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Evaluation of Prostate-Specific Membrane Antigen (68Ga) PET/CT as a tool to guide treatment choice in patients with high risk prostate cancer

Submission date
06/09/2017

Recruitment status
No longer recruiting

Registration date
13/11/2017

Overall study status
Completed

Last Edited
12/10/2023

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-a-psma-scan-for-prostate-cancer-panorama (added 08/12/2021)

Background and study aims
We want to study the levels of a molecule called PSMA (Prostate Specific Membrane Antigen) in the prostate cancer within the prostate gland and in the lymph nodes that might be affected by cancer. This is particularly important in patients who have been diagnosed with prostate cancer and are planning to receive an operation to remove the prostate and lymph nodes in the pelvis.

Most prostate cancers grow very slowly but in some men, prostate cancer can grow more quickly. In some cases, prostate cancer may spread to other parts of the body.

A common place for prostate cancer to spread to is the lymph nodes (sometimes called lymph glands). Lymph nodes are part of the lymphatic system. They are found throughout the body and some of the lymph nodes are in the pelvic area, near the prostate. The process of determining how much cancer is in the body and where it is located is known as staging. At present it is very difficult to find out if the prostate cancer has spread to the lymph glands in the pelvis. It is important to know this as it will help us to plan treatment better.

In some cases, it may be recommended that the pelvic lymph nodes should be removed. However, examination of the lymph nodes under the microscope after surgery may reveal no evidence of cancer. In these patients, surgery to remove the lymph nodes could be avoided if we have better (more reliable) tests.

We want to find out whether the PSMA molecule linked to a radioactive tracer (68Ga-HBED-PSMA-11) is effective at finding cancer cells in lymph glands. Patients will have already had a PET /CT scan which combines 2 scans, a PET scan using the 68Ga-HBED-PSMA-11 tracer, and a CT scan. At the moment, PSMA PET/CT scans are performed to check that the rest of the body

outside the pelvis is free from prostate cancer. It is unclear whether a PSMA scan can also help doctors to determine if the lymph nodes in the pelvis are at risk of being affected by cancer.

This study will combine imaging information from scans with pathology information from lymph glands removed at the time of surgery. By combining this information, we will be able to determine whether the absence of PSMA in lymph glands on the scan reliably indicates the absence of cancer in the tissue. This will help us to determine whether or not 68Ga-HBED-PSMA-11 PET/CT is able to show if cancer has spread to the lymph nodes, and avoid unnecessary lymph node removal.

Who can participate?
Male patients aged 18 and over that have been diagnosed with prostate cancer are eligible to participate in this study. Patients must have had a PSMA PET/CT scan and have opted for surgery to remove the prostate gland and the lymph nodes around/near the prostate within the pelvis (radical prostatectomy and lymph node dissection).

What does the study involve?
Participants who decide to take part in the PANORAMA study will be given an information sheet to keep and will be asked to give consent, either by signing the consent form in the clinic or verbally giving consent on the telephone.

Participants who are eligible to take part in the trial will be contacted. The hospital will carry out a meeting with each participant, either in the clinic or by telephone to ensure that they are suitable for the study based on their medical history and the PSMA PET/CT scan received as part of routine clinical care.

Participants will be expected to attend a follow-up clinic visit 6 weeks after surgery. At this clinic, in addition to routine postoperative assessments, research staff will monitor their progress closely. If participants are followed up remotely by phone, then the research team will contact them in addition to the clinical team.

What are the possible benefits and risks of participating?
By taking part in this study, participants will not be required to do anything additional to the planned elective surgery. The study team will be able to review all the information remotely and carry out the necessary evaluation. There are no specific additional risks to participants as there are no more tests or hospital visits than routine practice.

There are no benefits to taking part in the study but it is hoped that the results from this and future studies will be used to identify patients whose cancer has not spread to the lymph nodes, thus avoiding the need for surgery to remove the lymph nodes in these patients. It will teach us more about tailoring treatment to the needs of individual patients, in terms of treatment to the pelvic lymph node areas. We hope that such information will enable us to improve the standard of treatment to help other patients in the future.

Where is the study run from?
Scottish Clinical Trials Research Unit (UK)

When is the study starting and how long is it expected to run for?
From January 2017 to April 2022

Who is funding the study?
Cancer Research UK (UK)

Who is the main contact?
Kathleen Riddle (Principal Trial Manager) and Kirsten Murray (Senior Trial Coordinator)
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
PANORAMA version 3.0, 23rd November 2020

Study information

Scientific Title
Analysis of PSMA expressioN in prOstate cancer and its Relationship with the presence of nodAl MetastAses

Acronym
PANORAMA

Study objectives
Current hypothesis as of 27/08/2019:
The aim of this study is to evaluate if the PSMA PET/CT scan will identify whether or not the cancer has spread to the lymph nodes. This will mean that for future patients, whose cancer shows no evidence of spread to the lymph nodes, can have less extensive surgery. They will not have to have their pelvic lymph nodes removed at the time of surgery.

Previous hypothesis:
The aim of this study is to evaluate if the PSMA PET/CT scan will identify whether or not the cancer has spread to the lymph nodes. This will mean that for future patients, whose cancer without evidence of having spread to the lymph nodes, can have less extensive surgery. They will not have to have their pelvic lymph nodes removed at the time of surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/11/2018 West of Scotland REC 1 (West of Scotland Research Ethics Service, Ward 11
Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE; +44(0)141-314-0212; WosRec1@ggc.scot.nhs.uk), ref: 17/WS/0201
2. Amendment approved 03/06/2019
3. Amendment approved 08/12/2020 (updated 09/09/2021)

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Interventions
Current interventions as of 09/09/2021:
PSMA Imaging is a feasibility study looking at patients who have high-risk prostate cancer (in the absence of clinical evidence for distant metastasis) opting for surgical intervention with radical prostatectomy and extended pelvic lymphadenectomy. The patient will have had a PSMA PET/CT scan as part of standard of care imaging. 60 patients will be recruited over a 6 month period from 4 centres within the United Kingdom.

Patients who have given informed consent and who have met all eligibility criteria will be enrolled in the trial.

Participants attend a screening visit. Informed consent, medical history, a physical examination, and a PSA blood test are taken at this visit.

Participants attend a six-week follow-up visit. A physical examination and the same blood test will be done again six weeks after their surgery. The surgeon will also discuss the outcome of the surgery that they have had and will discuss any future management of care.

Previous interventions:
PSMA Imaging is a feasibility study looking at patients who have high risk prostate cancer (in the absence of clinical evidence for distant metastasis) opting for surgical intervention with radical prostatectomy and extended pelvic lymphadenectomy. 60 patients will be recruited over a 6 month period from 4 centres within the United Kingdom.
Patients who have signed informed consent and who have met all eligibility criteria will be enrolled into the trial.
Once enrolled all patients will have a PSMA PET/CT scan prior to (and within 2 weeks of) surgery, in addition to standard of care imaging as per local clinical practice.

Participants attend a screening visit. Informed consent, medical history, a physical examination and a number of blood tests are taken at this visit.

Participants receive only one extra scan (out with any other standard care scans required) which is called a (Ga68) PSMA PET/CT scan. Participants then have their elective surgery as schedules.

Participants attend a six week follow up visit. A physical examination and the same blood tests will be done again six weeks after their surgery. The surgeon will also discuss the outcome of the surgery that they have had and will discuss any future management of care.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 24/06/2019:
1. To establish whether prostate tumours with high PSMA expression have enhanced risk of pelvic nodal metastasis.
2. To establish best practice and optimise protocols for multi-centre application of PSMA PET/CT imaging.

Previous primary outcome measure:
1. SUVmax is measured for each lesion using the 68Ga-PSMA PET/CT within 2 weeks of a scheduled RP and ePLND this will be used along with independent nuclear medicine physicians to determine the sensitivity, specificity, positive predictive and negative predictive values of 68Ga-THP-PSMA imaging in detecting pelvic nodal metastasis
2. The establishment of best practice will be measured by the production of protocols for multi-centre application of PSMA PET/CT imaging

Secondary outcome measures
Current secondary outcome measures as of 24/06/2019:
1. To evaluate the feasibility of a future large scale randomised controlled trial (RCT), and develop quality assurance measures across the study team/network.
2. To develop a platform to carry out RCT to study the usefulness of novel imaging/biomarkers for evidence-based treatment decisions in patients at risk of pelvic nodal prostate cancer.

Previous secondary outcome measures:
1. The use of novel 68Ga-THP-PSMA radiopharmaceutical is measured using the successful assessment of 60 patients through to the end of study and inclusion in the study analysis
2. Feasibility of a future large scale randomised controlled trial is measured using recruitment of 60 patients into the study within the proposed timelines and by the development of quality assurance measures across the study team/network
3. The development of a platform to carry out RCT to study the usefulness of novel imaging /biomarkers for evidence-based treatment decisions in patients at risk of pelvic nodal prostate cancer is measured by the future development of RCT's in this area.

Overall study start date
01/01/2017

Completion date
30/04/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 09/09/2021:
1. High-risk prostate cancer with no detectable distant metastasis using standard of care imaging (MRI prostate/pelvis, isotope bone scan, CT, non-PSMA PET/CT) undergoing radical prostatectomy and pelvic lymph node dissection
2. 68Ga-PSMA PET/CT done as part of the staging investigation
3. Histologically proven prostate cancer
4. No prior prostate cancer treatment including androgen deprivation therapy
5. Male aged ≥18 years
6. Considered suitable candidate for radical surgery for prostate cancer
7. Willingness to comply with scheduled visits

Previous participant inclusion criteria:
1. High risk prostate cancer with no detectable metastasis using standard of care imaging (MRI prostate/pelvis, isotope bone scan, CT, non-PSMA PET/CT) undergoing radical prostatectomy and pelvic lymph node dissection
2. Histologically proven prostate cancer
3. No prior prostate cancer treatment including androgen deprivation therapy
4. Male aged 18 or over
5. Considered suitable candidate for radical surgery for prostate cancer
6. Adequate hepatic, bone marrow, coagulation and renal function as defined by the following criteria:
6.1. Haemoglobin > 9.0 g/dL
6.2. Platelets > 100 x 109 L
6.3. Creatinine <2 x ULN
6.4. Hepatic function: total bilirubin ≤ 2 x ULN; ALT and AST ≤ 3 x ULN
6.5. Prothrombin time ≤ 1.5 x ULN; APTT ≤ 1.5 x ULN
7. Willingness to comply with scheduled visits (including an additional PET/CT scan)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
60

Total final enrolment
5

Key exclusion criteria
Current participant exclusion criteria as of 09/09/2021:
1. Evidence of demonstrable distant metastasis on standard of care imaging using combination of MRI, CT, isotopic bone scan, non-PSMA PET/CT, or PSMA-PET/CT where undertaken as standard of care
2. Patients not willing to receive surgical treatment with radical prostatectomy and pelvic node dissection
3. Patients who are unable or unwilling to give informed consent

Previous participant exclusion criteria:
1. Evidence of demonstrable metastasis on standard of care imaging using combination of MRI, CT and isotopic bone scan
2. Patients not willing to receive surgical treatment with radical prostatectomy and pelvic node dissection
3. Patients not able to undergo PET/CT scan because of weight (e.g. >180 kg), claustrophobia, or

not able to lie still during the scanning duration
4. Patients who already had PSMA PET/CT scan for diagnosis of prostate cancer
5. Patients who are unable or unwilling to give informed consent

Date of first enrolment
21/07/2021

Date of final enrolment
21/01/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
St Bartholomew's Hospital
West Smithfield
London
United Kingdom
EC1A 7BE

Study participating centre
Addenbrooke's Hospital
Hill's Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University College London Hospital
235 Euston Road
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London
United Kingdom
NW1 2BU

Study participating centre

Beatson West of Scotland Cancer Centre
1053 Great Western Road
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Sponsor information

Organisation
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Sponsor type
Government

Website
https://www.publichealthscotland.scot/

ROR
https://ror.org/023wh8b50

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4	22/09/2021	14/10/2022	No	No
HRA research summary			28/06/2023	No	No
Plain English results		06/10/2022	12/10/2023	No	Yes