Testing the Addition of the Drug Apalutamide to the Usual Hormone Therapy and Radiation Therapy After Surgery for Prostate Cancer, INNOVATE Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Pathologically (histologically) proven diagnosis of prostate adenocarcinoma. Any type of radical prostatectomy is permitted, including retropubic, perineal, laparoscopic or robotically assisted * Any T-stage is eligible (American Joint Committee on Cancer \[AJCC\] 8th edition \[ed\]) * Appropriate stage for study entry based on fluciclovine F-18 PET scan (FACBC, Axumin) F-18 prostate-specific membrane antigen (PSMA) PET (PyLarify) scan, Gallium-68 PSMA PET scan, flotufolastat F-18 PSMA PET scan (Posluma), or C-11 or F-18 Choline PET within 90 days prior to registration that is negative for distant metastatic (M1a, M1b, M1c) disease. For patients with PSA \< 0.20 ng/mL at time of registration, PET scan is recommended but not required * Pathologically node positive disease with nodal involvement only in the pelvis in the prostatectomy specimen or nodal disease on imaging at time of recurrence (including external iliacs, internal iliacs, and/or obturator nodes); peri-prostatic and peri-rectal nodes can also be considered regional lymphadenopathy and are allowed * History/physical examination within 90 days prior to registration * Age \>= 18 * Eastern Cooperative Oncology Group (ECOG) performance status of 0-1 within 90 days prior to registration * Detectable PSA after radical prostatectomy. Detectable PSA is defined as serum PSA \> 0 ng/mL at least 30 days after prostatectomy * Patients who have already started on post-prostatectomy GnRH agonist/antagonist for =\< 180 days prior to registration are eligible (Note: patients who started on an oral antiandrogen are eligible if started =\< 180 days and stopped prior to registration) * Hemoglobin \>= 9.0 g/dL, independent of transfusion and/or growth factors (within 90 days prior to registration) * Platelet count \>= 100,000 x 10\^9/uL independent of transfusion and/or growth factors (within 90 days prior to registration) * Serum potassium \>= 3.5 mmol/L within 90 days prior to registration * Creatinine clearance (CrCl) \>= 30 mL/min estimated by Cockcroft-Gault (please use actual weight for calculation unless greater than 30% above ideal body weight then use the adjusted body weight) (within 90 days prior to registration) * Total bilirubin =\< 1.5 x institutional upper limit of normal (ULN) (Note: In subjects with Gilbert's syndrome, if total bilirubin is \> 1.5 x ULN, measure direct and indirect bilirubin and if direct bilirubin is =\< 1.5 x ULN, subject is eligible) (within 90 days prior to registration) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\]) or alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) =\< 2.5 x institutional ULN (within 90 days prior to registration) * Serum albumin \>= 3.0 g/dL (within 90 days prior to registration) * Discontinue or substitute concomitant medications known to lower the seizure threshold at least 30 days prior to registration * The patient must agree to use a condom (even men with vasectomies) and another effective method of birth control if he is having sex with a woman of childbearing potential or agree to use a condom if he is having sex with a woman who is pregnant while on study drug and for 3 months following the last dose of study drug * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial and have a CD4 count \>= 200 cells/microliter within 30 days prior to registration. Note: HIV testing is not required for eligibility for this protocol * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy within 30 days prior to registration, if indicated. Note: HBV viral testing is not required for eligibility for this protocol * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load within 30 days prior to registration * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial. Note: Any patient with a cancer (other than keratinocyte carcinoma or carcinoma in situ) who has no evidence of disease for \< 3 years must contact the principal investigator, Ronald Chen, Doctor of Medicine (MD) * The patient or a legally authorized representative must provide study-specific informed consent prior to study entry

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Exclusion Criteria:

* Definitive radiologic evidence of metastatic disease (M1a, M1b or M1c) on molecular imaging (e.g. Fluciclovine F-18 PET, \[FACBC, Axumin\], F-18 PSMA PET \[Pylarify\], flotufolastat F-18 PSMA PET scan \[Posluma\], Gallium-68 PSMA PET scan or C-11 choline PET) * Prior systemic chemotherapy for the study cancer; note that prior chemotherapy for a different cancer is allowed (completed \> 3 years prior to registration) * Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields * Androgen deprivation therapy (ADT) prior to radical prostatectomy * Prior treatment with androgen receptor signaling inhibitor (including but not exclusive to a growing list of: abiraterone acetate, enzalutamide, apalutamide, darolutamide), unless started =\< 180 days and stopped prior to registration, which is allowed * Current use of 5-alpha reductase inhibitor. NOTE: if the alpha reductase inhibitor is stopped prior to randomization the patient is eligible * History of any of the following: * Seizure or known condition that may pre-dispose to seizure (e.g. prior stroke within 1 year prior to registration, brain arteriovenous malformation, Schwannoma, meningioma, or other benign central nervous system \[CNS\] or meningeal disease which may require treatment with surgery or radiation therapy) * Severe or unstable angina, myocardial infarction, arterial or venous thromboembolic events (e.g., pulmonary embolism, cerebrovascular accident including transient ischemic attacks), or clinically significant ventricular arrhythmias within 12 months prior to registration * New York Heart Association functional classification III/IV (Note: 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.) * History of any condition that in the opinion of the investigator, would preclude participation in this study * Current evidence of any of the following: * Known gastrointestinal disorder affecting absorption of oral medications * Active uncontrolled infection * Presence of uncontrolled hypertension (persistent systolic blood pressure \[BP\] \>= 160 mmHg or diastolic BP \>= 100 mmHg). Subjects with a history of hypertension are allowed, provided that BP is controlled to within these limits by anti-hypertensive treatment * Any chronic medical condition requiring a higher dose of corticosteroid than 10 mg prednisone/prednisolone once daily * Baseline moderate and severe hepatic impairment (Child-Pugh Class B \& C) * Inability to swallow oral pills * Any current condition that in the opinion of the investigator, would preclude participation in this study * Patients must not plan to participate in any other therapeutic clinical trials while receiving treatment on this study * Patients with inflammatory bowel disease

Conditions & Interventions

Interventions:

DRUG: Apalutamide, PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Scan, PROCEDURE: Computed Tomography, DRUG: Hormone Therapy, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Positron Emission Tomography, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration, RADIATION: Radiation Therapy

Conditions:

Prostate Adenocarcinoma, Stage I Prostate Cancer AJCC v8, Stage II Prostate Cancer AJCC v8, Stage III Prostate Cancer AJCC v8, Stage IVA Prostate Cancer AJCC v8

Keywords:

Prostate Cancer, Apalutamide, Abiraterone Acetate

More Information

More Information

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IRB Number: HM20021914
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