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, The Guidance Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Pathologically (histologically or cytologically) proven diagnosis of adenocarcinoma of the prostate within 270 days prior to registration * Unfavorable intermediate risk prostate cancer, defined as having ALL the following bulleted criteria: * Has at least one intermediate risk factor (IRF): * PSA 10-20 ng/mL * Clinical stage T2b-c (digital rectal examination \[DRE\] and/or imaging) by American Joint Committee on Cancer (AJCC) 8th edition * Gleason score 7 (Gleason 3+4 or 4+3 \[International Society of Urological Pathology (ISUP) Grade Group 2-3\]) * Has ONE or more of the following 'unfavorable' intermediate-risk designators: * \> 1 immature reticulocyte fraction (IRF) * Gleason 4+3=7 (ISUP Grade Group 3) * \>= 50% of biopsy cores positive * Biopsies may include 'sextant' sampling of right/left regions of the prostate, often labeled base, mid-gland and apex. All such 'sextant' biopsy cores should be counted. Men may also undergo 'targeted' sampling of prostate lesions (guided by MRI, ultrasound or other approaches). A targeted lesion that is biopsied more than once and demonstrates cancer (regardless of number of targeted cores involved) should count as a single additional positive core sampled and positive. In cases of uncertainty, count the biopsy sampling as sextant core(s) * Absence of high-risk features * Appropriate stage for study entry based on the following diagnostic workup: * History/physical examination within 120 days prior to registration; * Negative bone imaging (M0) within 120 days prior to registration; Note: Tc-99m bone scan or sodium fluoride (NaF) positron emission tomography (PET) are allowed. Equivocal bone scan findings are allowed if plain films X-ray, computed tomography (CT) or magnetic resonance imaging (MRI) are negative for metastasis at the concerned site(s). While a negative fluciclovine, choline, or prostate specific membrane antigen (PSMA) PET may be counted as acceptable substitute for bone imaging, any suspicious findings must be confirmed and correlated with conventional imaging (Tc-99m bone scan, NaF PET, CT, X-ray, or MRI) to determine eligibility based on the latter modalities (e.g. M0 based on conventional imaging modalities) * Clinically negative lymph nodes (N0) as established by conventional imaging (pelvic +/- abdominal CT or MR), within 120 days prior to registration. Patients with lymph nodes equivocal or questionable by imaging are eligible if the nodes are =\< 1.0 cm in short axis and/or if biopsy is negative. Note: While a negative fluciclovine, choline, or prostate specific membrane antigen (PSMA) PET may be counted as acceptable substitute for pelvic imaging, any suspicious findings must be confirmed by conventional imaging (CT, MRI or biopsy). If the findings do not meet pathological criteria based on the latter modalities (e.g. node =\< 10 mm in short axis, negative biopsy), the patient will still be eligible * Age \>= 18 * Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 within 120 days prior to registration * Non-castrate testosterone level (\> 50 ng/dL) within 120 days prior to registration * Absolute neutrophil \>= 1,000 cells/mm\^3 (within 120 days prior to registration) * Hemoglobin \>= 8.0 g/dL, independent of transfusion and/or growth factors (within 120 days prior to registration) * Platelet count \>= 100,000 cells/mm\^3 independent of transfusion and/or growth factors (within 120 days prior to registration) * Creatinine clearance (CrCl) \>= 30 mL/min estimated by Cockcroft-Gault equation (within 120 days prior to registration) * For African American patients specifically whose renal function is not considered adequate by the formula above, an alternative formula that takes race into account (Chronic Kidney Disease Epidemiology Collaboration CKD-EPI formula) should be used for calculating the related estimated glomerular filtration rate (GFR) with a correction factor for African American race creatinine clearance for trial eligibility, where GFR \>= 30 mL/min/1.73m\^2 will be considered adequate * Total bilirubin: 1.5 =\< institutional upper limit of normal (ULN) (within 120 days prior to registration) (Note: In subjects with Gilbert's syndrome, if total bilirubin is \> 1.5 x ULN, measure direct and indirect bilirubin. If direct bilirubin is less than or equal to 1.5 x ULN, subject is eligible) * Aspartate aminotransferase (AST)(serum glutamic-oxaloacetic transaminase \[SGOT\]) and alanine aminotransferase (ALT)(serum glutamate pyruvate transaminase \[SGPT\]): =\< 2.5 x institutional ULN (within 120 days prior to registration) * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial; 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, if indicated. * Note: Known positive test for hepatitis B virus surface antigen (HBV sAg) indicating acute or chronic infection would make the patient ineligible unless the viral load becomes undetectable on suppressive therapy. Patients who are immune to hepatitis B (anti-Hepatitis B surface antibody positive) are eligible (e.g. patients immunized against hepatitis B) * For 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 * Note: Known positive test for hepatitis C virus ribonucleic acid (HCV RNA) indicating acute or chronic infection would make the patient ineligible unless the viral load becomes undetectable on suppressive therapy * The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the United States (U.S.), authorization permitting release of personal health information

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Exclusion Criteria:

* Previous radical surgery (prostatectomy) or any form of curative-intent ablation whether focal or whole-gland (e.g., cryosurgery, high intensity focused ultrasound \[HIFU\], laser thermal ablation, etc.) for prostate cancer * Definitive clinical or radiologic evidence of metastatic disease (M1) * Prior invasive malignancy (except non-melanomatous skin cancer) unless disease free for a minimum of 3 years. History of or current diagnosis of hematologic malignancy is not allowed * Prior radiotherapy to the prostate/pelvis region that would result in overlap of radiation therapy fields * Previous bilateral orchiectomy * Previous hormonal therapy, such as luteinizing hormone-releasing hormone (LHRH) agonists (e.g., leuprolide, goserelin, buserelin, triptorelin) or LHRH antagonist (e.g. degarelix), anti-androgens (e.g., flutamide, bicalutamide, cyproterone acetate). ADT started prior to study registration is not allowed * Prior use of 5-alpha-reductase inhibitors is allowed, however, it must be stopped prior to enrollment on the study with at least a 30 day washout period before baseline study PSA measure and registration * Active testosterone replacement therapy; any replacement therapy must be stopped at least 30 days prior to registration * Severe, active co-morbidity defined as follows: * Current severe or unstable angina; * 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 * Inability to swallow oral pills * High risk features, which includes any of the following: * Gleason 8-10 \[ISUP Grade Group 4-5\] * PSA \> 20 * cT3-4 by digital exam OR gross extra-prostatic extension on imaging \[indeterminate MRI evidence will not count and the patient will be eligible\]

Conditions & Interventions

Interventions:

DRUG: Bicalutamide, DRUG: Buserelin, DRUG: Darolutamide, DRUG: Degarelix, DRUG: Flutamide, DRUG: Goserelin, DRUG: Histrelin, DRUG: Leuprolide, RADIATION: Radiation Therapy, DRUG: Relugolix, DRUG: Triptorelin

Conditions:

Prostate Adenocarcinoma

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT05050084
