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Preoperative planning PSMA-PET in Melanoma Surgery (PPPIMS)

Submission date 02/09/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/09/2024	**Overall study status** Ongoing	
Last Edited 30/12/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
This study is investigating the ability of a new diagnostic biomarker, prostate-specific membrane antigen (PSMA), to detect melanoma metastases using a PSMA PET/CT scan.

Who can participate?
Patients aged 18 years and over with operable advanced metastatic melanoma

What does the study involve?
Patients will undergo the standard preoperative scans determined by the consultant; either whole-body PET/CT or FDG-PET/CT and MRI brain, with the addition of the PSMA PET/CT scan, investigating the presence of metastases. The patients will then undergo surgery determined by the patient's consultant.
The PSMA-PET scans will be carried out in the Nuclear Medicine Department at the Royal Marsden Hospital and interpreted by a Consultant Radiologist with a special interest in Nuclear Medicine. These will be compared to the standard-of-care scans. If there is no PSMA activity identified by the first five patients, the researchers will terminate the trial.

What are the possible benefits and risks of participating?
It can be a distressing time for potential patients in a regular outpatient consultation in terms of understanding diagnosis and treatment decisions. Being approached about the study and having to make a decision to participate in research may further distress at this time. In order to minimise this risk, the study information will be given and informed consent sought by an experienced member of the surgical melanoma team trained in the study protocol and GCP. Furthermore, the melanoma surgery team are highly experienced in discussing research and seeking consent from patients newly diagnosed with cancer and are sensitive to the risks involved.
Patients will be required to have an intravenous injection of the radiotracer 68Ga-PSMA-11. 68Ga-PSMA-11 is a radioactive compound and exposure to high levels of radioactivity is associated with an increased risk of cancer. PSMA PET will give a dose of 4.6 mSv and standard-of-care FDG-PET will give 7.6 mSV; slightly less and similar to chest CT at 7 mSV respectively and around double the yearly average exposure to background radiation.
Prospective Phase I trials show 68Ga-PSMA-11 to be safe with no serious adverse reactions 1 and

it was approved by the FDA in December 2020. The most commonly reported side effects were nausea, diarrhoea, and dizziness, occurring at a rate of <1%.
There is a risk for misdiagnosis because Ga 68 PSMA-11 binding may occur in other types of cancer as well as certain non-malignant processes which may lead to image interpretation errors. These scans will be interpreted by a Consultant Radiologist and will be compared with the standard-of-care scans. If necessary, a biopsy can be taken to ensure disease. This is also standard of care.
Patients will undergo both a standard-of-care baseline scan and a PSMA-PET scan. This results in one extra dose of radiation due to the additional scan. Exposure to a higher level of radioactivity is associated with an increased risk of cancer. This is also why there is an early limit on the number of patients undergoing the trial if no positive results are found. However, if the PSMA scan is able to detect metastases, the benefits of delivering the most effective and patient-specific treatment will outweigh the extra dose of radiation.

Where is the study run from?
Royal Marsden NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2023 to July 2027

Who is funding the study?
BRC Pump Priming (UK)

Who is the main contact?
Dr Myles Smith, myles.smith@rmh.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06560905

Clinical Trials Information System (CTIS)
2022-001208-16

Integrated Research Application System (IRAS)
1005470

Protocol serial number
CCR5614

Study information

Scientific Title
Preoperative planning PSMA-PET in Melanoma Surgery (PPPIMS)

Acronym
PPPIMS

Study objectives
The main objective is to investigate whether the diagnostic biomarker, prostate-specific membrane antigen (PSMA), can detect metastatic disease in melanoma patients using a PSMA PET/CT

The secondary objective is to compare FDG PET/CT in identifying known metastases with PSMA PET/CT

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/08/2024, South Central – Hampshire B REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8088; hampshireb.rec@hra.nhs.uk), ref: 23/LO/0807

Study design
Non-randomized single-centre Phase II CTIMP trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Metastatic melanoma

Interventions
Within the 2 weeks prior to surgery, all patients will undergo both PSMA PET-CT and FDG PET-CT scans at least 48 hours apart. The Investigational Medicinal Product (IMP) under investigation in this trial is 68Ga-PSMA (gozetotide). This is an imaging radionuclide tracer and is in chemical form. Up to 200 MBq. The route of administration is intravenous. Follow-up duration is 4-6 weeks after surgery per standard of care.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Gozetotide

Primary outcome(s)
1. Proportion of successes for detecting metastatic disease by PSMA PET-CT, measured at a single timepoint before surgery

Key secondary outcome(s))
1. Proportion of successes for detecting metastatic disease by both PSMA PET-CT and FDG PET-CT, measured at a single timepoint before surgery
2. The Standardised Uptake Value (SUV) by both FDG PET-CT and PSMA PET-CT, measured at a single timepoint before surgery

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. Males ≥18 years of age
2. Biopsy-proven first and recurrent metastatic melanoma with palpable nodal disease who have undergone a staging FDG PET-CT scan as part of routine clinical care and are scheduled for surgery for resection of the primary site

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Male

Total final enrolment

0

Key exclusion criteria
1. Patients unable to give voluntary written informed consent to participate in this study
2. Patients not willing to complete all the study assessments
3. Patients who are females
4. Patients who are taking androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists
5. Patients who have or have previously been diagnosed with prostate cancer
6. Patients who have had Lu-177 PSMA therapy or barium studies within a period of 10 days prior to undergoing PSMA PET-CT scanning
7. Patients not fluent in English

Date of first enrolment
01/03/2025

Date of final enrolment
30/12/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
Royal Marsden NHS Foundation Trust

ROR
https://ror.org/0008wzh48

Funder(s)

Funder type
Research organisation

Funder Name
BRC Pump Priming

Results and Publications

Individual participant data (IPD) sharing plan
Data obtained through this study may be provided to qualified researchers with academic interest in Melanoma biomarkers. Data or samples shared will be coded, with no patient health information included. Approval of the request and execution of all applicable agreements (i.e. a material transfer agreement) are prerequisites to the sharing of data with the requesting party.

Data requests can be submitted starting 3 months after article publication and the data will be made accessible for up to 24 months. Extensions will be considered on a case-by-case basis.

Access to trial IPD can be requested by qualified researchers engaging in independent scientific research and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA).

IPD sharing plan summary
Available on request