how acceptable a short MRI-based prostate cancer screening process will provide the first step to a larger national trial using this new MRI technique to allow earlier detection of prostate cancer in men (~16%) that present with late-stage metastatic disease.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
April 2021 to December 2025

Who is funding the study?
Cancer Research UK

Who is the main contact?
ncita.limit@ucl.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-screening-for-prostate-cancer-using-a-new-mri-scan-limit-pca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
287898

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54223, IRAS 287898

Study information

Scientific Title
LIMIT P Ca – inviting men for prostate cancer screening using luminal index, bi-parametric and PSA density, to identify men with suspicious lesions and to evaluate acceptability

Acronym
LIMIT P Ca

Study objectives
It is hypothesised that diagnosing these men at an earlier stage will reduce mortality from prostate cancer (PCa). The challenge is to determine the best strategy to enable this to occur. To address this challenge, the researchers have assembled a multi-disciplinary, multi-institutional team with the aim of defining and testing the feasibility of a pathway for early detection of PCa using a novel, disruptive and potentially game-changing MRI technology: luminal index MRI (LI-MRI) - which enables community-based testing through its simplicity, lower cost and high performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2023, East Midlands - Nottingham 1 Research Ethics Committee (Health Research Authority, 2nd Floor, Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8115/+44 (0)207 104 8283; nottingham1.rec@hra.nhs.uk), ref: 22/EM/0225

Study design
Both; Design type: Screening, Imaging, Cross-sectional

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Strategy 1 - Participants recruited via the GP practices. An existing database of participating GP practices will be searched to identify potential participants. The latter will be sent a personalised invitation letter from their GP. Participants who have agreed to participate in the study will be requested to come for a single visit to the participating local hospital study site where they will be required to sign a consent form. Upon consent, a study ID will be assigned to the participant and they will undergo an MRI scan (comprising of LI-MRI sequence and abbreviated bp-MRI sequences) using the study ID. They will have their blood drawn by trained hospital staff and labelled by their study ID (for PSA testing to calculate PSA density, processed by the local hospital lab and then stored for biobanking purposes to explore biomarkers of metastatic prostate cancer risk). Participants will then complete a baseline questionnaire (which will include measures for demographics, lifestyle risk factors such as age, ethnicity, BMI, education status and earning thresholds, first four characters of their postcode and any family history) and psychological status.
Study radiologists will independently report their LI-MRI and abbreviated bp-MRI scan, blinded to either study.

Communication of screen-negative results:
A screen negative result is when all three tests are reported negative. A structured letter reporting the results of the three tests will be communicated to the participant and the participant's GP no more than 3 weeks after the scan.

Communication of screen-positive results:
A screen positive test is when either one of the three tests is positive. GPs will be sent a structured report of the test results and will be advised by the local study urologist to refer the positive screen participants through the NHS referral pathway for suspected prostate cancer for an appointment within two weeks of the results.
Three months after their initial visit, participants will be required to answer an online questionnaire to assess their beliefs about prostate cancer, their perception of prostate cancer risk, anxiety levels after the screening process, any positive screen results and any further clinical assessment they may have been subject to as a result of screening, cancer-specific worry, satisfaction with the tests and quality of life. These questionnaires will be assessed by the study staff.
A subset of participants (up to 30) will be interviewed by the study group for further evaluation based on their experience of the screening process (face-to-face or digitally) within the first 3 months after their initial visit.
Participants will be asked if they consent to be contacted after 3 years to fill in an online follow-up questionnaire to assess oncological outcomes.
The participant exits the study after completion of the online questionnaire.
The MRI images with the study ID but no identifiable data will be stored on a UCL online repository platform. The blood samples labelled as the study ID but no identifiable data will be stored as part of the biobanking process at the Bristow lab at Manchester.

Strategy 2 – Participants recruited via community approaches. Potential participants will be identified using informal means to attract more participants from Black Asian Minority Ethnic

(BAME) groups, such as radio stations, posters on social media platforms, flyers at churches and other places of worship, multicultural agencies, barber shops and other places of work with high BAME backgrounds, banners on local buses or tube, talks, seminars and word of mouth.
Participants who agree to participate will be requested to arrive at a walk-in mobile community van (this will be sub-contracted) where a member of research staff will check eligibility criteria and if they are eligible, they will be ushered to an allocated area for discussion and then requested to sign a consent form.
Once consented, participants will be assigned a study ID. They will then undergo an MRI scan in the mobile scanner unit within the van, participants will not be scanned with any identifiable data but with their study ID. Then, blood will be taken by a trained member of the research staff via two approaches, one for an immediate PSA result (PSA point-of-care test) and the other drawn for laboratory testing to be sent for processing to UCLH within their blood handling and storing protocol. Additional blood will be taken for biobanking of biomarkers for metastatic prostate cancer risk exploration. The participant will then be asked to fill in the baseline questionnaire. The radiologist at the mobile scanner will give them the results of their PSA density, and MRI results after they have completed the questionnaire on the very same visit.

