Open Clinical Trials for Patients With Prostate Cancer

The clinical trials listed below are all open as of July 12, 2024; have ≥ 1 US Department of Veterans Affairs (VA) medical center (VAMC) or US Department of Defense (DoD) military treatment facility location recruiting patients; and are focused on treatments for prostate cancer. For additional information and full inclusion/exclusion criteria, please consult clinicaltrials.gov.

Actively Recruiting

➔ Patient Decision Making About Precision Oncology in Veterans With Advanced Prostate Cancer

This clinical trial explores and implements methods to improve informed decision making regarding precision oncology tests among veterans with prostate cancer that may have spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body (advanced). Precision oncology, the use of germline genetic testing and tumor-based molecular assays to inform cancer care, has become an important aspect of evidence-based care for men with advanced prostate cancer. Veterans with metastatic castrate-resistant prostate cancer may not be carrying out informed decision making due to unmet decisional needs. An informed decision is a choice based on complete and accurate information. The information gained from this study will help researchers develop a decision support intervention and implement the intervention. A decision support intervention may serve as a valuable tool to reduce ongoing racial disparities in genetic testing and encourage enrollment to precision oncology trials.

ID: NCT05396872
Sponsor; Collaborator: University of California, San Francisco; DoD
Location: San Francisco VAMC

➔ DeADT - Living Well With Prostate Cancer

The goal of this pilot randomized implementation trial is to compare 2 strategies to reduce low-value androgen deprivation therapy (ADT) use for prostate cancer care. The aim of the study is to compare implementation of the 2 strategies: use of a clinical reminder order check intervention vs a clinician script/patient education approach, and their impacts on low-value ADT use after 6 months. The main goal of both interventions will be to decrease ADT overuse for patients with prostate cancer, but to do this in a way that is acceptable to the provider who treat these patients. Provider participants will engage with 1 of the interventions triggered in the electronic health record when their patients are deemed likely to receive low-value ADT. Provider participants receive only 1 intervention. The intervention is triggered for every clinic visit involving a patient deemed to be receiving low-value ADT, so provider participants may receive their assigned intervention multiple times. Researchers will compare provider use of both strategies to determine implementation outcomes and whether 1 was more effective in reducing low-value ADT use.

ID: NCT06199986
Sponsor; Collaborator: University of Michigan; VA, National Cancer Institute
Location: VA Ann Arbor Healthcare System

➔ VA Seamless Phase II/III Randomized Trial of STAndard Systemic theRapy With or Without PET-Directed Local Therapy for Oligometastatic pRosTate Cancer (VA STARPORT)

This is a prospective, open-label, multicenter, seamless phase II to phase III randomized clinical trial designed to compare somatostatin with or without positron emission tomography (PET)-directed local therapy in improving the castration-resistant prostate cancer-free survival for veterans with oligometastatic prostate cancer. Oligometastasis will be defined as 1 to 10 sites of metastatic disease based on the clinical determination.

ID: NCT04787744
Sponsor; Investigators: VA Office of Research and Development; Abhishek Solani, MD, MS, Edward Hines Jr.
Locations: VA Long Beach Healthcare System, VA Greater Los Angeles Healthcare System, Bay Pines VA Healthcare System, Edward Hines Jr. VA Hospital, Richard L. Roudebush VAMC, Baltimore VAMC, VA Boston Healthcare System, VA Ann Arbor Healthcare System, Minneapolis VA Health Care System, Kansas City VAMC, VA New Jersey Healthcare System, VA NY Harbor Healthcare System, Durham VAMC, Louis Stokes VAMC, Corporal Michael J. Crescenz VAMC, Michael E. DeBakey VAMC, Hunter Holmes McGuire VAMC, William S. Middleton Memorial Veterans Hospital, Clement J. Zablocki VAMC

➔ The Prostate Cancer, Genetic Risk, and Equitable Screening Study (ProGRESS)

Prostate cancer is the most common non-skin cancer among veterans and the second leading cause of male cancer death. Current methods of screening men for prostate cancer are inaccurate and cannot identify which men do not have prostate cancer or have low-grade cases that will not cause harm and which men have significant prostate cancer needing treatment. False-positive screening tests can result in unnecessary prostate biopsies for men who do not need them. However, new

genetic testing might help identify which men are at highest risk for prostate cancer. This study will examine whether a genetic test helps identify men at risk for significant prostate cancer while helping men who are at low risk for prostate cancer avoid unnecessary biopsies. If this genetic test proves beneficial, it will improve the way that health care providers screen male veterans for prostate cancer.
ID: NCT05926102
Sponsor; Investigator: VA Office of Research and Development; Jason L. Vassy, MD, MPH
Location: VA Boston Healthcare System

