IPCSG - Prostate Cancer Clinical Trials

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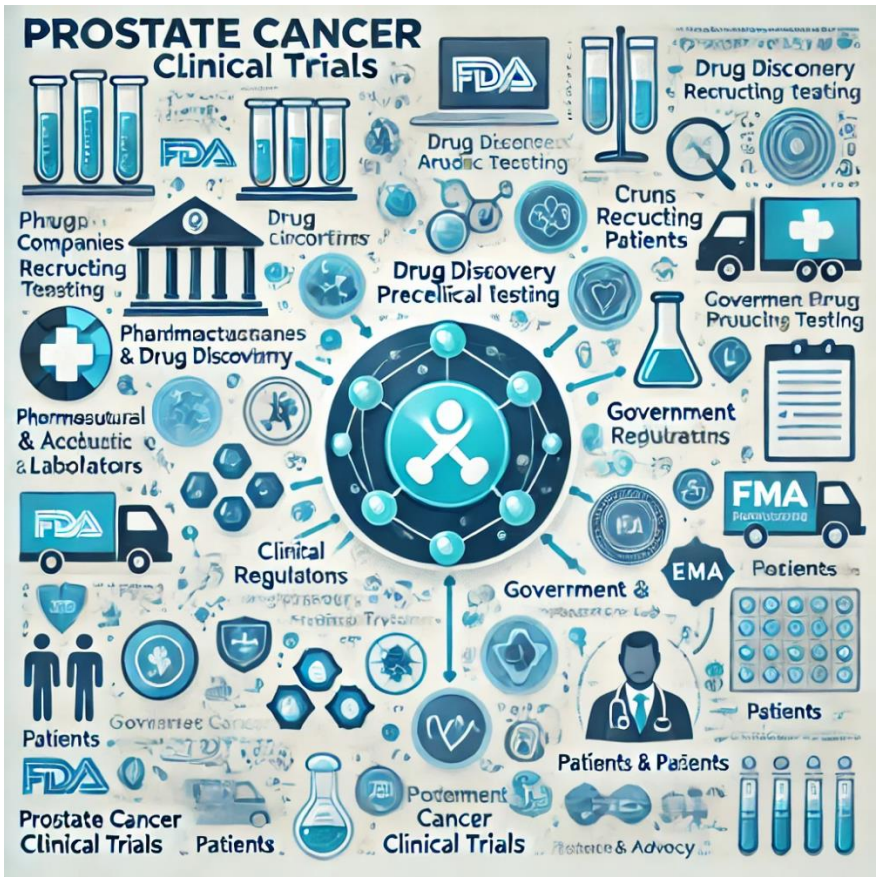

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The Clinical Trial Process

Clinical trials for prospective prostate cancer treatments follow a structured process that involves multiple stakeholders, including pharmaceutical companies, academic laboratories, healthcare providers, government regulators, and patients. Each plays a critical role in the formulation, execution, and oversight of these trials.

1. Formulating Clinical Trials

The process begins with **preclinical research** in pharmaceutical companies and academic laboratories. Scientists test new drugs or treatment approaches in **cell cultures and animal models** to determine safety and potential efficacy. Once a candidate therapy shows promise, researchers develop a **clinical trial protocol**, which outlines the study's objectives, methodology, inclusion criteria, and endpoints.

2. Role of Key Stakeholders

Pharmaceutical Companies & Academic Laboratories

- **Drug Discovery & Preclinical Testing:** Pharmaceutical companies and university labs collaborate to develop novel drugs, biologics, or therapies.
- **Clinical Trial Sponsorship:** Pharma companies typically fund trials and coordinate logistics, including manufacturing and distributing the investigational drug.
- **Data Collection & Analysis:** They gather data on safety, efficacy, and patient response.

Clinical Healthcare Providers (Hospitals & Research Centers)

- **Trial Implementation:** Physicians and researchers at medical institutions conduct the trials, ensuring adherence to protocols.
- **Patient Recruitment & Care:** They identify eligible participants and monitor their health throughout the study.
- **Data Reporting:** Clinicians document adverse effects, treatment responses, and patient outcomes.

Government Regulators (FDA, EMA, etc.)

- **Regulatory Approval & Oversight:** Agencies like the **U.S. Food and Drug Administration (FDA)** and the **European Medicines Agency (EMA)** review trial designs to ensure compliance with ethical and safety standards.
- **Institutional Review Boards (IRBs):** Local ethics committees evaluate the trial's risk-benefit ratio to protect participants.
- **Approval for Market Use:** If trials demonstrate safety and effectiveness, regulators approve the therapy for public use.

Patients & Advocacy Groups

- **Informed Consent:** Patients voluntarily participate after understanding risks and benefits.
- **Real-World Data:** Their experiences provide insights into the effectiveness and tolerability of the treatment.
- **Patient Advocacy Organizations:** Groups like **ZERO - The End of Prostate Cancer** help shape trial designs and ensure patient-centric outcomes.

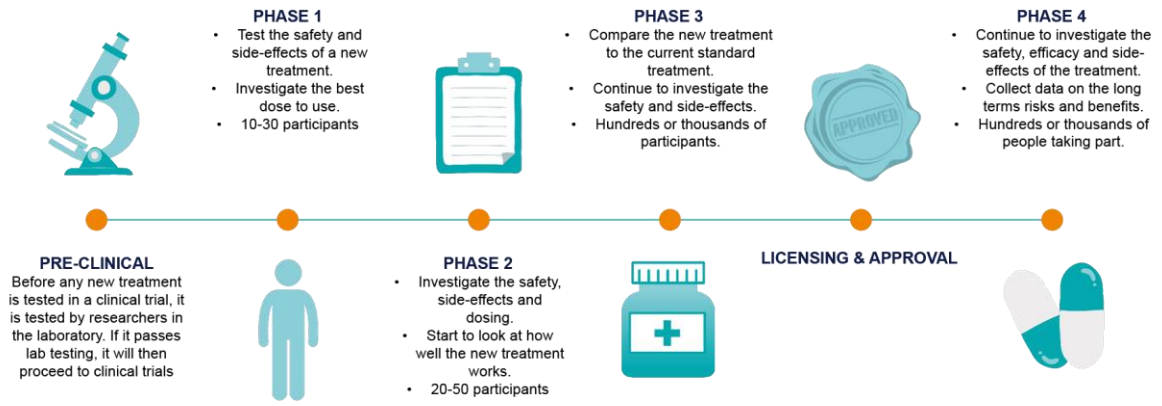

Figure 1 Phases of Clinical Trials

3. Clinical Trial Phases

Clinical trials for prostate cancer therapies progress through four key phases:

- **Phase 1:** Tests safety and dosage on a small group (20-100 participants).
- **Phase 2:** Evaluates efficacy and side effects in a larger group (100-300).
- **Phase 3:** Confirms effectiveness in a broad population (1,000+ patients), comparing the new treatment with existing standards.
- **Phase 4:** Post-approval monitoring to assess long-term effects.

4. Documentation & Reporting

- **Clinical Trial Registry (ClinicalTrials.gov):** Trials are registered to ensure transparency.
- **Peer-Reviewed Publications:** Results are published in scientific journals.
- **Regulatory Reports:** Data is submitted to regulatory agencies for review.

Conclusion

Successful prostate cancer clinical trials require collaboration between scientists, healthcare professionals, regulatory bodies, and patients. This intricate process ensures that new treatments meet high safety and efficacy standards before reaching widespread clinical use.

Cost of Prostate Cancer Clinical Trials

The cost of clinical trials for prostate cancer treatments can vary widely depending on several factors, including trial phase, study design, patient enrollment size, and regulatory requirements. On average:

- **Phase 1** (Safety & Dosage): $1-5 million
- **Phase 2** (Efficacy & Side Effects): $10-20 million
- **Phase 3** (Large-Scale Testing): $50-100+ million
- **Phase 4** (Post-Market Surveillance): $10-50 million

A full clinical trial program from Phase 1 through approval can cost anywhere from **$200 million to over $2 billion** for a new prostate cancer drug.

Funding Sources for Prostate Cancer Clinical Trials

Funding for clinical trials comes from multiple sources:

1. Pharmaceutical & Biotechnology Companies (Primary Source)

- **Industry-sponsored trials** account for the majority of clinical trials.
- Companies such as Pfizer, Johnson & Johnson, and AstraZeneca invest heavily in prostate cancer research.
- Funding covers research, site management, patient monitoring, and regulatory submissions.

2. Government & Public Funding

- **National Cancer Institute (NCI):** Provides grants through programs like the Cancer Therapy Evaluation Program (CTEP).
- **National Institutes of Health (NIH):** Funds early-stage and investigator-initiated trials.
- **Department of Defense (DoD):** Funds prostate cancer research via the Prostate Cancer Research Program (PCRP).
- **FDA Orphan Drug Grants:** Supports drug development for rare cancers.

3. Academic & Nonprofit Organizations

- Universities and cancer research centers conduct investigator-led trials with support from private donors.
- **Prostate Cancer Foundation (PCF):** Funds translational research to bridge the gap between lab discoveries and clinical application.
- **American Cancer Society (ACS):** Provides grants for innovative treatment approaches.

4. Patient Advocacy & Crowdfunding

- Some clinical trials are supported by **patient advocacy groups** that raise awareness and secure funding.
- **Crowdfunding platforms** like GoFundMe help fund access to experimental treatments.

Financial Barriers & Solutions

Despite these funding sources, clinical trials remain expensive and risky. To lower costs and improve efficiency, researchers use:

- **Adaptive trial designs** to reduce patient numbers and costs.
- **Collaborations between industry and academia** to share research expenses.
- **Decentralized trials** (virtual monitoring, telehealth) to reduce site costs.

The high costs of clinical trials underscore the need for **sustainable funding models** and **collaborative efforts** between industry, government, and nonprofit sectors to accelerate prostate cancer treatment development.

Payoff to Patients for Participating in Prostate Cancer Clinical Trials

Patients who enroll in **prostate cancer clinical trials** can experience several **potential benefits**, but there are also **risks** to consider. The key payoffs include **access to cutting-edge treatments, expert medical care, and contributing to future advancements in cancer therapy**.

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1. Access to New & Potentially Better Treatments

Early Access to Innovative Therapies

- Patients may receive **experimental drugs** or advanced therapies not yet available to the public.
- These could be **targeted therapies, immunotherapy, hormone therapy, or gene-based treatments** that might work better than standard options.

Improved Treatment Effectiveness

- Some new therapies show promise in treating **advanced or resistant prostate cancer**.
- If standard treatments are ineffective, clinical trials may offer a **lifeline for patients with limited options**.

Better Side Effect Profiles

- Some investigational drugs **reduce side effects** compared to traditional chemotherapy or radiation.
- **Quality of life improvements** may be a key trial goal.

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2. Expert Medical Supervision & Comprehensive Care

Access to Top Specialists

- Patients are treated by **leading oncologists, urologists, and researchers** at prestigious cancer centers.
- These experts follow the **latest treatment protocols** and advancements.

Close Monitoring & Advanced Diagnostics

- Participants receive **frequent medical checkups, imaging scans, and lab tests** to track their response to treatment.
- Any side effects are **carefully monitored and managed**.

More Personalized Care

- Trials often include **genomic testing and biomarker analysis**, which can provide insights into the best treatment strategies for each patient.

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3. Reduced Costs & Financial Assistance

Free or Subsidized Treatment

- Many trials **cover the cost of experimental drugs, tests, and medical visits**, reducing financial burdens.
- Some also provide **travel reimbursement** or lodging for long-distance participants.

Insurance Coverage & Cost Savings

- Even if a trial does not cover all expenses, some insurance companies **help pay for routine medical care** during the study.
- **Medicare & Medicaid** often cover routine costs for clinical trial patients.

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4. Contribution to Future Cancer Research & Helping Others

Advancing Science & Medicine

- Participating in a clinical trial helps researchers develop **better prostate cancer treatments** for future patients.
- If a treatment works well, it may become the **new standard of care** worldwide.

Helping Other Patients & Saving Lives

- Clinical trials pave the way for **more effective, less toxic treatments**.

- Patients can **help future generations of men** diagnosed with prostate cancer.

Potential Downsides & Considerations

⚠ Unknown Risks & Side Effects

- Experimental treatments **may have unexpected side effects** or be less effective than standard care.
- Close monitoring helps, but **risks still exist**.

⚠ Placebo Groups & Randomization

- Some trials use a **placebo or standard treatment** as a control group.
- You may **not receive the experimental drug**, depending on the study design.

⚠ Time Commitment & Travel

- Some trials require **frequent hospital visits**, long monitoring periods, or travel to major cancer centers.
- Consider whether the time investment fits your personal and work life.

Bottom Line: Is It Worth It?

For many patients, participating in a prostate cancer clinical trial offers:
✔ **Access to potential breakthrough treatments**
✔ **Expert medical care at leading cancer centers**
✔ **Reduced financial burdens in some cases**
✔ **A chance to contribute to lifesaving research**

However, it's crucial to weigh **risks vs. benefits** and discuss options with your doctor before enrolling in a trial.

Risks, Costs, and Rewards for Pharmaceutical Companies & Academic Institutions in Prostate Cancer Clinical Trials

Conducting **prostate cancer clinical trials** is a high-stakes endeavor for **pharmaceutical companies and academic institutions**. The process involves **massive financial investments, regulatory hurdles, and significant risks**, but the potential **rewards**—including **blockbuster drug revenue, scientific breakthroughs, and institutional prestige**—can be substantial.

