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

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* STEP 1 REGISTRATION: DISEASE-RELATED CRITERIA: All patients must have a histologically or cytologically proven diagnosis of adenocarcinoma of the prostate. Patients with pure small cell carcinoma* (SCC), sarcomatoid, or squamous cell carcinoma are not eligible. (*morphology must be consistent with SCC; synaptophysin or chromogranin positive by immunohistochemical staining is insufficient to diagnose SCC). * STEP 1 REGISTRATION: DISEASE-RELATED CRITERIA: Patients must have an intact prostate. No prior local therapy for prostate adenocarcinoma is allowed (e.g., brachytherapy, high-intensity focused ultrasound \[HIFU\], cryotherapy, laser ablative therapies). Any prior therapy for benign conditions, such as obstruction, are acceptable (e.g., transurethral resection of the prostate, greenlight laser ablation, microwave ablation). * STEP 1 REGISTRATION: DISEASE-RELATED CRITERIA: Patients must have evidence of metastatic disease on technetium bone scan and computed tomography (CT) or magnetic resonance imaging (MRI) within 42 days prior to starting standard systemic therapy. Metastatic disease that is detected by positron emission tomography (PET) scan only (sodium fluoride \[NaF\], prostate-specific membrane antigen \[PSMA\], anti-1-amino-3-18F-fluorocyclobutane-1-carboxylic acid \[FACBC\], carbon \[C\]11) but not conventional imaging (technetium \[Tc\]99 bone scan, CT or MRI) or solitary metastases by conventional imaging, must be confirmed histologically or cytologically. * STEP 1 REGISTRATION: DISEASE-RELATED CRITERIA: Patients with known brain metastases are not eligible. Brain imaging studies are not required for eligibility if the patient has no neurologic signs or symptoms suggestive of brain metastasis. If brain imaging studies are performed, they must be negative for disease. * STEP 1 REGISTRATION: PRIOR/CONCURRENT THERAPY CRITERIA: Patients must have received no more than 28 weeks of standard systemic therapy (SST). SST is defined as current National Comprehensive Cancer Network (NCCN) guidelines for metastatic prostate cancer. * STEP 1 REGISTRATION: PRIOR/CONCURRENT THERAPY CRITERIA: Patients must not have progressed while on SST. * STEP 1 REGISTRATION: PRIOR/CONCURRENT THERAPY CRITERIA: Patients with oligometastatic prostate cancer may receive metastasis directed therapy to up to four sites of disease prior to randomization. * STEP 1 REGISTRATION: CLINICAL/LABORATORY CRITERIA: Patients must have a complete physical examination and medical history within 28 days prior to registration. * STEP 1 REGISTRATION: CLINICAL/LABORATORY CRITERIA: Patients must have a PSA documented prior to initiation of SST and within 28 days prior to registration. Any additional PSAs measured while receiving SST should be recorded. * STEP 1 REGISTRATION: CLINICAL/LABORATORY CRITERIA: Patients must have a testosterone lab documented within 28 days prior to randomization. Any additional testosterone labs measured while receiving SST should be recorded as well as pretreatment initiation if available. * STEP 1 REGISTRATION: CLINICAL/LABORATORY CRITERIA: No other prior malignancy is allowed except for the following: adequately treated basal cell or squamous cell skin cancer, adequately treated stage 0, I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease free for three years. * STEP 1 REGISTRATION: SPECIMEN SUBMISSION CRITERIA: Patients must be offered the opportunity to participate in translational medicine studies and specimen banking for future studies. * STEP 1 REGISTRATION: QUALITY OF LIFE CRITERIA: Patients who can complete Patient-Reported Outcome instruments in English, Spanish or French, must participate in the quality of life studies. * STEP 1 REGISTRATION: REGULATORY CRITERIA: Patients must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines. * STEP 2 RANDOMIZATION: DISEASE-RELATED CRITERIA: As a part of the OPEN registration process the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system. * STEP 2 RANDOMIZATION: DISEASE-RELATED CRITERIA: Patients must have no evidence of disease progression during the 28 weeks of SST by PSA measure, bone scan and CT or MRI or symptomatic deterioration (as defined by physician discretion) within 28 days prior to randomization. * STEP 2 RANDOMIZATION: DISEASE-RELATED CRITERIA: Patients must have consultation with a urologist and have surgically resectable disease regardless of definitive treatment intent or randomization. * STEP 2 RANDOMIZATION: PRIOR/CONCURRENT THERAPY CRITERIA: Patients must have received between 22 and 28 weeks of SST as measured from the date of first hormonal therapy or surgical castration. SST is defined by current NCCN guidelines for metastatic prostate cancer. * STEP 2 RANDOMIZATION: PRIOR/CONCURRENT THERAPY CRITERIA: Patients must not be planning to receive docetaxel after randomization. * STEP 2 RANDOMIZATION: PRIOR/CONCURRENT THERAPY CRITERIA: Any toxicities from SST must have resolved to =\< grade 1 (Common Terminology Criteria for Adverse Events \[CTCAE\] version 5.0) prior to randomization. * STEP 2 RANDOMIZATION: PRIOR/CONCURRENT THERAPY CRITERIA: Patients may have received elective metastasis directed therapy to oligometastatic sites (=\< 4 sites). All treatment must be completed prior to randomization. * STEP 2 RANDOMIZATION: CLINICAL/LABORATORY CRITERIA: Patients must have a PSA performed within 28 days prior to randomization. * STEP 2 RANDOMIZATION: CLINICAL/LABORATORY CRITERIA: Patients must have a testosterone \< 50 ng/dL within 28 days prior to randomization. * STEP 2 RANDOMIZATION: CLINICAL/LABORATORY CRITERIA: Patients must have a Zubrod performance status of 0 ? 1 within 28 days prior to randomization.

Conditions & Interventions

Interventions:

DRUG: Abiraterone, DRUG: Bicalutamide, DRUG: Degarelix, DRUG: Docetaxel, DRUG: Flutamide, DRUG: Goserelin Acetate, DRUG: Histrelin Acetate, DRUG: Leuprolide Acetate, DRUG: Nilutamide, PROCEDURE: Orchiectomy, DRUG: Prednisone, OTHER: Quality-of-Life Assessment, RADIATION: Radiation Therapy, PROCEDURE: Radical Prostatectomy, DRUG: Triptorelin

Conditions:

Castration Levels of Testosterone, Metastatic Prostatic Adenocarcinoma, Stage IV Prostate Cancer AJCC v8, Stage IVA Prostate Cancer AJCC v8, Stage IVB Prostate Cancer AJCC v8

More Information

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System ID: NCT03678025