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A clinical trial to find out if using the findings from PSMA PET scans to escalate treatment can improve cancer control in patients with high-risk prostate cancer

Submission date
08/01/2026

Recruitment status
Recruiting

Registration date
27/01/2026

Overall study status
Ongoing

Last Edited
28/01/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The study is looking at whether we can improve outcomes for patients with newly-diagnosed high-risk prostate cancer

Who can participate?
Adults over the age of 18 who have been newly diagnosed with high-risk prostate cancer

What does the study involve?
Patients will undergo three imaging tests (CT, bone scan and PSMA PET-CT). After they have completed all the imaging tests they will be randomly placed in 1 of 2 groups. The participant will have an equal chance of being in group 1 or group 2. If they are in Group 1, their care will follow standard NHS practice. Their clinical team will see the results of only the CT and bone scan and any normal treatment that is routinely given in the NHS will continue. If they are in Group 2, the clinical team will see only the PSMA PET-CT results. Their treatment will be directed by the PSMA PET-CT scan results. If the participant joins the study, they will not be able to see the results of all the imaging tests, even if they withdraw, until 51 months after signing the consent form. This is to ensure that the treatment in each group is only guided by the imaging tests that can be seen for that group. Otherwise, the results of the study will not be good enough to make any decisions on whether PSMA PET-CT should be used in future.

What are the possible benefits and risks of participating?
There may not be any personal benefits for the participant, however patients who are randomised to have the PSMA PET-CT might have metastases detected earlier, but we do not know if the change in the treatment that this might lead to will change cancer control. This study is needed because we are not sure which approach is better. We cannot promise the study will help the participant directly, but the information we get might help improve the treatment of patients with prostate cancer in the future.
If a patient take part in this study they will have PSMA PET-CT scans, CT scans and bone scans.

Some of these will be extra to those that the participant would have if they did not take part. These procedures use ionising radiation to form images of their body to provide their doctor with clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to the participant as a consequence of taking part in this study are about 0.6%. These scans also require an injection into the participant vein. This can sometimes lead to mild bruising of the skin.
As with any tests for cancer there can be false negatives and false positives. No medical test is completely accurate. We have evidence that PSMA PET-CT detects more metastases than CT and bone scans. However, they may not pick up all metastases. At the same time, the tests can sometimes be positive in patients who do not have metastases. These patients will be offered a different set of treatments based on this scan result.

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

When is the study starting and how long is it expected to run for?
February 2026 to November 2031

Who is funding the study?
Prostate Cancer UK

Who is the main contact?
AVIDITY@imperial.ac.uk, and/or Trial Manager j.sukumar@imperial.ac.uk

Contact information

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Additional identifiers

Central Portfolio Management System (CPMS)
72253

Grant Code
MA-TIA23-006

Integrated Research Application System (IRAS)
364205

Study information

Scientific Title
A multicentre randomised controlled trial to assess the clinical effectiveness and cost-effectiveness of PSMA PET-CT imaging to stage newly diagnosed high risk prostate cancer compared to standard of care CT and bone scan imaging

Acronym
IP10 - AVIDITY

Study objectives
Primary Objective:
To evaluate the clinical effectiveness in using PSMA PET-CT compared to CT and bone-scan to direct treatment of high-risk prostate cancer using metastases-progression free survival (MPFS) up to 48 months after randomisation of each patient.

Secondary Objectives:
Safety:
To evaluate adverse events and complications of tests and treatments in the randomised group and in each cancer stage subgroup.

Cancer (Oncological):
1. To evaluate how the primary objective varies across different cancer staging subgroup in each randomised group.
2. To see how long it takes (prognostic value) for patients with no distant cancer deposits (miM0) reported on PSMA PET-CT to develop cancer deposits on conventional imaging up to 48 months.

Imaging (radiological):
1. To report the number of equivocal scan results using PSMA PET-CT with that of conventional imaging
2. To assess the agreement between radiologists of different cancer stages (miN1, miN2, miM1) diagnosed on PSMA PET-CT by comparing blinded central imaging radiologist to the local trial site radiologist.
3. To evaluate whether PSMA PET-CT-derived parameters can help predict how long it takes to reach the primary endpoint (MPFS).'

Patient report outcome measures (PROMS):
1. To assess patient-reported outcome measures (PROMS) on urinary, sexual and bowel function using validated questionnaires in each randomised group and in each stage subgroup.
2. To assess overall health-related quality of life using validated questionnaires in each randomised group and in each stage subgroup.

Health economic:
1. To evaluate the cost-effectiveness measured using the incremental cost per quality-adjusted life years (QALYs) gained in using PSMA PET-CT compared to conventional imaging (CT and bone scan) to direct treatment of high-risk prostate cancer using MPFS in each randomised group up to 48 months.

Internal Pilot (n=37) Primary Objective:
1. To evaluate the feasibility of the primary trial design.

Internal Pilot Secondary Objectives:
1. To report the adverse events during the pilot phase.
2. To report the number of patients with no or low expression of PSMA in the primary prostate tumour.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/12/2025, Wales REC 5 (Health and Care Research Wales, Floor 4, Crown Building, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC5@wales.nhs.uk), ref: 25/WA/0367

Study design
Randomized; Interventional; Design type: Process of Care, Other

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The participant will undergo three imaging tests: CT, bone scan, and PSMA PET-CT. After completing all imaging tests, they will be randomly allocated to one of two groups. The participant will have an equal chance of being placed in either group.

Group 1 will follow current standard NHS practice. The clinical team will see the results of the CT and bone scan only, and any normal treatment given within the NHS will continue.

In Group 2, the clinical team will see only the PSMA PET-CT results. The participant's treatment will be directed by the PSMA PET-CT scan findings.