➔ Prostate Active Surveillance Study (PASS)

This research study is for men who have chosen active surveillance as a management plan for their prostate cancer. Active surveillance is defined as close monitoring of prostate cancer with the offer of treatment if there are changes in test results. This study seeks to discover markers that will identify cancers that are more aggressive from those tumors that grow slowly.
ID: NCT00756665
Sponsor; Collaborators: University of Washington; Canary Foundation, Early Detection Research Network
Locations: VA San Francisco Health Care System, VA Puget Sound Health Care System

➔ A Study of CHeckpoint Inhibitors in Men With prOgressive Metastatic Castrate Resistant Prostate Cancer Characterized by a Mismatch Repair Deficiency or Biallelic CDK12 Inactivation (CHOMP)

The primary objective is to assess the activity and efficacy of pembrolizumab, a checkpoint inhibitor, in veterans with metastatic castration-resistant prostate cancer characterized by either mismatch repair deficiency (dMMR) or biallelic inactivation of CDK12 (CDK12-/-). The secondary objectives involve determining the frequency with which dMMR and CDK12-/- occur in this patient population, as well as the effects of pembrolizumab on various clinical endpoints (time to prostate-specific antigen progression, maximal prostate-specific antigen response, time to initiation of alternative antineoplastic therapy, time to radiographic progression, overall survival, and safety and tolerability). Lastly, the study will compare the pretreatment and at-progression metastatic tumor biopsies to investigate the molecular correlates of resistance and sensitivity to pembrolizumab via RNA-sequencing, exome-sequencing, selected protein analyses, and multiplexed immunofluorescence.
ID: NCT04104893
Sponsor; Collaborator: VA Office of Research and Development; Merck Sharp & Dohme LLC
Locations: San Francisco VAMC, VA Greater Los Angeles Healthcare System, Washington DC VAMC, Bay Pines VA Healthcare System Jesse Brown VAMC, VA Ann Arbor Healthcare System, James J. Peter VAMC, VA NY Harbor Healthcare System, Durham VAMC, Corporal Michael J. Crescenz VAMC, Hunter Holmes McGuire VAMC, VA Puget Sound Health Care System

➔ A Single-Arm Phase II Study of Neoadjuvant Intensified Androgen Deprivation (Leuprolide and Abiraterone Acetate) in Combination With AKT Inhibition (Capivasertib) for High-Risk Localized Prostate Cancer With PTEN Loss (SNARE)

The purpose of this study is to learn about how an investigational drug intervention completed before doing prostate surgery (specifically, radical prostatectomy with lymph node dissection) may help in the treatment of high-risk localized prostate cancers that are most resistant to standard treatments. This is a phase II research study. For this study, capivasertib, the study drug, will be taken with intensified androgen deprivation therapy drugs (iADT; abiraterone and leuprolide) prior to radical prostatectomy. This study drug treatment will be evaluated to see if it is effective in shrinking and destroying prostate cancer tumors prior to surgery and to further evaluate its safety prior to prostate cancer surgery.
ID: NCT05593497
Sponsor; Investigator: VA Office of Research and Development; Ryan P. Kopp, MD
Locations: VA Greater Los Angeles Healthcare System, James J. Peters VAMC, VA Portland Health Care System, South Texas Veterans Health Care System, VA Puget Sound Health Care System

Active, Not Recruiting

➔ Intramuscular Mechanisms of Androgen Deprivation-related Sarcopenia

Prostate cancer is the most common cancer among men and is even more common in the military and veteran population. For patients with advanced prostate cancer, the most common treatment includes androgen deprivation therapy (ADT), or the lowering of the levels of the hormone testosterone as much as possible. Unfortunately, ADT also causes patients to be fatigued, weak, and to lose muscle. This is often referred to as "sarcopenia," and it leads to falls, poor quality of life, and higher risk of death. Currently, there is no treatment for sarcopenia because the investigators do not understand the mechanisms that cause it. The mitochondria are part of the cells responsible for providing energy to muscles, but to this date, the investigators do not know if it is affected in prostate cancer patients with sarcopenia due to ADT.
ID: NCT03867357
Sponsor; Collaborators: Seattle Institute for Biomedical and Clinical Research; DoD, University of Washington
Location: VA Puget Sound Health Care System

➔ Radiation Therapy With or Without Androgen-Deprivation Therapy in Treating Patients With Prostate Cancer

RATIONALE: Radiation therapy uses high-energy X-rays and other types of radiation to kill tumor cells and shrink tumors. Androgens can cause the growth of prostate cancer cells. Androgen deprivation therapy (ADT) may lessen the amount of androgens made by the body. It is not yet known whether radiation therapy is more effective with or without ADT in treating patients with prostate cancer.
PURPOSE: This randomized phase III trial is studying radiation therapy to see how well it works compared with radiation therapy given together with ADT in treating patients with prostate cancer.
ID: NCT00936390
Sponsor; Collaborators: Radiation Therapy Oncology Group; National Cancer Institute, NRG Oncology
Locations: 518 locations, James A. Haley VA Hospital

➔ Enzalutamide With or Without Abiraterone and Prednisone in Treating Patients With Castration-Resistant Metastatic Prostate Cancer

This randomized phase III trial studies enzalutamide to see how well it works compared to enzalutamide, abiraterone, and prednisone in treating patients with castration-resistant metastatic prostate cancer. Androgens can cause the growth of prostate cancer cells. Drugs, such as enzalutamide, abiraterone acetate, and prednisone, may lessen the amount of androgens made by the body.
ID: NCT01949337
Sponsor; Collaborators: Alliance for Clinical Trials in Oncology; NCI, Astellas Pharma US, Inc., Medivation, Inc., Biologics, Inc.
Locations: 539 locations, including VA Connecticut Healthcare System

➔ S1216, Phase III ADT+TAK-700 vs ADT+ Bicalutamide for Metastatic Prostate Cancer (S1216)

The purpose of this study is to compare overall survival in newly diagnosed metastatic prostate cancer patients randomly assigned to ADT + TAK-700 vs androgen deprivation therapy (ADT) + bicalutamide.
ID: NCT01809691
Sponsor; Collaborators: SWOG Cancer Research Network; Millennium Pharmaceuticals, Inc., NCI
Locations: 560 locations, including VA New York Harbor Healthcare System

➔ Androgen Ablation Therapy With or Without Chemotherapy in Treating Patients With Metastatic Prostate Cancer (CHAARTED)

RATIONALE: Androgens can cause the growth of prostate cancer cells. Androgen ablation therapy may stop the adrenal glands from making androgens. Drugs used in chemotherapy, such as docetaxel, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether androgen-ablation therapy is more effective with or without docetaxel in treating metastatic prostate cancer.
PURPOSE: This randomized phase III trial is studying androgen ablation therapy and chemotherapy to see how well they work compared to androgen ablation therapy alone in treating patients with metastatic prostate cancer.
ID: NCT00309985
Sponsor; Collaborator: ECOG-ACRIN Cancer Research Group; NCI
Locations: 343 locations, including Mather VAMC

Not Yet Recruiting

➔ Abiraterone, Enzalutamide, or Apalutamide in Castrate-Sensitive Prostate Cancer

The investigators have used national Veterans Health Administration (VHA) data to demonstrate real-world efficacy of abiraterone and enzalutamide in veterans with metastatic castration-resistant prostate cancer. In the real world that is the VHA, the investigators have successfully estimated g values that accurately predict overall survival, and the use of this metric in other settings should now be explored. In the egalitarian system that is the VHA, the treatment of prostate cancer is excellent, uniform across the US and indifferent to race. The choices made are clearly personalized, given not all men received all therapies, and younger veterans were treated more aggressively.
ID: NCT05422911
Sponsor: James J. Peters VAMC
Location: James J. Peters VAMC

➔ 18F-DCFPyL PET/CT Impact on Treatment Strategies for Patients With Prostate Cancer (PROSPYL)