Communication of screen negative results:
A structured letter reporting the results of the three tests will be communicated to the participant no more than 3 weeks after the scan

Communication of screen-positive results:
For participants who have a GP, it will be similar to strategy 1 above. For the small proportion of participants without a GP, the study urologist will refer the men to the required NHS referral pathway at the trust of their choice.
Three months after their initial visit, participants will be required to answer an online questionnaire to assess their beliefs about prostate cancer, their perception of prostate cancer risk, anxiety levels after the screening process, any positive screen results and any further clinical assessment they may have been subject to as a result of screening, cancer-specific worry, satisfaction with the tests and quality of life.
A subset of participants (up to 30) will be interviewed for further evaluation based on their experience of the screening process (face-to-face or digitally).
Participants will be asked if they consent to be contacted after 3 years to fill in an online follow-up questionnaire to assess oncological outcomes.
The participant exits the study after completion of the online questionnaire.

The MRI images with the study ID but no identifiable data will be stored on a UCL online repository platform. The blood samples labelled as the study ID but no identifiable data will be stored as part of the biobanking process in the Bristow lab at Manchester.

Intervention Type
Other

Primary outcome(s)
The prevalence of men with a test result (LI-MRI, bpMRI or PSA density) requiring referral for suspicion of prostate cancer at 3 years. This is equivalent to the recall rate for screening. Test result that triggers referral is defined in the analysis as
1. For LI-MRI the presence of a suspicious lesion in LI-MRI reporting
2. For bp-MRI the presence of a suspicious lesion in bp-MRI reporting
3. For PSA density this is a test result of 0.12 ng/ml or more
All are calculated as part of the study analysis when all data is collected

Key secondary outcome(s))
All are calculated as part of the study analysis when all data is collected:
1. The uptake of screening invitation and MRI-based screening tests:
1.1. The proportion of men attending screening who complete one or more MRI tests for each individual strategy
1.2. Descriptive analysis of recruitment
1.2.1. In each strategy (GP recruitment vs community recruitment)
1.2.2. Across each participating site (London, Cambridge and Manchester)
1.2.3. By ethnicity
1.2.4. Comparison of percentage recruitment by ethnic groups for GP vs community recruitment
1.3. Time to completion of recruitment pathway in each strategy
2. The acceptability of screening procedures:
2.1. Quantitative assessment across all participants, define participant acceptability
2.2. In-depth qualitative assessment of acceptability in a randomly selected sub-sample of participants, GPs, urologists, radiographers and commissioners aiming to access a broader range of views of the process and confirm GP's acceptability of communication of results and management plan and urologists' referral pathway (within trial study)
3. The net benefit of screening with each test based on the number of men identified with clinically significant cancer, taking into account the number of men undergoing biopsy who are found not to have significant cancer
4. The prevalence of LI-MRI-defined suspicious lesions with subsequent confirmed presence of clinically significant cancer by recruitment
4.1. In each strategy (GP recruitment vs community recruitment)
4.2. Across each participating site (London, Cambridge and Manchester)
4.3. By ethnicity
5. For LI-MR, abbreviated bp-MRI and PSA density, individual assessment of:
5.1. Diagnostic yield of clinically significant cancer, based on the percentage of significant cancers according to referral and uptake of urologist appointment and further testing (mpMRI, biopsy)
5.2. Reading time (LI-MRI and bp-MRI only)

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Men aged 50-75 years
2. No prior prostate cancer diagnosis/treatment
3. Willing and able to provide a written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

50 years

Upper age limit
75 years

Sex
Male

Key exclusion criteria
1. Previous diagnosis of prostate cancer
2. Contraindication to MRI scan (contraindication for MRI scanning [as assessed by the MRI safety questionnaire of the PET/MRI department] which includes but is not limited to: intracranial aneurysm clips or other metallic objects; intra-orbital metal fragments that have not been removed; pacemakers or other implanted cardiac rhythm management devices and non-MRI compatible heart valves; inner ear implants; and history of claustrophobia)
3. Men who require assisted living e.g. care home living
4. Lacks the capacity to consent

Date of first enrolment
31/07/2024

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Uclh
250 Euston Road
London
United Kingdom
NW1 2PQ

Study participating centre
The Christie
550 Wilmslow Road
Withington
Manchester
United Kingdom
M20 4BX

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: EICEDAAP\100008

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (https://ncita.org.uk/limit-study). Post-primary paper being

submitted, data can be requested. This request will go through a panel of the Trial Steering Committee and the Trial Management Group, who will grant or deny access. There will be phased control access to the data and at an appropriate time, the data will be made public. Patients have the option to consent to their data being stored in a non-public repository. All data information obtained as a result of the study will be regarded as confidential. Publication of the results will not include identifiable personal data. There are no ethical or legal restrictions in place. The sponsor will retain ownership of all data arising from the study.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes