



Record 1 of 1



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Not yet recruiting ⓘ

Alpha-Emitting Radionuclide or Beta-Emitting Radionuclide With Metastasis-Directed Stereotactic Body Radiotherapy for the Treatment of Recurrent, Oligometastatic Prostate Adenocarcinoma (ANDROMEDA)

ClinicalTrials.gov ID ⓘ NCT07150715

Sponsor ⓘ Jonsson Comprehensive Cancer Center

Information provided by ⓘ Jonsson Comprehensive Cancer Center (Responsible Party)

Last Update Posted ⓘ 2025-09-02

Study Details Tab

Study Overview

Brief Summary

This phase II trial compares the use of 225Ac-PSMA-617 to 177Lu-PSMA-617, along with stereotactic body radiotherapy for the treatment of prostate cancer that has come back after a period of improvement (recurrent) and that has spread from where it first started (primary site) to multiple other places in the body (oligometastatic). 225Ac-PSMA-617 and 177Lu-PSMA-617 are radioactive drugs. They bind to a protein called a PSMA receptor, which is found on some prostate tumor cells. 225Ac-PSMA-617 or 177Lu-PSMA-617 builds up in these cells and gives off either alpha or beta radiation that may kill them. It is a type of radioc conjugate and a type of PSMA analog. Stereotactic body radiation therapy (SBRT) is a type of external radiation therapy that uses special equipment to position a patient and precisely deliver radiation to tumors in the body (except the brain). The total dose of radiation is divided into smaller doses given over several days. This type of radiation therapy helps spare normal tissue. Giving 225Ac-PSMA-617 or 177Lu-PSMA-617 and metastasis directed stereotactic body radiotherapy may be effective in treating patients with recurrent, oligometastatic prostate cancer.

Detailed Description

PRIMARY OBJECTIVE:

I. To assess progression-free survival for men with oligorecurrent prostate cancer after stereotactic body radiotherapy (SBRT) in combination with 2 cycles of Lutetium Lu 177 Vipivotide Tetraxetan (177Lu-PSMA-617) versus SBRT in combination with 1 cycle of Actinium Ac 225 Vipivotide Tetraxetan (225Ac-PSMA-617), with progression defined on the basis of prostate specific membrane antigen (PSMA) positron emission

Study Start (Estimated) ⓘ

2025-10-31

Primary Completion (Estimated) ⓘ

2030-10-31

Study Completion (Estimated) ⓘ

2031-10-31

Enrollment (Estimated) ⓘ

107

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Patent Owner Exhibit 2083
IPR2025-01582



tomography (PET)/computed tomography (CT) scans obtained at 24 months post-SBRT or at the time of prostate specific antigen (PSA)-based biochemical progression, initiation of salvage therapy or death.

SECONDARY OBJECTIVES:

- I. To evaluate burden of disease (including local control of irradiated lesions and presence of other disease) on a PSMA PET/CT obtained 24 months after SBRT + 177Lu-PSMA-617 versus SBRT + 225Ac-PSMA-617 in patients with oligometastatic disease who have not progressed by that point.
- II. To assess physician-scored toxicity (common terminology criteria for adverse events [CTCAE] version 5.0) of SBRT + 177Lu-PSMA-617 versus SBRT + 225Ac-PSMA-617 in patients with oligometastatic disease.
- III. To assess patient-reported quality of life (based on the Xerostomia Inventory scale) after SBRT + 177Lu-PSMA-617 versus SBRT + 225Ac-PSMA-617 in patients with oligometastatic disease.
- IV. To assess androgen deprivation therapy (ADT)-free survival after 177Lu-PSMA-617 versus SBRT + 225Ac-PSMA-617 in patients with oligometastatic disease.
- V. To determine local control of irradiated lesions at 24 months after last radionuclide infusion in patients with oligometastatic disease (based on a scheduled PSMA-PET), comparing 177Lu-PSMA-617 versus SBRT + 225Ac-PSMA-617.
- VI. To assess time to locoregional progression, time to distant progression, time to new metastasis, and duration of response after last radionuclide infusion in patients with oligometastatic disease (as defined by PSMA PET/CT).

CORRELATIVE OBJECTIVES:

- I. To quantitatively sequence T-cell receptor (TCR) repertoires using peripheral blood monocytes at baseline, 3 months, 6 months, and 12 months after last infusion of radionuclide.
- II. To perform radiomics analysis on PSMA PET/CT scans performed at 24 months after last infusion of radionuclide, or at time of progression.

OUTLINE: Patients are randomized to 1 of 2 arms.

ARM I: Patients receive 177Lu-PSMA-617 intravenously (IV) over 1-10 minutes on day one of each cycle. Cycles repeat every 6 weeks for 2 cycles. 4-6 weeks after completion of 177Lu-PSMA-617 patients receive Gallium Ga 68 Gozetotide (68Ga-PSMA-11) IV and undergo PSMA PET/CT scan. Within 4 weeks of the scan, patients receive SBRT for 1-5 treatments over 1- 1- days. Treatment is given in the absence of disease progression or unacceptable toxicity. Patients undergo PSMA PET/CT scan and blood sample collection throughout the study.

ARM II: Patients receive 225Ac-PSMA-617 IV once. 4-6 weeks after completion of 225Ac-PSMA-617 patients receive 68Ga-PSMA-11 IV and undergo PSMA PET/CT scan. Within 4 weeks of the scan, patients receive SBRT for 1-5 treatments, over 1- 1- days. Treatment is given in the absence of disease progression or unacceptable toxicity. Patients undergo PSMA PET/CT scan and blood sample collection throughout the study.

After completion of study treatment, patients are followed up every 3 months for 2 years and at 60 months.

Official Title

Alpha-Emitting Radionuclide or Beta-Emitting Radionuclide Combined With Metastasis-Directed Stereotactic Body Radiotherapy for Oligorecurrent Prostate Adenocarcinoma (ANDROMEDA)

Conditions

- Oligometastatic Prostate Adenocarcinoma
- Recurrent Prostate Adenocarcinoma

Intervention / Treatment

- Drug: Actinium Ac 225 Vipivotide Tetraxetan
- Procedure: Biospecimen Collection
- Other: Gallium Ga 68 Gozetotide

- Drug: Lutetium Lu 177 Vipivotide Tetraxetan
- Procedure: PSMA PET-CT Scan
- Radiation: Stereotactic Body Radiation Therapy

Other Study ID Numbers ⓘ

- 25-1338
- NCI-2025-05583 (Registry Identifier) (REGISTRY: CTRP (Clinical Trial Reporting Program))

Resource links provided by the National Library of Medicine **NLM**

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (https://dailymed.nlm.nih.gov/dailymed/) available for: [Gallium Ga-68 gozetotide](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Gallium+Ga-68+gozetotide) (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Gallium+Ga-68+gozetotide), [Lutetium Lu-177 vipivotide tetraxetan](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Lutetium+Lu-177+vipivotide+tetraxetan) (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Lutetium+Lu-177+vipivotide+tetraxetan)

[FDA Drug and Device Resources](https://www.clinicaltrials.gov/fda-links) (https://www.clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://www.clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (https://www.clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

Study Contact ⓘ

Name: Christy Palodichuk
Phone Number: 3107942971
Email: cpalodichuk@mednet.ucla.edu

Study Contact Backup

Name: Care Felix
Phone Number: 310-825-9771
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This study has 1 location

United States

California Locations

 **Los Angeles, California, United States, 90095**
UCLA / Jonsson Comprehensive Cancer Center
Contact : Christy Palodichuk
310-825-9775 cpalodichuk@mednet.ucla.edu
Contact : Care Felix
3108259771 cfelix@mednet.ucla.edu
Principal Investigator : Amar Kishan, MD

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://www.clinicaltrials.gov/study-basics/learn-about-studies) (https://www.clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Oligorecurrent prostate cancer as determined by the presence of 1-5 asymptomatic lesions outside the prostate or prostate bed identified on PSMA PET/CT by local readers
- Serum testosterone > 150 ng/dL
- Age ≥ 18 years
- Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2
- No indication for urgent or emergent radiation
- Histological confirmation of prostate adenocarcinoma (histology from original treatment acceptable)
- White blood cell count ≥ 2.5 × 10⁹/L
- Platelets ≥ 100 × 10⁹/L
- Hemoglobin ≥ 9 g/dL
- Total bilirubin ≤ 1.5 × institutional upper limits of normal (ULN) or up to 3 × ULN if known history of Gilbert's syndrome
- Alanine aminotransferase or aspartate aminotransferase ≤ 3.0 × ULN or ≤ 5.0 × ULN for patients with liver metastases
- Glomerular filtration rate creatinine-cystatin C (GFR_{Cr-cys}) ≥ 60 mL/min 1.73m² using the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) 2021 equation
- Serum albumin > 3.0 g/dL
- Partner and patient must use a method of birth control with adequate barrier protection, deemed acceptable by the principal investigator during the study and for 3 months after last study drug administration
- Ability to understand, and willingness to sign, the written informed consent

Exclusion Criteria:

- Patients with neuroendocrine or small cell carcinoma of the prostate
- Patients with castrate-resistant disease (i.e., prostate specific antigen [PSA] > 0.5 ng/mL with serum testosterone <150 ng/dL)
- Patients who received androgen deprivation therapy or cytotoxic chemotherapy within 6 months of trial enrolment
- Concurrent systemic therapy for a solid organ malignancy
- Spinal cord compression
- Inability to lie flat
- Known hypersensitivity to components of 177-Lu-PSMA-617 or 225-Ac-Lu-PSMA-617
- Inadequate renal function of GFR_{Cr-cys} < 60 mL/min 1.73m² using the CKD-EPI 2021 equation
- Total bilirubin > 1.5 × ULN or > 3.0 × ULN if known history of Gilbert's syndrome
- Alanine aminotransferase or aspartate aminotransferase > 3 × ULN (or 5 × ULN for patients with known liver metastases)
- De novo oligometastatic disease

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

Male

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Masking ⓘ : None (Open Label)

Arms and Interventions

Participant Group/Arm 	Intervention/Treatment 
<p>Experimental: Arm I (177Lu-PSMA-617)</p> <p>Patients receive 177Lu-PSMA-617 IV, over 1-10 minutes, on day one of each cycle. Cycles repeat every 6 weeks for 2 cycles. 4-6 weeks after completion of 177Lu-PSMA-617 patients receive 68Ga-PSMA-11 IV and undergo PSMA PET/CT scan. Within 4 weeks of the scan, patients receive SBRT, for 1-5 treatments, over 1-1- days. Treatment is given in the absence of disease progression or unacceptable toxicity. Patients undergo PSMA PET/CT scan and blood sample collection throughout the study.</p>	<p>Drug: Actinium Ac 225 Vipivotide Tetraxetan</p> <ul style="list-style-type: none"> Given IV Other Names: <ul style="list-style-type: none"> 225Ac-labeled PSMA-617 225Ac-PSMA-617 225Ac-Vipivotide Tetraxetan Actinium (225AC) PSMA-617 Actinium Ac 225 PSMA-617 Actinium Ac 225-PSMA-617 VIPIVOTIDE TETRAXETAN ACTINIUM AC-225 <p>Procedure: Biospecimen Collection</p> <ul style="list-style-type: none"> Undergo blood sample collection Other Names: <ul style="list-style-type: none"> Biological Sample Collection Biospecimen Collected Specimen Collection <p>Drug: Lutetium Lu 177 Vipivotide Tetraxetan</p> <ul style="list-style-type: none"> Given IV Other Names: <ul style="list-style-type: none"> 177Lu-labeled PSMA-617 177Lu-PSMA-617 AAA 617 AAA-617 AAA617 Lu177-PSMA-617 Lutetium Lu 177-PSMA-617 LUTETIUM LU-177 VIPIVOTIDE TETRAXETAN Lutetium-177-PSMA-617 Pluvicto <p>Procedure: PSMA PET-CT Scan</p> <ul style="list-style-type: none"> Undergo PSMA PET/CT scan Other Names: <ul style="list-style-type: none"> PET-CT (PSMA) Prostate-specific Membrane Antigen PET-CT PSMA PET-CT <p>Radiation: Stereotactic Body Radiation Therapy</p> <ul style="list-style-type: none"> Undergo SBRT Other Names: <ul style="list-style-type: none"> SABR SBRT

			<ul style="list-style-type: none"> ◦ Stereotactic Ablative Body Radiation Therapy 		
		<p>Experimental: Arm II (225Ac-PSMA-617)</p> <p>Patients receive 225Ac-PSMA-617 IV once. 4-6 weeks after completion of 225Ac-PSMA-617 patients receive 68Ga-PSMA-11 IV and undergo PSMA PET/CT scan. Within 4 weeks of the scan, patients receive SBRT, for 1-5 treatments, over 1- 1- days. Treatment is given in the absence of disease progression or unacceptable toxicity. Patients undergo PSMA PET/CT scan and blood sample collection throughout the study.</p>	<p>Drug: Actinium Ac 225 Vipivotide Tetraxetan</p> <ul style="list-style-type: none"> • Given IV • Other Names: <ul style="list-style-type: none"> ◦ 225Ac-labeled PSMA-617 ◦ 225Ac-PSMA-617 ◦ 225Ac-Vipivotide Tetraxetan ◦ Actinium (225AC) PSMA-617 ◦ Actinium Ac 225 PSMA-617 ◦ Actinium Ac 225-PSMA-617 ◦ VIPIVOTIDE TETRAXETAN ACTINIUM AC-225 <p>Procedure: Biospecimen Collection</p> <ul style="list-style-type: none"> • Undergo blood sample collection • Other Names: <ul style="list-style-type: none"> ◦ Biological Sample Collection ◦ Biospecimen Collected ◦ Specimen Collection <p>Other: Gallium Ga 68 Gozetotide</p> <ul style="list-style-type: none"> • Given IV • Other Names: <ul style="list-style-type: none"> ◦ (68)Ga labeled Glu-NH-CO-NH-Lys(Ahx)-HBED-CC ◦ (68)Ga-labeled Glu-urea-Lys(Ahx)-HBED-CC ◦ (68)Ga-PSMA Ligand Glu-urea-Lys(Ahx)-HBED-CC ◦ (68)Gallium-PSMA Ligand Glu-urea-Lys(Ahx)-HBED-CC ◦ (68Ga)Glu-urea-Lys(Ahx)-HBED-CC ◦ 68Ga-DKFZ-PSMA-11 ◦ 68Ga-HBED-CC-PSMA ◦ 68Ga-labeled Glu-NH-CO-NH-Lys(Ahx)-HBED-CC ◦ 68Ga-PSMA ◦ 68Ga-PSMA-11 ◦ 68Ga-PSMA-HBED-CC ◦ [68Ga] Prostate-specific Membrane Antigen 11 ◦ [68Ga]GaPSMA-11 ◦ AAA 517 ◦ AAA-517 ◦ AAA517 ◦ Ga PSMA ◦ Ga-68 labeled DKFZ-PSMA-11 ◦ Ga-68 labeled PSMA-11 ◦ GA-68 PSMA-11 ◦ Gallium Ga 68 PSMA-11 ◦ Gallium Ga 68-labeled PSMA-11 ◦ GALLIUM GA-68 GOZETOTIDE 		