The main purpose of this phase II trial study is to determine whether a positron emission tomography (PET) /computed tomography (CT) scan using 18F-DCFPyL affects the clinical management plan in veterans. In this study, the management plan prior to and after 18F-DCFPyL PET/CT will be recorded by specific questionnaires, and corresponding changes in management will be analyzed. The scan will be used to see how the disease has spread. Both the treatment strategies and probable disease outcomes as relevant to clinical endpoints will be assessed. This study is open to veterans only.
ID: NCT04390880
Sponsor, Investigator: VA Greater Los Angeles Healthcare System; Gholam Berenji, MD
Location: VA Greater Los Angeles Healthcare System

18F-DCFPyL PET-CT Scan and Prostate Cancer

The primary objective of this study is to assess the efficacy of 18F-DCFPyL PET-CT for initial staging of prostate cancer in veterans compared to conventional imaging (99mTc-MDP bone scan and diagnostic CT or MRI). The primary clinical endpoint of our study is the percentage of veterans with prostate cancer in which the 18F-DCFPyL PET-CT identifies M1 disease at initial staging. Secondary objectives included frequency of the change in primary treatment plan after initial staging.

ID: NCT03852654
Sponsor, Investigator: Lida Jafari, MD
Location: VA Greater Los Angeles Healthcare System

Neoadjuvant Therapy With Docetaxel and Ketoconazole in Patients With High-Risk Prostate Cancer: A Pilot Study (IST 16167)

Eligible patients with high-risk prostate cancer who are scheduled to undergo radical prostatectomy will receive 4 cycles of therapy with ketoconazole and docetaxel prior to surgery resection. A cycle of therapy is defined as 21 days (3 weeks). Pharmacokinetic analysis will be performed during the first and second cycles of therapy. All patients will be evaluated for toxicity, tumor response, and recurrence.

ID: NCT00870714
Sponsor, Collaborator: Kansas City VAMC; Sanofi
Location: Kansas City VAMC

A Study of Epirubicin With Estramustine Phosphate and Celecoxib for the Treatment of Prostate Cancer

The purpose of this clinical trial is to find out the effect of epirubicin with estramustine phosphate and celecoxib on PSA and objective response in patients with hormone-resistant prostate cancer, as well as to evaluate the toxicity and quality of life of this combination. Celecoxib is an FDA-approved drug that treats arthritis. Epirubicin, alone or with estramustine phosphate, has been used in the treatment of hormone-resistant prostate cancer. These drugs have demonstrated evidence of tumor blood vessel suppression and a combination of these 3 drugs could possibly arrest further tumor growth or even make the tumor decrease in size.

ID: NCT00218205
Sponsor, Collaborator; Investigator: VA New Jersey Health Care System; Pfizer; Basil Kasimis, MD
Location: VA New Jersey Health Care System

A Phase II Trial of Combination Therapy With Celecoxib and Taxotere for the Treatment of Stage D3 Prostate Cancer

The purpose of this clinical trial is to find out the safety and effectiveness as well as the patient's quality of life while taking the combination of Taxotere and celecoxib on patients with hormone refractory prostate cancer. Celecoxib (Celebrex) is an FDA-approved drug that treats arthritis. Taxotere (Docetaxel) is an FDA-approved chemotherapy drug to treat certain forms of cancer. Both drugs have demonstrated evidences of tumor blood vessel suppression and combination of these 2 drugs could possibly arrest further tumor growth or make the tumor decrease in size.

ID: NCT00215345
Sponsor, Collaborator; Investigator: Department of Veterans Affairs, New Jersey; Pfizer, Sanofi; Basil Kasimis, MD
Location: VA New Jersey Health Care System

A Yoga Program for Patients Undergoing Prostate Cancer Surgery

Men with localized prostate cancer are often treated with surgery, a treatment that is associated with high rates of adverse effects such as erectile dysfunction (ED) and urinary incontinence (UI) which impact quality of life. Yoga may improve control of UI and improve ED by bringing awareness to and strengthening the pelvic floor musculature. The randomized controlled pilot study is to assess the feasibility of an innovative hybrid (in-person and virtual) twice-weekly yoga program that includes a prehabilitation component and to obtain preliminary data that will help assess its potential effectiveness in alleviating prostate cancer treatment symptom burden (primarily ED and UI). The long-term goal is to develop a scalable and sustainable yoga program that helps cancer survivors manage their treatment side effects.

ID: NCT05929300
Sponsor, Investigator: VA Office of Research and Development; Abigail Silva, PhD, MPH
Location: Edward Hines Jr. VA Hospital

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