

Preoperative planning PSMA-PET in Melanoma Surgery (PPPIMS)

Submission date 02/09/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/09/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/07/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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 December 2025

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

Contact name

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Additional identifiers

EudraCT/CTIS number

2022-001208-16

IRAS number

1005470

ClinicalTrials.gov number

NCT06560905

Secondary identifying numbers

CCR5614, IRAS 1005470

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

02/09/2023

Completion date

31/12/2025

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

16

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

01/12/2025

Locations**Countries of recruitment**

United Kingdom

Study participating centre

Not provided at time of registration

United Kingdom

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Sponsor information**Organisation**

Royal Marsden NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.royalmarsden.nhs.uk/pages/home.aspx>

ROR

<https://ror.org/0008wzh48>

Funder(s)

Funder type

Research organisation

Funder Name

BRC Pump Priming

Results and Publications

Publication and dissemination plan

1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Publication on website
5. Other publication

Intention to publish date

01/04/2026

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