The participant's case will always be discussed at an NHS prostate cancer multidisciplinary team (MDT) meeting, and they will be offered appropriate treatment options. If more than one treatment is relevant, the participant will be able to choose with their clinician, as per normal NHS practice.

If allocated to Group 2 and found to have between one and five metastases, the participant may also undergo targeted radiotherapy, known as SABR, to those areas. This treatment would only be offered in the new treatment group and is not currently approved for use in standard care for patients newly diagnosed with metastatic prostate cancer.

During the initial screening visit (Visit 1), the participant will have completed the following: informed consent form, inclusion and exclusion criteria assessment, demography, partial postcode collection, medical history, clinical assessment such as vital signs, PROMS questionnaires, and randomisation. PSA test results, which are performed as part of routine standard care, will also be recorded if available.

Data collection at each time point may be carried out via postal, electronic, telephone, or face-to-face communication. All clinical information, follow-up data, adverse events, questionnaires, blood test results, and results of other investigations performed elsewhere as part of routine GP or hospital care may be collected.

Unless the participant specifically requests face-to-face visits, attendance will only be required for hospital visits defined by the local hospital's follow-up protocol (standard of care). Physical examination is the only element that cannot be conducted via postal, electronic, or telephone communication.

Within one month of Visit 1, the participant will attend for imaging tests, including CT, bone scan, and PSMA PET-CT. Visits at six months and twelve months will involve assessment of PSA results, performed as part of routine standard care, and completion of additional questionnaires. During this period, participants will also undergo their treatment phase, which may include surgery or radiotherapy, and potentially SABR for those in Group 2.

Visit 5 at 24 months, Visit 6 at 36 months, and Visit 7 at 48 months will consist of post-treatment follow-up. At each of these visits, PSA results will be assessed and PROMS questionnaires completed. CT scans of the chest, abdomen, and pelvis will be performed at two years (Visit 5) and four years (Visit 7).

Follow-up visits for treatment administration and clinical review will occur according to the local hospital's follow-up protocols. For participants undergoing surgery or radiotherapy, treatment dates will be scheduled in line with local hospital waiting lists.

This random-disclosure controlled trial will recruit 476 patients and has an embedded pilot (n=37). A contingency plan has been made for a traditional two-arm randomised controlled trial (n=1100) should recruitment to the primary design be deemed not feasible on interim analysis.

Intervention Type
Other

Primary outcome(s)
1. Rate of no new metastases or no progression of existing metastases or death from any cause measured using CT and bone scan at 48 months

Key secondary outcome(s))
1. Number of adverse events in both trial arms measured using Clavien-Dindo grade ≥ 3 at 12 and 48 months

2. Clinical TNM staging measured using CT and bone scan at 48 months

3. Rate ratio between trial arms of metastases measured using CT and bone scan at 48 months

4. Occurrence of equivocal results of baseline imaging measured using CT, bone scan, and PSMA PET-CT at baseline

5. Agreement of PSMA PET-CT reporting measured using PSMA PET-CT at baseline

6. PSA, Gleason Grade Group, clinical stage, number of metastases, and PET factors measured using path results, imaging reports, and blood tests at 0–48 months

7. Quality of life measured using EQ-5D-5L, EPIC 26, IPSS, and IIEF-5 at baseline, 12, 24, and 48 months

8. QALYs measured using EQ-5D-5L scores and NHS and PSS costs at 48 months

Completion date
30/11/2031

Eligibility

Key inclusion criteria
1. Histologically confirmed prostate adenocarcinoma
2. NCCN high-risk cancer defined as any of:
2.1. Stage >/= cT3 OR
2.2. ISUP Grade Group 4 and 5 (or Gleason score 8, 9 or 10) OR
2.3. PSA >20 ng/ml
3. M0 on standard prostate MRI
4. Patient suitable for standard local therapy (surgery or radiotherapy with curative intent) to the prostate as deemed by clinical team
5. Age >= 18 years

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
Male

Total final enrolment
0

Key exclusion criteria
1. M1 on standard prostate MRI
2. Unable to undergo prostate/pelvic MRI, CT-TAP, radio-isotope bone-scan, or PSMA PET-CT
3. Unable to receive iodinated contrast (eg contrast allergy, significant renal impairment)
4. Previous imaging, other than screening pelvic MRI, for the primary purpose of staging pelvic nodal or distant metastatic disease of prostate cancer within 8 weeks prior to randomisation
5. Previous local or systemic (including any ADT/ARTA/docetaxel chemotherapy) treatment of prostate cancer (5-alpha reductase inhibitors are permitted)
6. Other malignancies diagnosed in previous 2 years (except non-melanoma skin cancer)
7. Variant/non-adenocarcinoma histology (e.g., spindle cell, neuroendocrine)
8. Already commenced hormone treatment

Date of first enrolment
02/02/2026

Date of final enrolment
06/02/2028

Locations

Countries of recruitment
United Kingdom

Study participating centre
Charing Cross Hospital
Department of Urology
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Prostate Cancer UK

Alternative Name(s)
Prostate Cancer, Prostate Action, ProstateUK, prostatecanceruk

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 trial data will be stored on OpenClinica database. There will be no weblink for or public availability of the database during the study to ensure credibility of the data during the collection phase. On conclusion of the trial (aiming 2031), data will be published in academic journals and full, anonymised data will be accessible by requesting this from the trial team. Any data extracted from the secure database will be anonymised. Formal consent will be taken from patients to store their data for 10 years, with optional consent for storage up to 20 years from signing the informed consent form. Ethical approval has been given which included endorsement of the data management plan. There are no legal restrictions.

IPD sharing plan summary
Available on request, Stored in non-publicly available repository