1. Risks & Challenges

A. High Costs & Financial Losses

Clinical trials, especially for cancer drugs, are **extremely expensive** and prone to failure.

 Estimated Costs per Phase:

- **Phase 1:** $1–5 million (small-scale safety testing)
- **Phase 2:** $10–20 million (efficacy & dosing studies)
- **Phase 3:** $50–100+ million (large-scale validation)
- **Phase 4:** $10–50 million (post-approval monitoring)

 Total Cost of Bringing a Prostate Cancer Drug to Market:

- Ranges from **$200 million to $2+ billion**
- The average **oncology drug approval** costs around **$648 million** (Source: Tufts Center for the Study of Drug Development).

 Example of a Costly Failure:

- **Custirsen (OncoGenex Pharmaceuticals)** – A promising **prostate cancer drug** failed in **Phase 3 trials** after millions were spent, leading to major financial losses.

B. High Risk of Failure (Odds of Success)

Clinical trials have **low success rates**, with cancer drugs facing particularly tough odds.

 Probability of Success for Oncology Drugs:

- **Preclinical to Approval: 3–7%** success rate
- **Phase 1 to Approval: ~10%**
- **Phase 3 to FDA Approval: ~50–60%**

 Example of High-Profile Failure:

- **Rilotumumab (Amgen)** – Despite strong **preclinical and early clinical data**, this prostate cancer treatment failed in **Phase 3 trials** due to lack of efficacy.

C. Regulatory & Compliance Challenges

- **Strict FDA & EMA Guidelines** – Extensive safety and efficacy data required.
- **Long Approval Timelines** – Can take **10–15 years** from discovery to market.
- **Litigation Risks** – Lawsuits from **patients or investors** if trials fail or cause harm.

 Example:

- **Zytiga (Abiraterone Acetate)** – Even after FDA approval, Janssen Pharmaceuticals faced **patent lawsuits which cut short their exclusive market time and enabled generic market competition**, affecting profits.

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2. Costs for Academic Institutions & Research Centers

While academic institutions receive **grants and funding**, running trials is still expensive.

 Estimated Costs for Universities & Nonprofits:

- **Basic Research:** $500,000–$5 million per project
- **Clinical Trial Execution (without Pharma funding):** $2–20 million per study

 Financial Risks for Universities:

- Institutions rely on **NIH, NCI, and foundation grants**, which are competitive.
- If trials fail, universities **lose funding opportunities** for future research.

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3. Rewards & Incentives

A. Big Pharma: Multi-Billion Dollar Revenues

If a drug succeeds, **pharmaceutical companies reap massive profits**.

 Successful Prostate Cancer Drug Revenue Examples:

- **Xtandi (Enzalutamide) – Pfizer/Astellas: $5+ billion/year**
- **Zytiga (Abiraterone) – Janssen: $3+ billion/year**
- **Provenge (Sipuleucel-T) – Dendreon:** Initially projected at **$1 billion/year** but underperformed.

 Example of Success:

- **Xtandi (Enzalutamide)** – After FDA approval, Xtandi became **one of the best-selling prostate cancer drugs**, generating **billions in revenue** annually.

B. Academic Institutions: Prestige & Research Advancements

Universities and medical centers benefit through:

- **Scientific Recognition** – Publications in top journals.
- **Funding & Grants** – Successful trials lead to **more research funding**.
- **Partnerships with Pharma** – Institutions secure **industry collaborations** and licensing deals.

 Example:

- **MD Anderson Cancer Center** partnered with **Pfizer** to research targeted therapies, leading to **funding and recognition**.

Final Takeaway

Factor	Pharma Companies	Academic Institutions
Upfront Costs	$200M–$2B	$2M–$20M (per trial)
Success Rate	3–10% overall	Highly dependent on funding
Potential Rewards	$1B–$5B/year (for successful drugs)	Prestige, more funding, partnerships
Biggest Risk	Financial loss & FDA rejection	Loss of funding & failed research

 For Pharma: The **high cost & risk** is offset by potential **blockbuster drug profits**.
 For Academia: Trials provide **scientific progress & reputation**, but funding is critical.

NCI Clinical Trials Information for Patients and Caregivers

Explore the basics of clinical trials, including what they are, how they work, and what to expect.

- Clinical Trial Facts - Wrong ideas about clinical trials can lead to worry and prevent good decisions. Consider all of the facts as you think about joining a trial.
- What to Expect During a Clinical Trial - Learn about the process of joining and participating in a clinical trial and what to expect.
- Paying for Clinical Trials - Learn about the types of costs related to participating in a clinical trial, who is expected to pay for which costs, and tips for working with insurance companies.

- Safety and Clinical Trials - Learn about informed consent, institutional review boards, and how trials are closely monitored to protect you.
- How Clinical Trials Work - Learn about who is eligible to join, how trials are designed, and the responsibilities of research team members.
- Why Participate in a Trial - Get information on what questions to ask and how to decide to participate.
- What Are Clinical Trials? - Learn about the purpose and importance of clinical trials, including the different types of clinical trials used in cancer research.
- Find a Clinical Trial - Find an NCI-supported clinical trial—and learn how to locate other research studies—that may be right for you or a loved one.

Three ongoing Phase III prostate cancer trials

Clinicaltrialsarena.com is one of a network of 40+ proprietary B2B websites, with an unrivalled global audience of active decision makers, influencers, and opinion leaders across the world with a combined readership of 55 million industry professionals each year. According to Clinical Trials Arena, there are several candidates under investigation for prostate cancer for patients at various stages of the disease including an oncolytic virus, PARP inhibitor and EZH2 inhibitor. Here are some promising ongoing Phase III trials of prostate cancer completing before the end of 2025.

Sponsor Name	Drug	End Date	Participants		
Candel Therapeutics	ProstAtak	December 2024	700	Inactivated herpetic virus	Pipeline
Johnson & Johnson	Akeega	November 2024	696	PARP inhibitor	Marketed
Pfizer	Mevrometostat	December 2025	600	EZH2 inhibitor	Pipeline

Source: GlobalData's Pharmaceutical Intelligence Center

Finding an Appropriate Clinical Trial

How to Find and Participate in a Prostate Cancer Clinical Trial

If you have been diagnosed with prostate cancer and are interested in participating in a clinical trial, follow these steps to find an appropriate study and enroll safely.

Step 1: Understand Your Condition and Goals

Before searching for a trial, consider:

- **Cancer Stage & Type:** Is it localized, advanced, or metastatic?

- **Previous Treatments:** Have you had surgery, radiation, or hormone therapy?
- **Goals of Participation:** Are you looking for a cure, symptom management, or access to cutting-edge treatments?

Discussing your medical history and treatment options with your **oncologist or urologist** can help determine the best trial for your condition.

Step 2: Search for Clinical Trials

Use trusted resources to find ongoing prostate cancer trials:

1. ClinicalTrials.gov (Best for Comprehensive Listings)

- Visit **ClinicalTrials.gov**
- Enter search terms like **"prostate cancer"** and refine by:
  - **Location** (your country or city)
  - **Recruitment status** (choose "Recruiting")
  - **Phase** (e.g., early-stage vs. late-stage trials)
  - **Treatment type** (drug therapy, immunotherapy, radiation, etc.)
- Review trial details, including eligibility criteria and contact information.

2. National Cancer Institute (NCI) Clinical Trial Finder

- Visit **cancer.gov**
- Provides **NCI-sponsored trials**, often with leading cancer centers.

3. Major Cancer Centers & Hospitals

Leading hospitals often have their own trial databases:

- **MD Anderson Cancer Center**
- **Memorial Sloan Kettering Cancer Center**
- **Dana-Farber Cancer Institute**
- **Mayo Clinic**
- **UCSD Health Moores Cancer Center**

Check their websites or call their research departments.

4. Patient Advocacy Groups & Networks

- **Prostate Cancer Foundation (PCF)**
- **ZERO - The End of Prostate Cancer**
- **Us TOO International Prostate Cancer Education & Support**

These organizations help connect patients with trials and provide financial assistance.

Step 3: Determine Eligibility

Each trial has **inclusion and exclusion criteria**, which may specify:

- **Age & Gender:** Most prostate cancer trials are for men, but some include transgender individuals.
- **Cancer Stage:** Some trials focus on early-stage, while others target metastatic cases.
- **Prior Treatments:** Some trials require that you have (or have not) undergone certain therapies.
- **Health Conditions:** Other illnesses (e.g., heart disease, diabetes) may affect eligibility.

If unsure, contact the study coordinator listed on ClinicalTrials.gov or consult your doctor.

Step 4: Contact the Research Team

Once you find a suitable trial, reach out to the trial coordinator. Prepare to ask:
✔ **Am I eligible based on my medical history?**
✔ **What is the trial's purpose and treatment approach?**
✔ **Where is the trial site located, and how often must I visit?**
✔ **What are the risks and benefits?**
✔ **Are there costs, or is treatment covered?**

Step 5: Give Informed Consent & Enroll

If you qualify and decide to proceed:

- You will receive an **informed consent document** explaining risks and benefits.
- Your **medical team will conduct baseline tests** before enrollment.
- Once approved, you will follow the trial's **treatment plan and monitoring schedule**.

Final Considerations

✔ **Insurance & Cost Coverage:** Some trials provide free treatment, while others may require insurance coverage.
✔ **Travel & Lodging:** Some trials offer stipends for travel; check with the trial team.

✔ **Right to Withdraw:** You can leave the trial at any time if you experience side effects or change your mind.

By following these steps, you can find and participate in a prostate cancer clinical trial that may offer **innovative treatment options and hope for better outcomes**.

Prostate Cancer Trials in San Diego

San Diego's leading medical institutions are currently recruiting patients for 19 innovative clinical trials targeting various stages of prostate cancer, from early detection to advanced metastatic disease. UC San Diego Health and Genesis Research are spearheading these efforts, offering hope through novel treatment combinations and advanced diagnostic techniques.

For Newly Diagnosed/Localized Disease:

- - The PREDICT-RT trial is evaluating personalized treatment intensities based on genetic risk scores for patients with high-risk and intermediate-risk prostate cancer, running at multiple locations including Encinitas.
- - A pioneering focal therapy registry study at La Jolla is tracking outcomes for patients choosing targeted treatment approaches for localized disease.
- - An advanced MRI study (ART-Pro) is testing improved detection methods for clinically significant prostate cancer using innovative imaging techniques.

For Biochemically Recurrent/Rising PSA:

- - A groundbreaking trial at UC San Diego is comparing standard systemic therapy with or without definitive treatment (surgery or radiation) for patients whose cancer has spread.
- - Researchers are studying targeted radiation therapy combined with apalutamide for patients whose cancer has returned after surgery.

For Metastatic Disease:

- - The TERPS trial is specifically studying treatment approaches for patients who present with metastatic lesions at initial diagnosis.
- - A promising combination therapy trial of cabozantinib and nivolumab is ongoing for patients with castration-resistant prostate cancer.
- - XmAb20717 (vudalimab) is being tested alone and in combination with standard therapies for metastatic castration-resistant prostate cancer.

Prevention Studies:

1. - A unique trial is evaluating whether green tea catechins can reduce cancer progression in men under active surveillance, offering a potential natural intervention option.

"These trials represent the full spectrum of prostate cancer care, from prevention to advanced disease treatment," said UC San Diego Health, which can be reached at 858-657-7000 for trial inquiries.

For patients interested in participating, Genesis Research in Encinitas (858-429-7050) and UC San Diego Health's High-Risk Prostate Cancer Clinic are the primary contact points for screening and enrollment. Eligibility criteria vary by trial, though most are open to men aged 18 and older with specific disease characteristics.

The trials highlight San Diego's position as a hub for prostate cancer research, offering local patients early access to potentially breakthrough treatments while contributing to the advancement of cancer care globally.

Prevention/Active Surveillance:

- Green Tea Catechins
  - Being studied for prevention of progression in low-risk patients under active surveillance

Novel Diagnostic Agents:

- Advanced MRI techniques (ART-Pro trial)
  - Testing improved imaging methods for cancer detection
  - Not a medication but a diagnostic approach

Medications Undergoing Trial

Let me analyze the clinical trials and organize the medications being studied:

Most of these trials are being conducted at UC San Diego Health facilities and require participants to be male, aged 18 or older, with specific eligibility criteria varying by trial phase and cancer stage. Each medication or combination is being studied for specific patient populations with particular genetic markers or disease characteristics.

For the most current information about these medication trials and specific eligibility requirements, patients can contact UC San Diego Health at 858-657-7000 or Genesis Research LLC at (858) 429-7050.

For Early Stage/Localized Prostate Cancer:

- Olaparib (PARP inhibitor) + LHRH agonist
  - Being tested as neoadjuvant therapy before radical prostatectomy
  - For patients with unfavorable intermediate-risk or high-risk localized cancer
  - Specifically for patients with HRR gene alterations

For High-Risk Localized/Locally Advanced:

- Apalutamide + ADT (Androgen Deprivation Therapy)
  - Being tested before and after radical prostatectomy
  - Treatment includes pelvic lymph node dissection

For Biochemically Recurrent (Rising PSA):

- Apalutamide
  - Being studied in combination with targeted radiation
- Abiraterone + Prednisone
  - Being tested in combination with apalutamide for post-surgery patients

For Hormone-Sensitive Metastatic Disease:

- Various trials combining standard ADT with:
  - Enzalutamide
  - Apalutamide
  - Abiraterone

For Metastatic Castration-Resistant Prostate Cancer (mCRPC):

- Cabozantinib + Nivolumab combination
  - Phase 2 multicenter trial
- Vudalimab (XmAb20717)
  - Being tested both as monotherapy and in combination with standard treatments
- Opevesostat (MK-5684)
  - Being evaluated both alone and in combination treatments

Prostate Cancer clinical trials at UCSD

43 in progress, 19 open to eligible people

XmAb20717 (Vudalimab)in Patients With Selected Advanced Gynecologic and Genitourinary Malignancies

open to eligible people ages 18 years and up
This is a Phase 2, multicenter, two-stage, open-label, parallel-group study designed to evaluate the efficacy and safety of vudalimab (XmAb20717) in patients with selected advanced gynecologic and genitourinary malignancies.
La Jolla, California and other locations

Biomarker Monitoring of Prostate Cancer Patients With RSI MRI (ProsRSI)

open to eligible males ages 18 years and up
Adult male patients with high-risk, localized prostate cancer and planning to undergo radiation therapy (RT) with androgen deprivation therapy (ADT) will undergo an advanced Magnetic Resonance Imaging (MRI) examination called Restriction Spectrum…
La Jolla, California

Sequential Testosterone and Enzalutamide Prevents Unfavorable Progression

open to eligible males ages 18-90
Asymptomatic men without pain due to prostate cancer progressing with metastatic CRPC after treatment with combination or sequential ADT + Abi will be treated on a randomized, open label study to determine if sequential treatment with high dose T…
San Diego, California and other locations

Standard Systemic Therapy With or Without Definitive Treatment in Treating Participants With Metastatic Prostate Cancer

open to eligible males ages 18 years and up
This phase III trial studies how well standard systemic therapy with or without definitive treatment (prostate removal surgery or radiation therapy) works in treating participants with prostate cancer that has spread to other places in the body.…
La Jolla, California and other locations

Cabozantinib and Nivolumab in Metastatic Castration Resistant Prostate Cancer

open to eligible males ages 18 years and up
This is a multicenter, single-arm, two-stage open-label phase 2 study of the combination of cabozantinib + nivolumab in subjects with advanced castration-resistant prostate cancer (CRPC).
La Jolla, California and other locations

Neoadjuvant PARP Inhibition Followed by Radical Prostatectomy in Patients With Unfavorable Intermediate-Risk or High-Risk Prostate Cancer With Select HRR Gene Alterations

open to eligible males ages 18 years and up
Phase 2 open-label, single-arm clinical trial evaluating the efficacy and safety of neoadjuvant olaparib + LHRH agonist administered for 6 months prior to radical prostatectomy (RP) in men with unfavorable intermediate-risk or high-risk localized…
La Jolla, California and other locations

Oral MRT-2359 in Selected Cancer Patients

open to eligible people ages 18 years and up
This Phase 1/2, open-label, multicenter study is conducted in patients with previously treated selected solid tumors, including non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), high-grade neuroendocrine cancer of any primary site,…
San Diego, California and other locations

Substudy 01A: Safety and Efficacy of Opevesostat (MK-5684)-Based Treatment Combinations or Opevesostat Alone in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) (MK-5684-01A)

open to eligible people ages 18 years and up
Substudy 01A is part of a larger research study that is testing experimental treatments for metastatic castration-resistant prostate cancer (mCRPC). The larger study is the umbrella study (U01). The goal of substudy 01A is to evaluate the safety and …
La Jolla, California and other locations

TERPS Trial for De Novo Oligometastic Prostate Cancer

open to eligible males ages 18 years and up
This research is being done to see if we can improve the outcome of prostate cancer patients who present with metastatic lesions at initial diagnosis.
La Jolla, California and other locations

Evaluate if Green Tea Can be Effective in Reducing the Progression of Prostate Cancer in Men on Close Monitoring

open to eligible people ages 21 years and up
This phase II trial studies how well green tea catechins work in preventing progression of prostate cancer from a low risk stage to higher risk stages in men who are on active surveillance. Green tea catechins may stabilize prostate cancer and lower …
Encinitas, California and other locations

Treating Prostate Cancer That Has Come Back After Surgery With Apalutamide and Targeted Radiation Based on PET Imaging

open to eligible males ages 18 years and up
This phase III trial tests two questions by two separate comparisons of therapies. The first question is whether enhanced therapy (apalutamide in combination with abiraterone + prednisone) added to standard of care (prostate radiation therapy and…
La Jolla, California and other locations

Two Studies for Patients With High Risk Prostate Cancer Testing Less Intense Treatment for Patients With a Low Gene Risk Score and Testing a More Intense Treatment for Patients With a High Gene Risk Score, The PREDICT-RT Trial

open to eligible males ages 18 years and up
This phase III trial compares less intense hormone therapy and radiation therapy to usual hormone therapy and radiation therapy in treating patients with high risk prostate cancer and low gene risk score. This trial also compares more intense…
Encinitas, California and other locations

Two Studies for Patients With Unfavorable Intermediate Risk Prostate Cancer Testing Less Intense Treatment for Patients With a Low Gene Risk Score and Testing a More Intense Treatment for Patients With a Higher Gene Risk Score

open to eligible males ages 18 years and up
This phase III trial uses the Decipher risk score to guide intensification (for higher Decipher gene risk) or de-intensification (for low Decipher gene risk) of treatment to better match therapies to an individual patient's cancer aggressiveness.…
Encinitas, California and other locations

XmAb®20717 (Vudalimab) Alone or in Combination With Chemotherapy or Targeted Therapy in Patients With Metastatic Castration-Resistant Prostate Cancer

open to eligible males ages 18 years and up
This Phase 2 study will investigate the safety and clinical activity of vudalimab (XmAb20717) alone or in combination with standard of care anticancer therapies in patients with metastatic castration-resistant prostate cancer (mCRPC) who have…
San Diego, California and other locations

ART-Pro: Clinical Trial Evaluating Biparametric MRI and Advanced, Quantitative Diffusion MRI for Detection of Prostate Cancer

open to eligible males ages 18 years and up
This is a multicenter, multinational trial to evaluate advanced MRI techniques for improved detection of clinically significant prostate cancer (csPCa). The study will enroll 500 participants at 5 clinical centers (100 participants per center). The…
San Diego, California and other locations

Focal Therapy for Localized Prostate Cancer

open to eligible males ages 18 years and up
This prospective registry and longitudinal study that is designed to carefully measure details of prostate cancer patients' outcomes with focal therapy. The goal of which is to improve patient care.
La Jolla, California

International Registry for Men With Advanced Prostate Cancer (IRONMAN)

open to eligible males ages 21 years and up
Our intent is to establish the International Registry to Improve Outcomes in Men with Advanced Prostate Cancer (IRONMAN) as a prospective, international cohort of minimum 5,000 men with advanced cancer, including men with mHSPC and M0/M1 CRPC. The…
San Diego, California and other locations

Precision-Based Genomics in Prostate Cancer

open to eligible males ages 18 years and up
Background: Prostate cancer is the most common cancer and the second leading cause of death in males in the United States. Researchers want to find additional gene mutations that may increase a man s risk for prostate cancer and may affect how…

La Jolla, California and other locations

- ***Prostate Assessment With Restriction Spectrum Imaging (RSI) MRI***

open to eligible males ages 18 years and up
This single-center study will enroll 40 male participants to complete 2 diffusion magnetic resonance images within 30 days of each other.
La Jolla, California

US Clinical Trials.gov

ClinicalTrials.gov: History, Purpose, and Administration

1. What is ClinicalTrials.gov?

ClinicalTrials.gov is a publicly accessible database of privately and publicly funded clinical studies conducted worldwide. It provides information on study protocols, locations, recruitment status, and results. The website is maintained by the **National Library of Medicine (NLM)** at the **National Institutes of Health (NIH)**.

2. How Did ClinicalTrials.gov Come to Be?

The platform was created in response to concerns about transparency in clinical research, particularly after high-profile cases where patients and physicians lacked access to clinical trial data.

- **1997:** The U.S. Congress passed the **Food and Drug Administration Modernization Act (FDAMA 1997)**, requiring the NIH to establish a registry for clinical trials on serious or life-threatening diseases.
- **2000:** ClinicalTrials.gov was launched, initially focusing on federally and privately funded studies of experimental treatments for serious diseases.
- **2004:** The **FDA issued regulations** requiring trial sponsors to register more types of trials, increasing public access to information.
- **2007:** The **FDA Amendments Act (FDAAA 2007)** expanded registration requirements, making it mandatory to report trial results.
- **2017:** The **Final Rule** of FDAAA 2007 enforced stricter compliance, requiring the timely reporting of results with penalties for noncompliance.

3. How is ClinicalTrials.gov Administered?

ClinicalTrials.gov is managed by the **National Library of Medicine (NLM)**, which is part of the **National Institutes of Health (NIH)**. Key responsibilities include:

- **Trial Registration:** Sponsors (pharmaceutical companies, universities, or government agencies) must register trials and provide key details such as study design, eligibility criteria, and locations.
- **Results Submission:** Sponsors are required to post summary results, including outcome data, even if the study does not lead to FDA approval.
- **Public Access & Compliance Monitoring:** The NIH and FDA oversee compliance, ensuring that sponsors follow registration and reporting guidelines.
- **Data Integrity & Updates:** NLM verifies submissions for accuracy and ensures the platform remains user-friendly for researchers, healthcare providers, and patients.

4. Impact of ClinicalTrials.gov

- **Increases transparency** in clinical research.
- **Improves patient access** to clinical trials.
- **Prevents publication bias** by making both positive and negative results publicly available.
- **Enhances scientific collaboration** by allowing researchers to track ongoing studies.

Conclusion

ClinicalTrials.gov has become the world's largest clinical trial registry, playing a crucial role in advancing medical research, ensuring transparency, and helping patients and healthcare providers access critical trial information.

Prostate Cancer Trials Recruiting in San Diego

- NCT Number Study Title Sponsor Phases Enrollment Funder Type Study Type Start Date
- NCT04597359 To Evaluate if Green Tea Can be Effective in Reducing the Progression of Prostate Cancer in Men on Close Monitoring ECOG-ACRIN Cancer Research Group PHASE2 360 NETWORK INTERVENTIONAL 10/5/2021
- NCT06579417 ART-Pro: Clinical Trial Evaluating Biparametric MRI and Advanced, Quantitative Diffusion MRI for Detection of Prostate Cancer University of California, San Diego 500 OTHER OBSERVATIONAL 12/15/2023
- NCT03151629 International Registry for Men With Advanced Prostate Cancer (IRONMAN) Prostate Cancer Clinical Trials Consortium 5000 OTHER OBSERVATIONAL 7/21/2017
- NCT02960022 A Study for Subjects With Prostate Cancer Who Previously Participated in an Enzalutamide Clinical Study Astellas Pharma Global Development, Inc. PHASE2 900 INDUSTRY INTERVENTIONAL 12/22/2016
- NCT05367440 Study of AZD5305 When Given in Combination With New Hormonal Agents in Patients With Metastatic Prostate Cancer AstraZeneca PHASE1|PHASE2 190 INDUSTRY INTERVENTIONAL 6/2/2022
- NCT04134260 Testing the Addition of the Drug Apalutamide to the Usual Hormone Therapy and Radiation Therapy After Surgery for Prostate CancerNRG Oncology PHASE3 586 OTHER INTERVENTIONAL 3/5/2020

- NCT05050084 Two Studies for Patients With Unfavorable Intermediate Risk Prostate Cancer Testing Less Intense Treatment for Patients With a Low Gene Risk Score and Testing a More Intense Treatment for Patients With a Higher Gene Risk Score NRG Oncology PHASE3 2050 OTHER INTERVENTIONAL 11/3/2021
- NCT06120491 Saruparib (AZD5305) vs Placebo in Men With Metastatic Castration-Sensitive Prostate Cancer Receiving Physician's Choice New Hormonal Agents AstraZeneca PHASE3 1800 INDUSTRY INTERVENTIONAL 11/21/2023
- NCT05005728 XmAbÂ®20717 (Vudalimab) Alone or in Combination With Chemotherapy or Targeted Therapy in Patients With Metastatic Castration-Resistant Prostate Cancer Xencor, Inc. PHASE2 85 INDUSTRY INTERVENTIONAL 10/22/2021
- NCT04513717 Two Studies for Patients With High Risk Prostate Cancer Testing Less Intense Treatment for Patients With a Low Gene Risk Score and Testing a More Intense Treatment for Patients With a High Gene Risk Score, The PREDICT-RT Trial NRG Oncology PHASE3 2478 OTHER INTERVENTIONAL 12/15/2020
- NCT04363164 Sequential Testosterone and Enzalutamide Prevents Unfavorable Progression Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins PHASE2 150 OTHER INTERVENTIONAL 8/19/2020
- NCT05489211 Study of Dato-Dxd as Monotherapy and in Combination With Anti-cancer Agents in Patients With Advanced Solid Tumours (TROPION-PanTumor03) AstraZeneca PHASE2 582 INDUSTRY INTERVENTIONAL 9/6/2022
- NCT05546268 Study of Oral MRT-2359 in Selected Cancer Patients Monte Rosa Therapeutics, Inc PHASE1|PHASE2 174 INDUSTRY INTERVENTIONAL 10/12/2022

cancer.gov

Clinical trials are research studies that involve people. The clinical trials on this list are studying lutetium lu 177 vipivotide tetraxetan. All trials on the list are NCI-supported clinical trials, which are sponsored or otherwise financially supported by NCI.

NCI's basic information about clinical trials explains the types and phases of trials and how they are carried out. Clinical trials look at new ways to prevent, detect, or treat disease. You may want to think about taking part in a clinical trial. Talk to your doctor for help in deciding if one is right for you.

Trials 1-17 of 17

Clinical Trials Using Lutetium Lu 177 Vipivotide Tetraxetan

- ONC-392 Plus Lutetium Lu 177 Vipivotide Tetraxetan in Patients With mCRPC

In this Phase 2 study, mCRPC patients with PSMA positive scans who progressed on prior ARTA and up to 2 lines of taxanes, and are naïve to lutetium Lu 177 vipivotide tetraxetan, will be enrolled. The study is open-label, randomized with active control, multi-center study.

Location: 13 locations

- Targeted Treatment for Metastatic Prostate Cancer, The PREDICT Trial

  This phase II trial evaluates whether genetic testing in prostate cancer is helpful in deciding which study treatment patients are assigned. Patient cancer tissue samples are obtained from a previous surgery or biopsy procedure and tested for deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) abnormalities or mutations in their cancer. Valemetostat tosylate is in a class of medications called EZH1/EZH2 inhibitors. It blocks proteins called EZH1 and EZH2, which may help slow or stop the spread of tumor cells. Carboplatin is in a class of medications known as platinum-containing compounds. It works in a way similar to the anticancer drug cisplatin, but may be better tolerated than cisplatin. Carboplatin works by killing, stopping or slowing the growth of tumor cells. Cabazitaxel injection is in a class of medications called microtubule inhibitors. It works by slowing or stopping the growth of tumor cells. Abiraterone acetate blocks tissues from making androgens (male hormones), such as testosterone. This may cause the death of tumor cells that need androgens to grow. It is a type of anti-androgen. Enzalutamide is in a class of medications called androgen receptor inhibitors. It works by blocking the effects of androgen (a male reproductive hormone) to stop the growth and spread of tumor cells. Lutetium Lu 177 vipivotide tetraxetan is in a class of medications called radiopharmaceuticals. It works by targeting and delivering radiation directly to tumor cells which damages and kills these cells. Assigning patients to targeted treatment based on genetic testing may help shrink or slow the cancer from growing.

  Location: 8 locations

- An Open-label Study Comparing Lutetium (177Lu) Vipivotide Tetraxetan Versus Observation in PSMA Positive OMPC.

  The purpose of this study is to evaluate the efficacy and safety of lutetium (177Lu) vipivotide tetraxetan (AAA617) in participants with oligometastatic prostate cancer (OMPC) progressing after definitive therapy to their primary tumor. The data generated from this study will provide evidence for the treatment of AAA617 in early-stage prostate cancer patients to control recurrent tumor from progressing to fatal metastatic disease while preserving quality of life by delaying treatment with androgen deprivation therapy (ADT).

  Location: 7 locations

- Carboplatin and 177Lu-PSMA-617 for the Treatment of Patients with Metastatic Castrate-Resistant Prostate Cancer, LuCarbo Trial

This phase I trial studies the side effects and best dose of carboplatin when given together with 177Lu-PSMA-617 and to see how well it works in treating prostate cancer that has spread from where it first started (primary site) to other places in the body (metastatic) and that remains despite treatment (resistant). Carboplatin is in a class of medications known as platinum-containing compounds. It works in a way similar to the anticancer drug cisplatin, but may be better tolerated than cisplatin. Carboplatin works by killing, stopping or slowing the growth of tumor cells. Carboplatin is known to sensitize cancer cells to deoxyribonucleic acid (DNA) damage. 177Lu-PSMA-617 works by binding to prostate cancer cells and inducing damage to DNA inside prostate cancer cells. Giving 177Lu-PSMA-617 and carboplatin may be safe, tolerable and/or effective in treating men with metastatic castrate-resistant prostate cancer (mCRPC).

Location: 3 locations

- Randomized Phase 2 Trial of Flexible and Extended Dosing of 177Lu-PSMA-617 Molecular Radioligand Therapy (FLEX-MRT)

  In advanced metastatic castration resistant prostate cancer (mCRPC) progressing after chemotherapy and androgen receptor (AR)-targeted therapy 177Lu-PSMA-617 is an effective treatment. 177Lu-PSMA-617 RLT is administered with a fixed schedule: 6 treatment cycles, administered every 6 weeks. However the optimum number of cycles of 177Lu-PSMA in patients who show good response remains unknown. Some patients may benefit from more than 6 cycles of therapy. Additionally, some patients experience a complete or almost complete response before the last cycle. It is unclear whether these patients benefit from the subsequent remaining treatment cycle(s). A treatment holiday period would spare these patients some exposure to the therapy agent and avoid potentially unnecessary toxicity when treatment efficacy is already maximal and additional treatment effect cannot be expected. This randomized phase 2 study compares a group of patients treated with LuPSMA on a flexible and extended dosing schedule including “treatment holiday” periods (investigational arm, up to 12 cycles, as described below) to a control group treated with a fixed dosing schedule of 6 treatments cycles maximum administered every 6 weeks. The flexible dosing schedule in the investigational arm, will be based on single photon emission computed tomography (SPECT)/computed tomography (CT) response assessments obtained 24h after injection of LuPSMA therapy cycle. The response assessment during treatment holiday period will be based on positron emission tomography/computed tomography (PET/CT) every 12 weeks. Single-time point SPECT/CT dosimetry protocol at every cycle will be performed and will allow to determine the number of cycles that subjects may receive under the study without exceeding the kidney dose threshold.

  Location: UCLA / Jonsson Comprehensive Cancer Center, Los Angeles, California

- Re-treatment with 177Lu-PSMA-617 for the Treatment of Metastatic Castration-Resistant Prostate Cancer, RE-LuPSMA Trial

This phase II trial tests how well re-treatment with 177Lu-PSMA-617 works in treating patients with prostate cancer that has spread from where it first started (primary site) to other places in the body (metastatic), that continues to grow or spread after the surgical removal of the testes or medical treatment to block androgen production (castration-resistant), and that has shown a favorable response to initial treatment with 177Lu-PSMA-617. 177Lu-PSMA-617 is a radioactive drug. It binds to a protein called prostate specific membrane antigen (PSMA), which is expressed by some types of prostate tumor cells. When 177Lu-PSMA-617 binds to PSMA-expressing tumor cells, it delivers radiation to the cells, which may kill them. Re-treatment with 177Lu-PSMA-617 in patients who had a favorable response to initial 177Lu-PSMA-617 treatment may improve survival outcomes and disease response in patients with metastatic castration-resistant prostate cancer.

Location: UCLA / Jonsson Comprehensive Cancer Center, Los Angeles, California

- Vorinostat and 177Lu-PSMA-617 for the Treatment of PSMA-Low Metastatic Castration-Resistant Prostate Cancer

  This phase II trial tests how well vorinostat works in treating patients with prostate-specific membrane antigen (PSMA)-low castration-resistant prostate cancer that has spread from where it first started (primary site) to other places in the body (metastatic) (mCRPC). Prostate cancer that has not spread to other parts of the body (localized) is typically treated through surgery or radiotherapy, which for many men is curable. Despite definitive local therapy, cancer that has come back after a period of improvement (recurrent) disease develops in 27-53% of men. Often this is detected by measurement of prostate-specific antigen (PSA) without visible evidence of metastatic disease. Lutetium Lu 177 vipivotide tetraxetan (177Lu-prostate specific membrane antigen [PSMA]-617) is a new small molecule PSMA-targeted radioactive therapy that has been approved by the Food and Drug Administration for the treatment of adult patients with PSMA-positive mCRPC who have been treated with androgen receptor inhibitors and taxane-based chemotherapy. Vorinostat is used to treat various types of cancer that does not get better, gets worse, or comes back during or after treatment with other drugs. Vorinostat is a drug which inhibits the enzyme histone deacetylase and may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth. Giving vorinostat and 177Lu-PSMA-617 may kill more tumor cells in in patients with PSMA-low mCRPC.

  Location: Fred Hutch/University of Washington/Seattle Children's Cancer Consortium, Seattle, Washington

- Pembrolizumab with 177Lu-PSMA-617 for the Treatment of Metastatic Castration-Resistant Prostate Cancer

  This phase II trial tests pembrolizumab with Lu 177 vipivotide tetraxetan (177Lu-prostate-specific membrane antigen [PSMA]-617) for treating patients with castration-resistant prostate cancer that has spread from where it first started (primary site) to other places in the body (metastatic). Metastatic castration-resistant prostate cancer (mCRPC)

keeps growing even when the amount of testosterone in the body is reduced to very low levels. Many early-stage prostate cancers need normal levels of testosterone to grow, but castrate-resistant prostate cancers do not. Because of this, traditional hormone therapy used to manage prostate cancer is no longer effective in stopping or slowing the disease. Immunotherapy with monoclonal antibodies, such as pembrolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Lutetium is a radioligand therapy (RLT). RLT uses a small molecule (in this case 177Lu-PSMA-617) that carries a radioactive component to destroy tumor cells. When lutetium is injected into the body, it attaches to the PSMA receptor found on tumor cells. After lutetium attaches to the PSMA receptor, its radiation component destroys the tumor cell. Pembrolizumab in combination with 177Lu-PSMA-617 may be more effective than traditional therapy in treating patients with metastatic castration-resistant prostate cancer.

Location: University of California San Francisco, San Francisco, California

- Abemaciclib before 177Lu-PSMA-617 for the Treatment of Metastatic Castrate Resistant Prostate Cancer

  This phase I/II trial tests the safety, side effects, and best dose of abemaciclib and whether it works before 177Lu-PSMA-617 in treating patients with castration resistant prostate cancer that has spread to other places in the body (metastatic). Abemaciclib is in a class of medications called kinase inhibitors. It is highly selective inhibitors of cyclin-dependent kinase 4 and 6, which are proteins involved in cell differentiation and growth. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. Radioligand therapy uses a small molecule (in this case 177Lu-PSMA-617), which carries a radioactive component to destroys tumor cells. When 177Lu-PSMA-617 is injected into the body, it attaches to the prostate-specific membrane antigen (PSMA) receptor found on tumor cells. After 177Lu-PSMA-617 attaches to the PSMA receptor, its radiation component destroys the tumor cell. Giving abemaciclib before 177Lu-PSMA-617 may help 177Lu-PSMA-617 kill more tumor cells.

  Location: University of California San Francisco, San Francisco, California

- Cabozantinib in Combination with Lutetium-177 for the Treatment of Metastatic Castration-Resistant Prostate Cancer, CaboLu Study

  This phase Ib trial tests the safety, side effects, and best dose of cabozantinb in combination with lutetium Lu 177 vipivotide tetraxetan (lutetium-177) in treating men with cancer that has spread from where it first started (primary site) to other places in the body (metastatic) and continues to grow and spread despite the surgical removal of the testes or mediation to block androgen production (castration). Cabozantinib binds to and inhibits small receptor tyrosine kinase (RTK), which is overexpressed in a variety of cancer types. Cabozantinib may help shrink tumors by blocking them from growing. Radioactive drugs, such as lutetium-177, may carry radiation directly to tumor cells and

not harm normal cells. Giving cabozantinib in combination with lutetium-177 may kill more tumor cells in patients with metastatic castration-resistant prostate cancer.

Location: Huntsman Cancer Institute/University of Utah, Salt Lake City, Utah

- Stereotactic Body Radiotherapy and 177Lu-PSMA-617 for the Treatment of Oligometastatic Prostate Cancer

  This phase I trial studies the feasibility of combining stereotactic body radiation therapy (SBRT) and 177Lu-prostate-specific membrane antigen (PSMA)-617 in patients with prostate cancer that has spread to a limited number of sites (oligometastatic). SBRT uses special equipment to position a patient and deliver radiation to tumors with high precision. This method may kill tumor cells with fewer doses over a shorter period and cause less damage to normal tissue. 177Lu-PSMA-617 specifically binds prostate cancer cells and may improve the effect of SBRT.

  Location: Memorial Sloan Kettering Cancer Center, New York, New York

- NEPC Study: An Exploratory Safety and Efficacy Study With PSMA, SSTR2 and GRPR Targeted Radioligand Therapy in Metastatic Neuroendocrine Prostate Cancer.

  The purpose of this study is to evaluate the change in the expression of treatment targets on the surface of tumor cells (Prostate Specific Membrane Antigen (PSMA), Somatostatin Receptor 2 (SSTR2), and Gastrin Releasing Peptide Receptor (GRPR) between the start and after the completion of radioligand therapy (RLT). Study will use radioligand imaging (RLI) to determine predominantly expressed target on the surface of tumor cells. Based on predominant expression of target, corresponding RLT targeting PSMA, SSTR2, or GRPR RLT will be given for up to 6 cycles every 6 weeks as intravenous (i.v.) injection in participants with metastatic neuroendocrine prostate cancer (mNEPC).

  Location: 2 locations

- A Phase II Study of AAA617 Alone and AAA617 in Combination With ARPI in Patients With PSMA PET Scan Positive CRPC

  The purpose of this study is to evaluate the efficacy and safety of AAA617 alone (Lutetium [177Lu] vipivotide tetraxetan) and in combination with an Androgen Receptor Pathway Inhibitors (ARPI) in participants with PSMA-positive, castration-resistant prostate cancer and no evidence of metastasis in conventional imaging (CI) (i.e., CT/MRI and bone scans). Approximately 120 participants will be randomized.

  Location: Cancer Therapy and Research Center at The UT Health Science Center at San Antonio, San Antonio, Texas

- Low PSMA SUV Boost (LPS-Boost): Intensified 177Lu-PSMA-617 Treatment for Patients With Metastatic Castrate-Resistant Prostate Cancer With Low PSMA Expressing Disease

  This phase II trial tests how well 177Lu-PSMA-617 works in treating patients with prostate cancer that has spread from where it first started (primary site) to other places in the body (metastatic) and that remains despite treatment (resistant). Lutetium Lu 177 (177Lu), the radioactive (tracer) component being delivered by prostate-specific membrane antigen (PSMA)-617, has physical properties that make it ideal radionuclide (imaging tests that uses a small dose tracer) for treatment of metastatic castrate-resistant prostate cancer (mCRPC). 177Lu-PSMA-617 works by binding to prostate cancer cells and inducing damage to deoxyribonucleic acid (DNA) inside prostate cancer cells. Giving 177Lu-PSMA-617 may improve treatment outcomes for patients with mCRPC.

  Location: 3 locations

- Stereotactic Body Radiation Therapy and 177Lu-PSMA-617 for the Treatment of Locally Advanced Prostate Cancer, STARLiT Trial

  This phase I/II trial studies the side effects and best dose of 177Lu-PSMA-617 when given together with stereotactic body radiation therapy (SBRT) and to see how well it works in treating patients with prostate cancer that has spread to nearby tissue or lymph nodes (locally advanced). Radioactive drugs, such as 177Lu-PSMA-617, may carry radiation directly to tumor cells and not harm normal cells. 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 177Lu-PSMA-617 with SBRT may work better in treating patients with locally advanced prostate cancer.

  Location: Case Comprehensive Cancer Center, Cleveland, Ohio

- Schedule De-Escalation of 177Lu-PSMA-617 for the Treatment of Metastatic Castrate Resistant Prostate Cancer

  This phase II trial studies how to improve the usage of Lu 177 vipivotide tetraxetan (177Lu-prostate-specific membrane antigen [PSMA]-617) for treating patients with castration-resistant prostate cancer that has spread from where it first started (primary site), to other places in the body (metastatic) utilizing a treatment pause after 5 cycles of therapy versus standard continuous treatment for 6 cycles. Lutetium is a radioligand therapy (RLT). RLT uses a small molecule (in this case 177Lu-PSMA-617) that carries a radioactive component to destroy tumor cells. When lutetium is injected into the body, it attaches to the PSMA receptor found on tumor cells. After lutetium attaches to the PSMA receptor, its radiation component destroys the tumor cell. Giving 177Lu-PSMA-617 for 5 cycles versus 6 cycles may better treat patients with metastatic castrate resistant prostate cancer.

Location: Mayo Clinic in Rochester, Rochester, Minnesota

- A Dosimetry Study of Lutetium (177Lu) rhPSMA-10.1 and Lutetium (177Lu) Vipivotide Tetraxetan (Pluvicto®) in Patients With Non-curative Metastatic Prostate Cancer

  A randomised, multi-centre, intra-patient imaging and dosimetry crossover study of lutetium (177Lu) rhPSMA 10.1 and lutetium (177Lu) vipivotide tetraxetan (Pluvicto®) in patients with non-curative metastatic prostate cancer

  Location: Emory University Hospital/Winship Cancer Institute, Atlanta, Georgia

triallibrary.com

Trial Library is a public benefit company with a mission to improve health equity by expanding access to cancer precision medicine.

We are a diverse team of experts who believe that health equity starts with patient and provider empowerment. Our technology is integrated with technology-enabled navigation to facilitate clinical trial discovery for anyone, anywhere.

This site is aimed primarily at physicians to help them refer their patients to clinical trials, but we patients can use it too. They engage with their expanding network of community partners to recruit qualified patients to clinical trials, ensuring equitable representation in oncology research

If you know your case history, treatments, and medications, it is fairly simple to go through the menu setup on the website. An example using the triallibrary search engine for prostate cancer trials within 250 miles of San Diego (note this covers most of southern California including a lot of dots on the map above) for a patient with mCRPC, having had surgery, radiation, ADT with Abiraterone and Enzalutamide, positive for mets on PSMA PET/CT scan, and no identified genetic anomalies, we get a list of 34 Phase 2 and 3 clinical trials, which can be sorted by probability of match or by distance.

Top 10 Matching trials out of 34 results currently recruiting

1. **FPI-2265 (225Ac-PSMA-I&T) for Patients with PSMA-Positive Metastatic Castration-Resistant Prostate Cancer (mCRPC)** Phase 2–3 Interventions / treatments • Drug: FPI-2265 Study design • Allocation: Randomized • Masking: None
2. Study of Oral MRT-2359 in Selected Cancer Patients Phase 1–2 Interventions / treatments • Drug: Oral MRT-2359 Study design • Allocation: Non-randomized • Masking: None
3. A Study of XmAb20717 (Vudalimab)in Patients With Selected Advanced Gynecologic and Genitourinary Malignancies Phase 2 Interventions / treatments • Biological: vudalimab Study design • Allocation: Not provided • Masking: None
4. Study of AZD5305 When Given in Combination With New Hormonal Agents in Patients With Metastatic Prostate Cancer Phase 1–2 Interventions / treatments • Drug: Abiraterone Acetate • Drug: Apalutamide • Drug: AZD5305 Study design • Allocation: Non-randomized • Masking: None
5. XmAb®20717 (Vudalimab) Alone or in Combination With Chemotherapy or Targeted Therapy in Patients With Metastatic Castration-Resistant Prostate Cancer Phase 2 Interventions / treatments • Biological: vudalimab monotherapy • Combination Product: vudalimab + cabazitaxel or docetaxel • Combination Product: vudalimab + carboplatin + cabazitaxel Study design • Allocation: Non-randomized • Masking: None
6. Study of AZD9574 as Monotherapy and in Combination With Anti-cancer Agents in Participants With Advanced Solid Malignancies Phase 1–2 Interventions / treatments • Drug: [11C]AZ1419 3391 • Drug: AZD9574 • Drug: Datopotamab Deruxtecan (Dato-DXd) Study design • Allocation: Non-randomized • Masking: None
7. The Evaluation of PC14586 in Patients With Advanced Solid Tumors Harboring a TP53 Y220C Mutation (PYNNACLE) Phase 1–2 Interventions / treatments • Drug: PC14586 • Drug: pembrolizumab Study design • Allocation: Non-randomized • Masking: None
8. Study of Dato-Dxd as Monotherapy and in Combination With Anti-cancer Agents in Patients With Advanced Solid Tumours (TROPION-PanTumor03) Phase 2 Interventions / treatments • Drug: 5-Fluorouracil • Drug: Bevacizumab • Drug: Capecitabine Study design • Allocation: Non-randomized • Masking: None

9. A Study to Investigate APL-5125 in Adults With Advanced Solid Tumors Phase 1–2
   Interventions / treatments • Drug: APL-5125 Study design •
   Allocation: Non-randomized • Masking: None
10. NUV-868 as Monotherapy and in Combination With Olaparib or Enzalutamide in Adult Patients With Advanced Solid Tumors Phase 1–2 Interventions / treatments • Drug: Enzalutamide • Drug: NUV-868 • Drug: Olaparib Study design •
    Allocation: Non-randomized • Masking: None

Do I Fit – Criteria Evaluation

Looking at the most probable trial opens the following window, Scanning the detailed trial description, our example patient discovers he needs to have been treated with Pluvicto LU177 prior. A treatment once every 6 weeks puts it in the realm of driving in so cal. He also discovers that since he may have bone and liver mets, he could be excluded. He remembers he had skin cancer at one time which was treated with Mohs surgery, which after careful reading looks like it wouldn't exclude. Also, since he has chronic peripheral neuropathy, he might or might not be excluded:

FPI-2265 (225Ac-PSMA-I&T) for Patients with PSMA-Positive Metastatic Castration-Resistant Prostate Cancer (mCRPC)

Brief summary

This is an open-label, randomized, multicenter study of FPI-2265 (225Ac-PSMA-I\&T). The dose optimization Phase 2 part will be investigating the safety, tolerability, and anti-tumor activity of novel dosing regimens of FPI-2265 in participants with PSMA-positive mCRPC who have been previously treated with 177Lu-PSMA-617 or another 177Lu-PSMA radioligand therapy (RLT).

Detailed description

The purpose of the dose optimization segment (Phase 2) is to determine the recommended FPI-2265 dose and regimen. Conclusions from Phase 2 will be based on safety, tolerability, and anti-tumor activity. Participants with PSMA positive scans will be randomized (1:1:1) to one of three different dosing arms:
Arm 1: Will consist of nine doses of FPI-2265, administered every four weeks at 50 kBq/kg.
Arm 2: Will consist of six doses of FPI-2265, administered every six weeks at 75 kBq/kg.
Arm 3: Will consist of four doses of FPI-2265, administered every eight weeks at 100 kBq/kg.
Participants will be monitored and assessed for efficacy response, disease progression and adverse events.

Criteria

Key Inclusion Criteria:
* Ability to understand and sign an approved informed consent form (ICF) and comply with all

protocol requirements.
* Phase 2: Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1
* Diagnosis of adenocarcinoma of prostate proven by histopathology.
* Must have had prior orchiectomy and/or ongoing **androgen-deprivation therapy** and a castrate level of serum/plasma testosterone
* Progressive **mCRPC**.
* Must have been **previously treated with lutetium-PSMA therapy (lutetium-177 vipivotide tetraxetan or other lutetium-177-PSMA RLT).** Treatment must have been completed \>6 weeks prior to the first dose of study drug.
* Participants with known **BRCA** mutations should have received FDA-approved therapies such as *PARP inhibitors*, per Investigator discretion.
* Positive **PSMA PET/CT scan**
* Adequate organ function
* For participants who have partners of childbearing potential: Partner and/or participant must not be planning to conceive and must use a method of birth control with adequate barrier protection deemed acceptable by the Principal Investigator during the study treatment and for six months after last study drug administration.

Key Exclusion Criteria:
* Participants who received more than two prior lines of cytotoxic **chemotherapy** for CRPC.
* Phase 2: participants *who progress within two cycles of prior treatment with 177Lu-PSMA therapy*
* All prior treatment-related adverse events must have resolved to Grade ≤1 (CTCAE v5.0). Alopecia and stable persistent *Grade 2 peripheral neuropathy* may be allowed at the discretion of the Investigator.
* Participants with known, unresolved, urinary tract obstruction are excluded.
* Administration of any systemic cytotoxic or investigational therapy ≤30 days of the first dose of study treatment or five half-lives, whichever is shorter. Completion of large-field external beam radiotherapy ≤four weeks of the first dose of study treatment.
* Participants with a history of central nervous system (CNS) metastases are excluded except those who have received therapy
* Participants with any *liver metastases* will be excluded from the Phase 2 segment of the study.
* Participants with *skeletal metastases* presented as a superscan on a ^{99m}Tc bone scan.
* **Previous or concurrent cancer** that is distinct from the cancer under investigation in primary site or histology, except treated cutaneous basal cell carcinoma or squamous cell carcinoma and superficial bladder tumors. Any cancer curatively treated \>two years prior to the first dose of treatment is permitted.
* Concurrent serious (as determined by the investigator) medical conditions
* Major surgery ≤30 days prior to the first dose of study treatment.

SparrowSearch.com

They started Sparrow Search because they believe in the power of clinical research to save lives, and wanted to bridge the gap between pharmaceutical companies looking for patients for their clinical trials, and patients looking for the best treatment possible. More than 71% of people worldwide who have never participated in a clinical trial say they would be willing to do so, yet only 0.2% of physicians say

they actively refer patients to clinical trials, and more than half of all clinical trial delays are related to recruitment problems. Their model works flips the usual clinical trial recruitment method on its head. They find trials for patients.

Now let's take the same patient, and go through the Sparrow Search engine https://sparrowsearch.health/. He will have to create a login and validate with email confirmation. Then he will have to enter details of his clinical treatment history, as well as his address and distance for screening trials up to 100 miles (next is global screening, no fractional PSA even if you are post radical). The results for the same patient, recruiting trials, is 70 trials. Here is the first page of trials

- **NCT ID Title Am I Eligible Intervention Distance (Miles) Status**

1. NCT06056791 Study of INKmune in Patients With mCRPC (CaRe Prostate) potentially eligible BIOLOGICAL : INKmune 99.33 Recruiting
2. NCT03860272 Fc-Engineered Anti-CTLA-4 Monoclonal Antibody in Advanced Cancer potentially eligible DRUG : Botensilimab 95.1 Recruiting DRUG : Balstilimab
3. NCT05794906 A Study to Compare Darolutamide Given With Androgen Deprivation Therapy (ADT) With ADT in Men With Hormone Sensitive Prostate Cancer and Raise of Prostate Specific Antigen (PSA) Levels After Local Therapies potentially eligible DRUG : Darolutamide (BAY1841788, Nubeqa) 71.01 Recruiting OTHER : Placebo matching darolutamide OTHER : ADT
4. NCT06084338 Randomized Phase II Trial of Targeted Radiation With no Castration for Mcrpc potentially eligible RADIATION : stereotactic ablative radiotherapy 83.13 Recruiting DRUG : Pluvicto DRUG : topical testosterone
5. NCT06228053 Study of SX-682 Plus Enzalutamide in Men With Abiraterone-Resistant Metastatic Castration Resistant Prostate Cancer potentially eligible DRUG : SX-682 99.33 Recruiting DRUG : Enzalutamide
6. NCT04221542 Study of AMG 509 in Participants With Metastatic Castration-Resistant Prostate Cancer potentially eligible DRUG : AMG 509 78.05 Recruiting DRUG : Abiraterone DRUG : Enzalutamide
7. NCT04585750 The Evaluation of PC14586 in Patients With Advanced Solid Tumors Harboring a TP53 Y220C Mutation (PYNNACLE) potentially eligible DRUG : PC14586 99.33 Recruiting DRUG : pembrolizumab
8. NCT ID Title Am I Eligible Intervention Distance (Miles) Status
9. NCT04848337 Pembrolizumab and Lenvatinib in Advanced/Metastatic Neuroendocrine Prostate Cancer potentially eligible DRUG : Pembrolizumab 95.1 Recruiting DRUG : Lenvatinib
10. NCT05107674 A Study of NX-1607 in Adults With Advanced Malignancies potentially eligible DRUG : NX-1607 95.1 Recruiting DRUG : Paclitaxel
11. NCT05458544 [Lu-177]Ludotadipep in Castration-resistant Prostate Cancer(CRPC): Investigation of Drug and Application potentially eligible DRUG : [177Lu]Ludotadipep 3.7 GBq 99.33 Recruiting

While there is a local page for each trial, I prefer the ClinicalTrials.gov page. Now let's look at write-up of the first trial on the list at clinical trials.gov.