- Gallium-68 PSMA
 - Gallium-68 PSMA Ligand Glu-urea-Lys(Ahx)-HBED-CC
 - GaPSMA
 - PSMA-HBED-CC GA-68
- Procedure: PSMA PET-CT Scan
- Undergo PSMA PET/CT scan
 - Other Names:
 - PET-CT (PSMA)
 - Prostate-specific Membrane Antigen PET-CT
 - PSMA PET-CT
- Radiation: Stereotactic Body Radiation Therapy
- Undergo SBRT
 - Other Names:
 - SABR
 - SBRT
 - Stereotactic Ablative Body Radiation Therapy

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Progression free survival (PFS)	A progression event will be based on prostate specific membrane antigen positron emission tomography/ computed tomography findings triggered either by a prostate specific antigen rise or at the timepoint defined by 24 months measured from the final radionuclide infusion (i.e., second infusion of 177Lu-PSMA-617 and first infusion of 225Ac-PSMA-617). The Kaplan-Meier (KM) method will be used to summarize PFS and log-rank test will be used to compare PFS between the two arms.	From the date of randomization to the date of disease progression or death, whichever happens earlier, up to 5 years

Secondary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Incidence of adverse events (AEs)	AEs will be summarized by type and grade.	From time of randomization, up to 5 years
Androgen deprivation therapy free survival	The KM method will be used to summarize.	Up to 5 years
Time to locoregional progression	The KM method will be used to summarize.	Up to 5 years
Time to new metastasis	The KM method will be used to summarize.	Up to 5 years
Overall survival	The KM method will be used to summarize.	Up to 5 years

Local control	Will be defined based on PSMA PET/CT criteria, with scans obtained at time of PSA-progression of 24 months (if no progression by either time point). Patients with complete response, partial response, or stable disease will be considered as exhibiting local control. The proportion of lesions that have a stable or better response will be estimated using generalized estimating equation. The KM method will be used to summarize.	Up to 5 years
Duration of response over time	The KM method will be used to summarize.	Up to 5 years
Quality of life as measured by xerostomia inventory	Will be evaluated based on responses to the xerostomia inventory.	At baseline, 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Jonsson Comprehensive Cancer Center

Collaborators ⓘ

- Novartis Pharmaceuticals

Investigators ⓘ

- Principal Investigator: Amar Kishan, UCLA / Jonsson Comprehensive Cancer Center

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website. [HHS Vulnerability Disclosure](#)

Study Registration Dates

First Submitted ⓘ

2025-08-25

First Submitted that Met QC Criteria ⓘ

2025-08-25

First Posted (Estimated) ⓘ

2025-09-02

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2025-08-25

Last Update Posted (Estimated) ⓘ

2025-09-02

Last Verified ⓘ

2025-08

More Information

Terms related to this study

Additional Relevant MeSH Terms

Actinoid Series Elements

Elements, Radioactive
Elements
Inorganic Chemicals
Metals, Heavy
Radioisotopes
Isotopes
Metals
Clinical Laboratory Techniques
Diagnostic Techniques and Procedures
Diagnosis
Investigative Techniques
Radiotherapy
Therapeutics
Stereotaxic Techniques
Neurosurgical Procedures
Surgical Procedures, Operative
(225)Ac-PSMA-617
Actinium
PSMA-617
Specimen Handling
gallium 68 PSMA-11
68Ga-DKFZ-PSMA-11
Pluvicto
Radiosurgery

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

Yes

Product Manufactured in and Exported from the U.S.

No