To Evaluate if Green Tea Can be Effective in Reducing the Progression of Prostate Cancer in Men on Close Monitoring

Status: RECRUITING

Eligibility Criteria

Age: 21 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* INCLUSION CRITERIA FOR PREREGISTRATION (STEP 0: SCREENING) * Patient must have biopsy-proven (consisting of \>= 12 tissue cores) adenocarcinoma of the prostate with cancer present in at least one biopsy core in the most recent biopsy using initial transrectal ultrasound (TRUS) biopsy or TRUS biopsy followed by multiparametric magnetic resonance imaging (mpMRI) of the prostate and a confirmatory targeted biopsy * Patient must be on active surveillance (very low, low and favorable intermediate risk as defined by the National Comprehensive Cancer Network \[NCCN\]) * Patient must be scheduled for a follow up prostate biopsy 6 months after the initiation of treatment on this study * Patient must have a serum PSA \< 10 ng/mL or prostate specific antigen density (PSAD) \< 0.15 ng/mL/ g obtained within 30 days of registration * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status 0-1 * Patient must be willing to abstain from consumption of any supplements containing green tea catechins * Patient must be willing to restrict tea consumption to less than three (3) servings of hot tea or three (3) servings of iced tea per week (serving size of 8 oz) * Patient must be willing to discontinue current vitamin/mineral supplement use and use one provided by study * Patient must be willing to take study agent or placebo at the dose specified with meals * Patient must have the ability to understand and the willingness to sign a written informed consent document * Absolute neutrophil count \>= 1,200/mm\^3 (\>= 1.2 k/uL) (obtained within 30 days prior to registration) * Platelets \>= 75,000/mm\^3 (\>= 75 k/uL) (obtained within 30 days prior to registration) * Total bilirubin =\< 1.2 mg/dL (or =\< 3.0 mg/dL for patients with Gilbert's syndrome) (obtained within 30 days prior to registration) * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) =\< 1.5 x upper limit of normal (ULN) (obtained within 30 days prior to registration) * Serum creatinine =\< 1.5 x ULN (obtained within 30 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 * Sexually active males must use an accepted and effective method of double barrier contraception (vasectomy must be combined with a physical barrier method) or abstain from sexual intercourse for the duration of their participation in the study * Patients must have archived formalin-fixed paraffin-embedded (FFPE) tumor tissue specimen available for Gleason score confirmation and % Ki-67 expression (5% or more) in tumor tissue for eligibility and stratification. Tumor tissue can be submitted any time during screening * Tumor tissue specimen has been collected and is ready to ship to H. Lee Moffitt Cancer Center \& Research Institute * H. Lee Moffitt Cancer Center \& Research Institute will perform Gleason score confirmation and % Ki-67 expression (5% or more) in tumor tissue and notify the Eastern Cooperative Oncology Group-American College of Radiology Imaging Network (ECOG-ACRIN) Operations Office and submitting institution within 3-4 business days of receipt of the tumor tissue specimen * INCLUSION CRITERIA FOR RANDOMIZATION (STEP 1) * Patient must meet all Step 0 eligibility criteria at the time of their registration to Step 1 * Patient must have Gleason score (3+3) or predominant Gleason pattern 3 (3+4), =\< 33% of biopsy cores, and =\< 50% involvement of any biopsy core * Patient must have % Ki-67 expression of 5% or more in tumor tissue

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Exclusion Criteria:

* EXCLUSION CRITERIA FOR PREREGISTRATION (STEP 0: SCREENING) * Patient must not have had prior treatment for prostate cancer, including focal therapy, with surgery, irradiation, local ablative (i.e., cryosurgery or high-intensity focused ultrasound), or androgen deprivation therapy * Patient must not have a history of renal or hepatic disease, including history of hepatitis B and C * Patient must not have prostate cancer with distant metastases * Patient must not have undergone treatment of hormone therapy, immunotherapy, chemotherapy and/or radiation for any malignancies within the past 2 years. 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 * Patient must not receive any other investigational agents while on this study * Patient must not have a history of allergic reactions attributed to tea or other compounds of similar chemical or biologic composition to green tea extracts

Conditions & Interventions

Interventions:
DRUG: Placebo Administration, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration, DRUG: Sinecatechins
Conditions:
Prostate Carcinoma

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT04597359