Study Overview

Brief Summary

This is an open-label, phase I/IIa dose escalation and expansion study of INKmune in men with mCRPC. INKmune is administered to patients intravenously over three doses, at least one-week apart. The study will consist of two stages.

Detailed Description

This is an open-label, phase I/IIa dose escalation and expansion study of INKmune in men with mCRPC. INKmune is administered to patients intravenously over 3 doses. The 3 infusions will occur over a minimum of a 2-week period, with each infusion at least 1 week apart. The study will consist of 2 stages:

- Dose escalation: exploring dose levels of 1x10^8, 3x10^8, and 5x10^8 cells per infusion.
- Dose expansion: following mBOIN termination and maximum tolerated dose (MTD) identification, patients will be enrolled in up to 2 candidate optimal dose levels for final optimal dose determination.

Eligible patients will sign informed consent prior to any study assessments being performed. Patients have up to 30 days in which to have all screening procedures and eligibility assessed. Patients will be infused with INKmune on Days 1, 8, and 15. Patients will also present to site on days 29, 57, 85, 113, and 141 to complete study assessments. Day 169 is the last study visit and patient will have completed trial after this visit has been completed. Option to enroll in the INKmune Long term Follow-up Registry will be presented at Day 169 visit.
Show less

Official Title

An Open-label, Phase I/IIa Dose Escalation and Expansion Study to Determine the Safety and Clinical Activity of an Immune Priming Cell Therapy (INKmune) in Patients With Metastatic Castration Resistant Prostate Cancer (mCRPC)

Conditions
Cancer
Metastatic Castration-resistant Prostate Cancer
mCRPC
Intervention / Treatment Biological: INKmune
Other Study ID Numbers INMB-INB16-003
Study Start (Actual) 2023-11-30
Primary Completion (Estimated) 2025-05-30
Study Completion (Estimated) 2025-11-30
Enrollment (Estimated) 30
Study Type Interventional
Phase Phase 1Phase 2
MedlinePlus Genetics related topics: Prostate cancer
FDA Drug and Device Resources

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.

Study Contact
Name: Nicole Kay-Mindick
Phone Number: 386 852 2361
Email: nmindick@inmunebio.com

This study has 8 locations
United States

California Locations

Los Angeles, California, United States, 90073 Recruiting VA Greater Los Angeles Healthcare System Principal Investigator: Matthew Rettig, MD

Los Angeles, California, United States, 90095 Recruiting University of California, Los Angeles Contact: Ankush Sachdeva asachdeva@mednet.ucla.edu Principal Investigator: Matthew Rettig, 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.
Eligibility Criteria
Description
Inclusion Criteria:

1. Male subjects over 18 years of age at time of screening.
2. Blood Prostate Specific Antigen (PSA) of >1.0 ng/ml at time of screening.
3. Eastern Cooperative Oncology Group (ECOG) Performance Status 0-1 at time of screening.
4. Histologic confirmation of adenocarcinoma prostate cancer.
5. A diagnosis of progressive metastatic castrate resistant prostate cancer (mCRPC), as defined by Prostate Cancer Clinical Trials Working Group 3 (PCWG3), following androgen deprivation therapy (ADT) and at least one androgen receptor signaling inhibitor, but not more than 3 therapies in addition to ADT. Progressive disease at the time of study entry as indicated by at least one of the following:
    - i. At least two rising PSA values at a minimum of a one-week interval. If PSA is the only measure of progression, then the minimum PSA value at the start of treatment must be ≥ 1 ng/mL.
    - ii. Radiographic progression per RECIST1.1 for soft tissue (at least 1 measurable lesion per RECIST 1.1), and/or
    - iii. Progression of bone metastases.
6. Castrate level of testosterone of < 50 ng/dL.
7. Adequate organ function indicated by the following laboratory parameters:
    - i. Hemoglobin ≥ 8.0 g/dL.

- ii. White Blood Cell Count (WBC) ≥ 3.0 x 10^9/L.
- iii. Lymphocytes ≥ 80% LLN
- iv. Absolute Neutrophil Count (ANC) ≥ 1.5 x 10^9/L.
- v. Platelets ≥ 100 x 10^9/L.
- vi. PT and APTT < 1.5x ULN (unless receiving therapeutic anticoagulation).
- vii. AST or ALT ≤ 2.5x ULN. AST or ALT ≤ 5x ULN for patients with liver metastases.
- viii. Bilirubin < 1.5x ULN (< 3x ULN in Gilbert's Syndrome).
- ix. Creatinine clearance/estimated GFR ≥ 30 mL/min (MDRD or Cockcroft-Gault).
- x. Resting room air PaO2 saturation of >95% as measured by pulse oximetry.

8. Negative screen for Human Immunodeficiency virus (HIV), Hepatitis B virus (HBV) antigen, and Hepatitis C virus (HCV). If testing was done within the past three months, there is no need to repeat testing if documentation of results is provided to the study site.
9. Subjects and their partners of reproductive potential must agree to use an effective form of contraception during the period of drug administration and for three months following the completion of the last administration of the study drug. An effective form of contraception is defined as oral contraceptives plus one form of barrier method or double barrier methods (condom with spermicide or condom with diaphragm).
10. Subjects must be able to understand the potential risks and benefits of the study and be able to read and give written informed consent.

Exclusion Criteria:

The participant may not enter the study if ANY of the following apply:

1. Diagnosis of small cell/neuroendocrine prostate cancer. Immunohistochemical staining for neuroendocrine markers (e.g., chromogranin A, neuron-specific enolase, and synaptophysin) is not sufficient to establish a small cell/neuroendocrine histology; morphologic features that are characteristic of small cell/neuroendocrine prostate cancer are required to confirm the presence of small cell/neuroendocrine prostate cancer.
2. History of concurrent malignant cancer within previous 3 years, with the exception of in situ carcinomas and non-melanoma skin cancer. If diagnosis or treatment for other cancers have occurred in the last 3 years, further discussion needed.
3. Uncontrolled autoimmune disease including, but not limited to, systemic lupus erythematosus, rheumatoid arthritis, ulcerative colitis, Crohn's disease, temporal arteritis, and thyroiditis. Autoimmune conditions that are well-controlled in the opinion of the investigator must first be discussed with the Sponsor prior to enrollment.
4. A requirement for daily systemic corticosteroids for any reason; or other immunosuppressive or immunomodulatory agents. Topical, nasal, modified-release oral, and/or physiologic corticosteroids may be permitted following discussion with the Sponsor.
5. Clinically significant cardiac disease (New York Heart Association Class III/IV) or severe debilitating pulmonary disease.
6. Patients with a current or recent history, as determined by the Investigator, of clinically significant, progressive, and/or uncontrolled renal, hepatic, hematological, endocrine, pulmonary, cardiac, gastroenterological, or neurological disease.
7. Cytotoxic chemotherapy within three weeks prior to start of study treatment (Day 1).
8. Radiation therapy within two weeks prior to start of study treatment (Day 1).
9. Patients may not have received a previous NK based therapy.
10. Evidence of central nervous system (CNS) metastatic disease at screening.

11. Patients with an active infection requiring antibiotic treatment within seven days of starting study treatment (Day 1).
12. Administration of live attenuated vaccines within eight weeks of start of study treatment (Day 1) and throughout the study.
13. Any other medical condition that in the opinion of the Investigator may interfere with a subject's participation in, or compliance with, the study
14. Participation in a therapeutic research study or receipt of an investigational drug within 4 weeks of start of treatment (Day 1) or 5 half-lives, whichever occurs first.
15. Expected survival of less than six months
16. At the time of consent, unable to comply with study procedures and assessments.

Going Global in your Search

If you can't find a trial that fits your needs in the US, there are several international sites which have some trials not covered in the US. We know that a lot of the early work in radio-ligand therapy with gallium and lutetium was done in Germany and Australia, before anything was done in the US. Some say the FDA's to blame. Several doctors from Europe came to UCLA to carry on work in this area. Luckily for us, the world wide web makes it easy to go global. It might particularly be beneficial to have an oncologist who is willing to help with this, with connections who can help evaluate the likely benefit of some of these trials. Particularly if you are the advanced stage of mCRPC, this might be of interest, so I've included a few sites here:

Mexico

Finding prostate cancer clinical trials in Mexico involves utilizing various resources to identify ongoing studies and understanding their eligibility criteria.Here are some steps and references to assist you:

1. ClinicalTrials.gov

This is a comprehensive database of privately and publicly funded clinical studies conducted worldwide.ou can search for prostate cancer trials in Mexico by using specific filters.

- **Website**: ClinicalTrials.gov

How to Search:

- Enter "prostate cancer" in the "Condition or disease" field.- input "Mexico" in the "Country" field.-R eview the list of trials, noting their status (recruiting, active, completed) and eligibility criteria.

2. National Institutes of Health (NIH) Clinical Research Studies

he NIH provides a platform to search for clinical research studies, including those related to prostate cancer in Mexico.

- **Website**: NIH Clinical Research Studies

3. Mexican Health Institutions and Research Centers

everal institutions in Mexico conduct clinical trials for prostate cancer.ontacting these centers can provide information on ongoing or upcoming studies:

- **Instituto Nacional de Cancerología (INCan)**: leading cancer research institute in Mexico. - **Website**: INCan
- **Centro Médico Nacional Siglo XXI**: art of the Mexican Social Security Institute (IMSS), this center often conducts clinical trials. - **Website**: CMN Siglo XXI

4. Pharmaceutical Companies

ome pharmaceutical companies sponsor clinical trials in Mexico.or example, AstraZeneca has conducted studies on prostate cancer treatments in the country.

- **AstraZeneca Clinical Trials**: nformation on their studies can be found here: - **Website**: AstraZeneca Clinical Trials

5. Local Hospitals and Oncology Centers

Many hospitals and specialized oncology centers in Mexico participate in clinical trials. Consulting with your healthcare provider or contacting local hospitals can provide leads on available trials.

6. Patient Advocacy Groups

Organizations dedicated to prostate cancer awareness and support may have information on clinical trials and can assist in connecting patients with research opportunities.

Considerations Before Participation:

- **Eligibility**: ach trial has specific inclusion and exclusion criteria.nsure you meet these requirements before applying.
- **Risks and Benefits**: nderstand the potential risks and benefits of participating in a clinical trial.iscuss these with your healthcare provider.
- **Informed Consent**: efore joining, you'll be asked to sign an informed consent form detailing the study's purpose, procedures, risks, and benefits. articipating in a clinical trial is a significant decision.t's essential to consult with your healthcare provider to determine the best course of action based on your individual health needs.

European (Euro) Clinical trials for prostate cancer

PIONEER

prostate-pioneer.eu

For patients - PIONEER - European Network of Excellence for Big Data in Prostate Cancer

Critical knowledge gaps in prostate cancer

Critical knowledge gaps in relation to the screening, diagnosis and treatment of prostate cancer patients make clinical practice decision-making difficult and inconsistent; this means that predicting which patients will have the best outcomes with specific treatments is currently suboptimal. These gaps are dispersed throughout the patient's journey (from diagnosis to treatment) and they compromise the quality of care provided to patients, as well as affecting their quality of life.

At the start of PIONEER, the EAU Prostate Cancer Guideline panel and other Key Opinion Leaders were contacted to identify the most important knowledge gaps. Afterwards, the PIONEER consortium performed a prioritisation survey among two stakeholder groups: healthcare professionals including pharmaceutical companies and prostate cancer patients to identify and prioritise a list of the top five research questions in prostate cancer.

In total, 73 healthcare professionals and 57 patients participated in round one of the surveys. Twelve questions were proposed during the first round. For the second round the patients' surveys were also translated into French, German, Italian and Spanish. Forty nine healthcare professionals and 169 patients (including 53 English; 19 French; 31 German; 53 Italian; 13 Spanish) participated in round two of the surveys. The results were analysed by calculating the percentage of respondents scoring each question as not important, important or critically important. These 56 questions were then re-ordered according to the highest percentage for "critically important", enabling identification of the top 5 questions from the two each stakeholder groups.

