

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

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* STEP 0: REGISTRATION ELIGIBILITY CRITERIA * Patient must be male and ≥ 18 years of age. * Patient must have had a radical prostatectomy (RP) as definitive therapy for histopathologically-proven prostatic adenocarcinoma * Patient must have biochemical recurrence (BCR) after RP, defined as follows: * If time to BCR, defined as time to first detectable PSA ($>$ lower limit of normal for assay used) after RP, is < 12 months, a minimum PSA level of ≥ 0.2 ng/mL and a confirmatory reading of ≥ 0.2 ng/mL is required, per the American Urological Association (AUA) definition (Note: patients with a persistent PSA reading of at least 0.2 ng/mL are eligible) * If time to BCR, defined as time to first detectable PSA ($>$ lower limit of normal for assay used) after RP, is ≥ 12 months, a minimum absolute PSA of 0.5 ng/mL is required * If the patient has a detectable PSA ($>$ lower limit of normal for assay used) at any time after RP AND has an eligible baseline SOC PET (PET1) with at least one positive lesion in any location, then there is no minimum PSA requirement * Patients must have no definite evidence for extrapelvic metastatic disease by conventional imaging modalities (CIM) (CT abdomen/pelvis or MRI abdomen/pelvis AND bone scintigraphy, or equivalent), within 26 weeks prior to Step 0 registration. If a patient only has a study-eligible PET/CT or PET/MR (i.e., PET done without prior CIM): if the PET is negative for extrapelvic lesions, then baseline CIM is NOT required. If the PET positive for extrapelvic lesions, then patient should have a baseline CT/MRI for soft tissue lesions and/or a bone scan for osseous lesions * Study eligible = PET using FDA-approved radiotracer and performed within 16 weeks prior to study registration * Extra-pelvic metastases is defined as any osseous metastases and/or any extrapelvic soft tissue, lymph nodes and organ metastases; extra-pelvic is defined as superior to common iliac bifurcation, outside of standard prostate bed + whole pelvis nodal RT fields. Baseline PET/CT or PET/MR scan (PET1) is eligible for this study if the SOC PET scan is completed with an FDA approved radiotracer for prostate cancer after Step 0 registration and prior to Step 1 randomization OR up to 16 weeks prior to Step 0 registration * Patient must be a candidate for SOC post-prostatectomy radiation therapy (RT) to the prostate bed and pelvic nodes with androgen deprivation therapy (ADT) * Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status 0-2 * Patient must not have started ADT for biochemical recurrence prior to baseline PET (PET1) imaging. A short course of low-dose anti-androgen such as bicalutamide, given after baseline study PET/CT but prior to study registration, is permitted as a brief temporizing measure in advance of starting protocol-approved SOC ADT. * Patient must not be enrolled in another therapeutic clinical trial * Patient must be able to lie flat and still for approximately 20-30 minutes or otherwise tolerate a PET scan and radiation treatment planning and delivery * Patients undergoing a PET/MR must meet local institutional safety guidelines for MRI * Patient must not have history of seizures or known condition that may cause predisposal to seizures (e.g., stroke or head trauma resulting in loss of consciousness) within 1 year prior to registration * Patient must not have history of inflammatory bowel disease or any gastrointestinal disorder affecting absorption that is expected to increase risk of complication from radiotherapy * Hemoglobin (Hgb) ≥ 9.0 g/dL (independent of transfusion and/or growth factors within 3 months prior to Step 0 registration) (obtained within 8 weeks prior to Step 0 registration) * Leukocytes $\geq 3,000$ /mcL (obtained within 8 weeks prior to Step 0 registration) * Absolute neutrophil count $\geq 1,500$ /mcL (obtained within 8 weeks prior to Step 0 registration) * Platelets $\geq 100,000$ /mcL (obtained within 8 weeks prior to Step 0 registration) * Total bilirubin $< 1.5 \times$ institutional upper limit of normal (ULN) (patients with Gilbert's syndrome, if total bilirubin is $> 1.5 \times$ ULN, must have a direct bilirubin of $< 1.5 \times$ ULN to be eligible) (obtained within 8 weeks prior to Step 0 registration) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase [SGOT])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase [SGPT]) $\leq 2.5 \times$ institutional ULN (obtained within 8 weeks prior to Step 0 registration) * Creatinine $< 1.5 \times$ institutional ULN (or measured creatinine clearance > 30 mL/min) * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class I or II (by patient symptoms) or A or B (by objective assessment) * Patient must not have completed a course of prior pelvic radiation therapy for any reason * Patient must agree not to father children while on study * Patient must be English or Spanish speaking to be eligible for the QOL component of the study * NOTE: Sites cannot translate the associated QOL forms * STEP 1: RANDOMIZATION ELIGIBILITY CRITERIA * Patient must have completed a baseline SOC PET/CT or PET/MR (PET1 scan) using FDA approved radiotracer with results of extra-pelvic metastases involvement known (positive or negative). The PET1 must have been completed after Step 0 registration and prior to Step 1 randomization OR up to 12 weeks prior to Step 0 registration * For patients with negative extra-pelvic metastases, PET-imaging status of intra-pelvic nodes must be known (positive or negative) * For patients with positive extra-pelvic metastases (defined as any PET positive lesions outside of standard salvage RT fields [prostate bed +/- typical whole pelvis]), the number of extra-pelvic lesions must be known (1

or > 5 extra-pelvic lesions)

Conditions & Interventions

Interventions:

RADIATION: 3-Dimensional Conformal Radiation Therapy, DRUG: Apalutamide, PROCEDURE: Computed Tomography, DRUG: Degarelix, RADIATION: External Beam Radiation Therapy, OTHER: Fluciclovine F18, DRUG: Goserelin Acetate, PROCEDURE: Intensity-Modulated Proton Therapy, RADIATION: Intensity-Modulated Radiation Therapy, DRUG: Leuprolide Acetate, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Positron Emission Tomography, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration, DRUG: Relugolix, RADIATION: Stereotactic Body Radiation Therapy, DRUG: Triptorelin, RADIATION: Volume Modulated Arc Therapy

Conditions:

Biochemically Recurrent Prostate Carcinoma, Metastatic Prostate Carcinoma, Prostate Adenocarcinoma, Stage IVB Prostate Cancer AJCC v8

More Information

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