PIONEER's top five research questions are:

1. What are the relevant tumour-specific and patient-specific variables that affect prognosis of PCa patients suitable for active surveillance?
2. What is the natural history of PCa patients undergoing conservative management (i.e., watchful waiting) and what is the impact of comorbidities and life expectancy on long-term outcomes?
3. Currently, the scientific community generally applies the EAU Guidelines PCa risk stratification, stratifying patients into low-, intermediate- and high-risk PCa. This is based on the risk of recurrent disease of patients after radical treatments. However, this risk stratification still has its limits and patients still have very heterogeneous outcomes especially in the high-risk group. What we still do not know is what differentiates patients with lethal vs non-lethal disease, irrespective of their risk stratification.
4. When should we treat patients, who experience prostate cancer recurrence after primary treatment, and which are the most effective therapeutic approaches?
5. Which specific patient groups benefit most of upfront chemotherapy? What are the side effects and What is impact on quality of life in real-life practice of chemotherapy in this setting?

For more information on how these questions will be addressed in PIONEER read our data analytics and research team overview.

For more patient friendly information on the project in general download the PIONEER Patient Brochure

European Union Clinical Trials Register

The European Union Clinical Trials Register allows you to search for protocol and results information on:

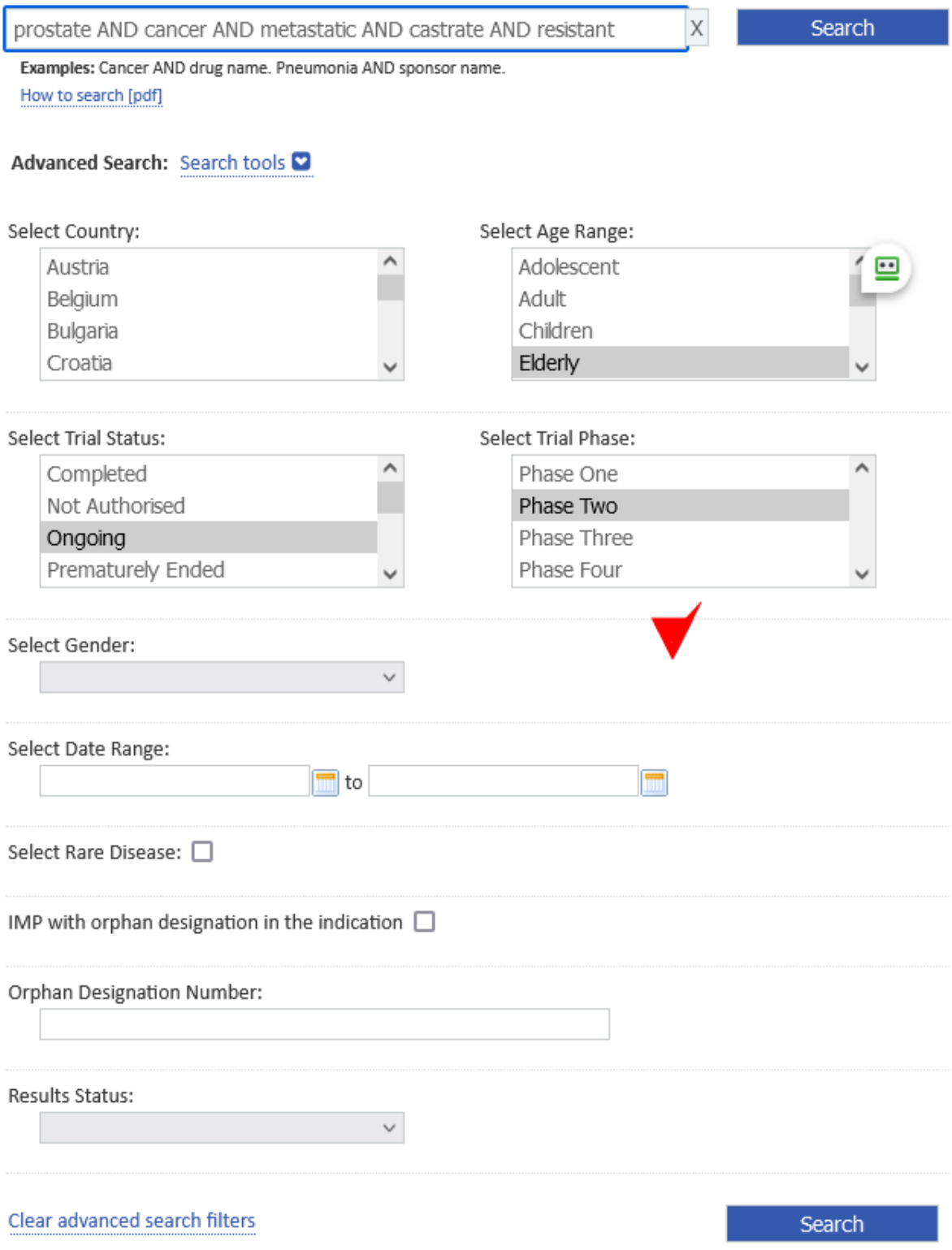
- interventional clinical trials that were approved in the European Union (EU)/European Economic Area (EEA) under the Clinical Trials Directive 2001/20/EC
- clinical trials conducted outside the EU/EEA that are linked to European paediatric-medicine development

EU/EEA interventional clinical trials approved under or transitioned to the Clinical Trial Regulation 536/2014 are publicly accessible through the Clinical Trials Information System (CTIS).

The EU Clinical Trials Register currently displays **44294** clinical trials with a EudraCT protocol, of which **7351** are clinical trials conducted with subjects less than 18 years old. The register also displays information on **18700** older paediatric trials (in scope of Article 45 of the Paediatric Regulation (EC) No 1901/2006).

Phase 1 trials conducted solely on adults and that are not part of an agreed paediatric investigation plan (PIP) are not publicly available (see Frequently Asked Questions).

Here's the first page of an example search result:



First page of 13 trials for mCRPC recruiting search results:

13 result(s) found for: prostate AND cancer AND metastatic AND castrate AND resistant. Displaying page 1 of 1.

EudraCT Number: 2016-004091-21 **Sponsor Protocol Number:** UCL/16/0587 **Start Date*:** 2017-08-23

Sponsor Name: University College London

Full Title: Nivolumab and ipilimumab treatment in prostate cancer with an immunogenic signature

Medical condition: Metastatic castrate resistant prostate cancer (prostate adenocarcinoma)

Disease:	Version	SOC Term	Classification Code	Term	Level
	21.0	100000004864	10001198	Adenocarcinoma of the prostate metastatic	LLT

Population Age: Adults, Elderly **Gender:** Male

Trial protocol: GB *(GB - no longer in EU/EEA)*

Trial results: *(No results available)*

EudraCT Number: 2020-001240-25 **Sponsor Protocol Number:** MOURO48 **Start Date*:** Information not available in EudraCT

Sponsor Name: Radboudumc

Full Title: Phase 2 INSPIRE trial: Ipilimumab with Nivolumab in molecular-selected patients with castration-resistant prostate cancer

Medical condition: (metastatic) castration-resistant prostate cancer

Disease:

Population Age: Adults, Elderly **Gender:** Male

Trial protocol: NL *(Ongoing)*

Trial results: *(No results available)*

EudraCT Number: 2013-003520-37 **Sponsor Protocol Number:** D081DC00008 **Start Date*:** 2014-02-04

Sponsor Name: AstraZeneca AB

Full Title: A Randomised, Double-Blind, Placebo-Controlled, Multicentre Phase II Study to Compare the Efficacy, Safety and Tolerability of Olaparib Versus Placebo When Given in Addition to Abiraterone Treatmen...

Medical condition: metastatic castrate-resistant prostate cancer

Disease:	Version	SOC Term	Classification Code	Term	Level
	18.1	10029104 - Neoplasms benign, malignant and unspecified (incl	10036909	Prostate cancer metastatic	PT

One of the results expended. You have to click through to get the details:

Summary	
EudraCT Number:	2020-001240-25
Sponsor's Protocol Code Number:	MOURO48
National Competent Authority:	Netherlands - Competent Authority
Clinical Trial Type:	EEA CTA
Trial Status:	Ongoing
Date on which this record was first entered in the EudraCT database:	2020-07-02
Trial results	

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D. IMP IDENTIFICATION
D.8 INFORMATION ON PLACEBO
E. GENERAL INFORMATION ON THE TRIAL
F. POPULATION OF TRIAL SUBJECTS
G. INVESTIGATOR NETWORKS TO BE INVOLVED IN THE TRIAL
N. REVIEW BY THE COMPETENT AUTHORITY OR ETHICS COMMITTEE IN THE COUNTRY CONCERNED
P. END OF TRIAL

Australia Trials

In Australia, the primary group conducting prostate cancer clinical trials is the **Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)**, which offers a range of trials for different stages of prostate cancer, with a focus on new treatments like immunotherapy combinations and targeted therapies like Lu-PSMA. [1, 2, 3, 4]

Key points about prostate cancer clinical trials in Australia: [1, 2, 4]

- **Main organization:** ANZUP is the primary group running prostate cancer clinical trials across Australia and New Zealand. [1, 2, 4]
- **Treatment focus:** Many trials are investigating new treatments like immunotherapy drugs (e.g., Nivolumab) in combination with other therapies, as well as targeted therapies like Lu-PSMA which can specifically target prostate cancer cells. [3, 4, 5]
- **Notable trials:** [1, 4]
  - **TheraP trial:** Compared Lu-PSMA to standard chemotherapy (cabazitaxel) for advanced prostate cancer, showing promising results with less severe side effects. [1, 4]
  - **EVOLUTION trial:** Investigates the combination of Lu-PSMA with immunotherapy drugs (Ipilimumab and Nivolumab) to treat advanced prostate cancer. [5, 6]
- **Accessing trials:** To find out about available prostate cancer clinical trials in Australia, contact your doctor or reach out to the Prostate Cancer Foundation of Australia (PCFA) for information and support. [2, 4, 7]

References.

[1] https://www.prostate.org.au/treatments-side-effects/clinical-trials/

[2] https://www.pcfa.org.au/news-media/news/a-look-at-current-clinical-trials-for-prostate-cancer/
[3] https://australianprostatecancer.org.au/news-stories/latest-news/clinical-trial-brings-hope/
[4] https://anzup.org.au/clinical-trial/therap-trial/
[5] https://anzup.org.au/clinical-trial/evolution/
[6] https://ctc.usyd.edu.au/our-research/research-areas/cancer/cancer-divisions/urogenital-prostate-cancers/open-trials/evolution/
[7] https://www.canceraustralia.gov.au/cancer-types/prostate-cancer/research-and-clinical-trials

Cost and Time Commitments _

Less cost than usual care
More time commitment than usual care
Additional travel commitments

Primary Sponsor:
Commercial sector/Industry
AdvanCell Isotopes Pty Ltd
L 7, 167 Macquarie St,
Sydney. NSW 2000
Australia

Secondary Sponsor:
None

Commercial sector/Industry
AdvanCell Isotopes Pty Ltd
L 7, 167 Macquarie St,
Sydney. NSW 2000
Australia

Australian Cancer Trials is not designed to provide medical advice or professional services and is intended to be for informational use only. The information provided through Australian Cancer Trials is not a substitute for professional care and should not be used for diagnosing or treating a health problem or a disease. If you have, or suspect you may have, a health problem consult your doctor.

Cancer Australia Search

Who is it for?

This website is for those who have cancer and are considering taking part in a trial to test a new treatment. It's for family, friends and also cancer specialists, to provide easy access to the very latest information about clinical trials.

How do I use this website?

This website is an information resource, to help you find out more about cancer trials as a basis for discussion with a cancer specialist. It is not a substitute for a discussion.

Who has funded this website?

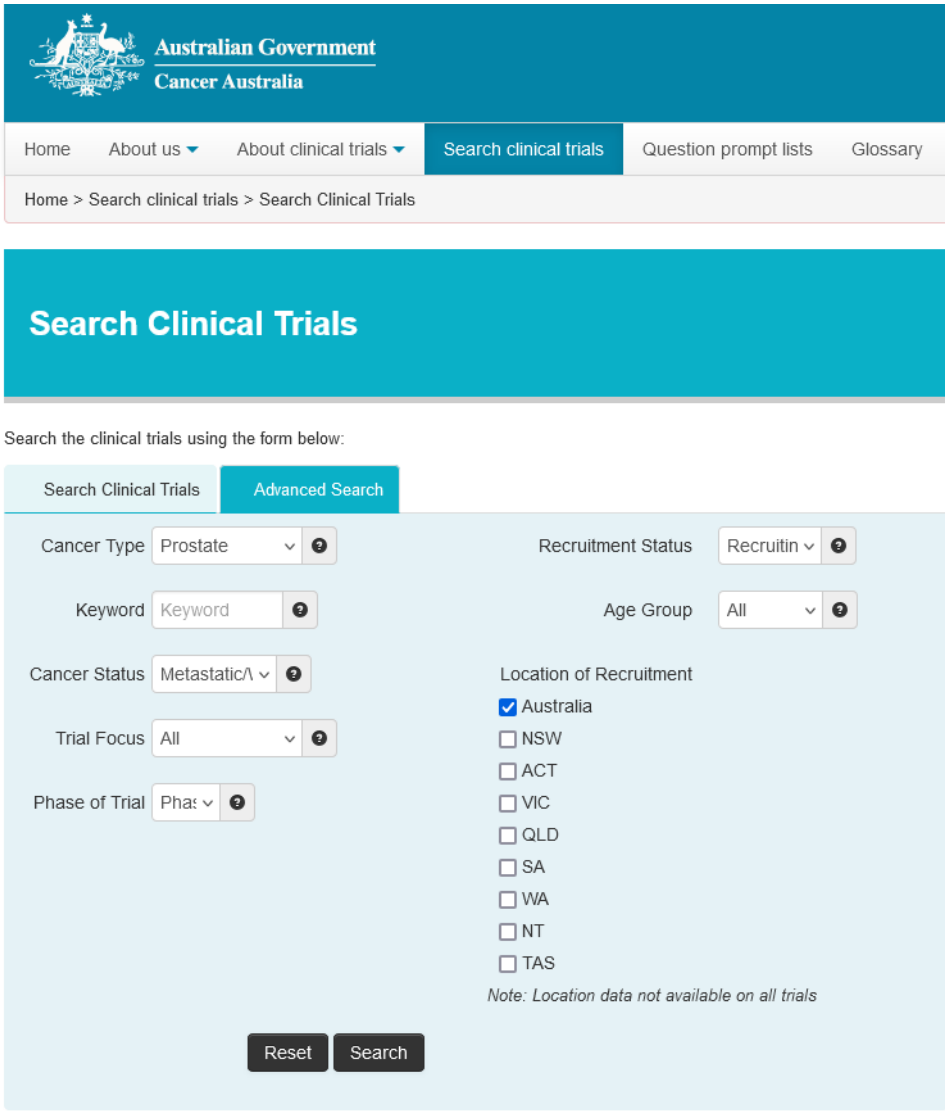
This project has been funded by Cancer Australia, with partial funding from a National Health and Medical Research Council (NHMRC) grant.

What service does it offer?

Australian Cancer Trials provides a database of research trials that are currently being carried out in Australia to find better ways of treating cancer. Some of these trials may offer treatment options that would not otherwise be available to you, your friends or family.

The website provides detailed information about cancer clinical trials. It offers people affected by cancer a 'Plain English' guide, which is comprehensive, accurate and brought up to date on a weekly basis. I found it easier to use than any sites I tried in the US.

Here's the search window for the website:



Sample Australian Search Results

Here's the first page 10 of 32 resulting trials from the above search. A lot of them have NCT numbers, and hence may have come up in the CancerTrials.gov search, but there are some significant ones unique to this database.

- 1. A Study of Two Dose Levels of Vobramitamab Duocarmazine in Participants With Metastatic Castration Resistant Prostate Cancer | Tamarack Status:Recruiting | Trial ID:NCT05551117 Recruitment date:13/06/2023 more info

- 2. Dose Escalation and Efficacy Study of 212Pb-ADVC001 in Patients With Metastatic Castration Resistant Prostate Cancer. Status:Recruiting | Trial ID:NCT05720130 Recruitment date:15/03/2023 more info

- 3. Phase II Randomised Controlled Trial of Patient-specific Adaptive vs. Continuous Abiraterone or eNZalutamide in mCRPC | ANZadapt Status:Recruiting | Trial ID:NCT05393791
Recruitment date:10/11/2022 more info

- 4. An early phase clinical trial to measure the safe dose of a new alpha-radiopharmaceutical for the treatment of advanced prostate cancer | TheraPb-phase I/II Status:Recruiting | Trial ID:ACTRN12622001378718
Recruitment date:26/10/2022 more info

- 5. EValuation of radIOLigand Treatment in mEn With Metastatic Castration-resistant Prostate Cancer With [161Tb]Tb-PSMA-I&T | VIOLET Status:Recruiting | Trial ID:NCT05521412
Recruitment date:29/09/2022 more info

- 6. Combination of Radium-223 and Lutetium-177 PSMA-I&T in Men With Metastatic Castration-Resistant Prostate Cancer | AlphaBet Status:Recruiting | Trial ID:NCT05383079
Recruitment date:13/09/2022 more info

- 7. External Beam Therapy With Theranostic Radioligand Therapy for Oligometastatic Prostate Cancer (ProstACT TARGET) Status:Recruiting | Trial ID:NCT05146973
Recruitment date:30/08/2022 more info

- 8. Copper-64 SAR Bombesin in PSMA Negative Prostate Cancer (BOP) | BOP
Status:Recruiting | Trial ID:NCT05613842
Recruitment date:09/08/2022 more info

- 9. Evolocumab in Metastatic Castration-Resistant Prostate Cancer Status:Recruiting | Trial ID:ACTRN12622001003763
Recruitment date:18/07/2022 more info

- 10. Cabazitaxel in Combination With 177Lu-PSMA-617 in Metastatic Castration-resistant Prostate Cancer | LuCAB Status:Recruiting | Trial ID:NCT05340374
Recruitment date:14/07/2022

Clinical Trials Details

australiancancertrials.gov.au

As an example, here ares the details for number 4 on the list, ID:ACTRN12622001378718 which is Australia unique, testing out a new alpha emitter radio-ligand therapy.

An early phase clinical trial to measure the safe dose of a new alpha-radiopharmaceutical for the treatment of advanced prostate cancer | TheraPb-phase I/II

Prof Stephen Rose
Head of Clinical Development, AdvanCell Isotopes Pty Ltd, Level 7, Macquarie House, 167 Macquarie Street, Sydney, NSW, 2000, Australia.
+61 498 322 488 (phone)
+61 2 8000 4198 (fax)
contact@advancell.com.au
Australia

Treatment: Radiotherapy
Treatment: Targeted and biological therapies

Anticipated start date
03/04/2023

Anticipated end date
28/06/2024

The aim of this study is to determine the maximum safe and effective dose of a novel therapeutic ADVC001 complexed with the radio-isotope alpha-212 ([212Pb]Pb-ADVC001) for the treatment of metastatic prostate cancer.

Who is it for?
You may be eligible for this study if you are aged 18 years or older, have a diagnosis of metastatic adenocarcinoma of the prostate, and have received at least one cycle of androgen receptor therapy and exposure to a taxane-based chemotherapy.

Study details
All participants will receive treatment with four cycles of [212Pb]Pb-ADVC001. The intervention will be administered intravenously on day 1 during each 6-week cycle. Participants will be monitored for any adverse events for up to 36 weeks after commencing therapy, and will undergo imaging and blood tests for the duration of treatment to determine their response to therapy. Participants will also have blood samples collected to determine how the study drug is metabolised by the body.

It is hoped that this study may help to determine the maximum dose at which [212Pb]Pb-ADVC001 is both safe and effective for the treatment of metastatic prostate cancer. This may help to direct how this novel treatment is used for individuals with metastatic prostate cancer in future.

Description of the Control
No control group.

Description of the Intervention
Treatment with a novel therapeutic ADVC001 complexed with 212-Pb (an alpha emitting radio-isotope). Patients with metastatic prostate adenocarcinoma are treated around every six weeks (for four cycles in total). There is no control group.

The starting dose is 60MBq. We are not dosing per kg; as is normal clinically in this patient group in Australia.

The cohorts will be escalated: 60 / 90 / 120/ 150 MBq

We intend 4 cohorts of three patients
All treatment is given by intravenous infusion

The frequency is intended to be 6 weekly but it can be +/- 2 weeks
At the completion of each cohort the data will be reviewed by the Safety Review Committee (SRC) and only if we have not reached a dose limiting toxicity (DLT) will the next cohort be enrolled. Under the 3+3 design if 2 of the 3 patients develop a DLT we will recruit 3 further patients at that dose level. A waiting period of 56 days will occur between cohorts. Within the cohort we will delay the patient (for a haematological DLT) and/or reduce dose at investigator discretion. The cohort will be treated (for cycle 1 and then 56 days after administration of the last patient in the dose escalation cohort (of three patients); the next cohort can be enrolled assuming the SRC are happy with the next cohort going ahead.

The radiopharmaceutical dose undergoes extensive quality assurance (QA) prior to administration so we know the exact activity injected; and this is a time critical dose. The time of the infusion will be recorded. Patient measurements will be taken at cycle one (C1) over the next 12 hours until it is safe to discharge.

Allocation to Intervention
Non-randomised trial

Incidence and severity of adverse events (AEs) and serious adverse events (SAEs), assessed in accordance with National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.
Up to Week 36 after starting treatment

Incidence and severity of dose-limiting toxicities, assessed in accordance with NCI CTCAE V5.
Up to Week 6 after starting treatment

Frequency of clinically significant changes from baseline in clinical chemistry and hematology blood laboratory values.

Frequency of clinically significant changes from baseline in clinical chemistry and hematology blood laboratory values.
Up to Week 36 after starting treatment

Whole body biodistribution and organ radiation dosimetry of [212Pb]Pb-ADVC001 from dosimetry scans
Up to Week 19 after starting treatment

Comparability of biodistribution of [212Pb]Pb-ADVC001 to PSMA targeting positron emission tomography (PET) imaging agents
Up to Week 19 after starting treatment

Therapeutic efficacy assessed by radiographic progression free survival (rPFS), objective response rate and prostate specific antigen (PSA) response.
Up to Week 36 after starting treatment

Change from baseline in serum alkaline phosphatase (ALP) values
Up to Week 36 after starting treatment

Dry mouth, Possible neutropenia, Possible renal impairment, Possible increase in pain.

• Male aged 18 years or older with metastatic adenocarcinoma of the prostate, defined by documented histopathology of prostate adenocarcinoma or metastatic disease typical of prostate cancer (i.e. Involving bone or pelvic lymph nodes or para-aortic lymph nodes)
• Patients with castration-resistant prostate cancer that have received at least one cycle of androgen receptor therapy and exposure to a taxane-based chemotherapy unless considered contraindicated by a medical oncologist or patient declines treatment
• Progressive disease with rising PSA level, or new lesion(s) in the viscera or lymph nodes as per RECIST 1.1 or in bone as per Prostate Cancer Working Group 3
• Significant PSMA avidity on [68Ga]Ga-PSMA PET/CT
• ECOG Performance status 0 to 2
• Adequate renal, bone and liver function (Absolute neutrophil count: greater than or equal to 2 x 109 /L , Hemoglobin: greater than or equal to 90 g/L, Platelet count: greater than or equal to 150,000 x 109/L, Serum creatinine: less than 1.5 x upper limit of normal (ULN) i.e = 125 umol/L or calculated creatinine clearance greater than or equal to 60 mL/min/1.73 m2 by Cockcroft-Gault formula, Serum total bilirubin: less than 1.5 x ULN (unless the patient has Gilbert's syndrome in which case direct bilirubin must be normal), Serum AST and ALT: less than 1.5 x ULN in the absence of liver metastases; less than 3 x ULN if due to liver metastases (in both circumstances bilirubin must meet entry criteria)
• Estimated life expectancy greater than 12 weeks
• Willing and able to comply with all study requirements, including the timing and nature of all required assessments (i.e. blood testing and scanning.)
• Have provided written Informed Consent for participation in this trial

Japan

In Japan, clinical trials for prostate cancer are **actively exploring treatments like androgen receptor inhibitors (like enzalutamide and abiraterone), with a focus on studies involving BRCA-mutated metastatic castration-resistant prostate cancer (mCRPC), often combining these drugs with other therapies like Lynparza (olaparib)**. Additionally, research is being conducted on imaging techniques using PSMA-targeted radiopharmaceuticals like 68Ga-PSMA-11 PET/CT to detect prostate cancer in Japanese patients. [1, 2, 3, 4, 5, 6]

Key points about prostate cancer clinical trials in Japan: [1, 3]

- **Focus on BRCA mutations:** Several trials investigate the use of PARP inhibitors like Lynparza in combination with other therapies for patients with BRCA-mutated mCRPC. [1, 3]
- **Androgen receptor inhibitors:** Studies are evaluating the efficacy of newer androgen receptor inhibitors like enzalutamide and abiraterone in Japanese patients with advanced prostate cancer. [1, 2, 3]
- **Imaging with PSMA-targeted PET:** Clinical trials are assessing the safety and diagnostic performance of 68Ga-PSMA-11 PET/CT for detecting prostate cancer in Japanese populations. [4, 5, 6]

Where to find information about Japanese prostate cancer clinical trials: [1, 4, 7]

- **ClinicalTrials.gov:** Search using keywords like "prostate cancer," "Japan," and specific treatment names. [1, 4, 7]
- **UMIN Clinical Trials Registry:** Japanese clinical trials are often registered on this platform. [5, 7]
- **University hospital websites:** Many Japanese universities with medical schools conduct prostate cancer clinical trials and may list them on their websites. [1, 7, 8]

Reference links:.

[1] https://www.astrazeneca.com/media-centre/press-releases/2023/lynparza-plus-abiraterone-approved-japan-treatment-brca-mutated-metastatic-castration-resistant-prostate-cancer.html
[2] https://pubmed.ncbi.nlm.nih.gov/26793974/
[3] https://academic.oup.com/jjco/advance-article/doi/10.1093/jjco/hyae177/7929259
[4] https://pubmed.ncbi.nlm.nih.gov/38750331/
[5] https://telixpharma.com/news-views/japanese-prostate-cancer-imaging-trial-meets-study-objectives/
[6] https://www.novartis.com/clinicaltrials/study/nct05114746
[7] https://www.nature.com/articles/s44276-024-00049-7
[8] https://telixpharma.com/news-views/telix-and-kanazawa-university-cleared-to-commence-prostate-cancer-imaging-study-in-japan/

Summary and Conclusions

This document provides a comprehensive overview of prostate cancer clinical trials, detailing the structured process involved, key stakeholders, and clinical trial phases. It explains the costs, funding sources, and financial challenges of conducting these trials. The document also highlights the potential benefits and risks for patients participating in clinical trials, including early access to new treatments and expert medical care. Furthermore, it discusses the risks, costs, and rewards for pharmaceutical companies and academic institutions. Specific clinical trials in San Diego, along with details on medications being tested and how to find appropriate trials, are included.