For Patients with Prostate Cancer

EA8184 Available Through ECOG-ACRIN Cancer Research Group

A Phase II Randomized Double Blinded Study of Green Tea Catechins (GTC) vs. Placebo in Men on Active Surveillance for Prostate Cancer: Modulation of Biological and Clinical Intermediate Biomarkers

Patient Population
See Section 3.0 for Complete Eligibility Details

Preregistration (Step 0, Screening):
- Age ≥ 21 years, ECOG PS 0-1, adequate lab values
- Must speak English or Spanish
- Must have biopsy-proven (consisting of ≥ 12 tissue cores) adenocarcinoma of the prostate with cancer present in at least 1 core in the most recent biopsy using a TRUS biopsy/TP/mpMRI-guided biopsy of the prostate
- Must be on active surveillance (local—Gleason 3+3/GG1 or Gleason 3+4/GG2) where < 6 of 12 cores are positive for cancer (see protocol for exception)
- Baseline biopsy must be 6-18 months prior to preregistration (follow-up prostate biopsy is 6 months after the initiation of EA8184 treatment)
- Must not consume supplements containing GTC; must restrict tea consumption per protocol
- No history of allergic reactions attributed to tea/other compounds of similar chemical/biologic composition to green tea extracts
- Must not have had prior treatment for prostate cancer (focal, surgery, irradiation, local ablative, androgen deprivation therapy)
- No history of renal/hepatic disease (see protocol)
- Must not have prostate cancer with distant metastases
- Must not have undergone treatment of hormone therapy, immunotherapy, chemotherapy and/or radiation for any malignancies within 2 years of pre-registration
- Must have FFPE tumor tissue specimen available for Gleason Score confirmation and % Ki-67 expression (3% or more) in tumor tissue

Randomization (Step 1) [intervention to commence 6 months prior to the planned prostate biopsy]:
- Gleason 3+3/GG1 or 3+4/GG2, where < 6 of 12 cores are positive for cancer (see protocol for exception); % Ki-67 expression ≥ 3% in at least 1 positive core

Treatment Plan
See Section 5.0 for Complete Treatment Details

- Double-blinded trial (patients randomized to Arm X)
- All treatment is administered on an outpatient basis

Arm A: Sunphenon® 90D PO twice daily, three capsules, 300 mg each, in the morning with breakfast and three capsules in the evening with dinner to provide a continuous dose of EGCG while reducing any gastrointestinal symptoms and to minimize toxicity

Arm B: Placebo PO twice daily, three capsules, 300 mg each, in the morning with breakfast and three capsules in the evening with dinner

For both arms: On the day of the month 3 and 6 follow-up visit, the study agent capsules should be taken within 4 hours of the office visit and blood draw for the required lab work. If the patient is scheduled to come in the afternoon, the dose should be taken with lunch that day instead of with dinner for that day. Patients will complete a daily pill calendar
- Patients will continue on treatment until disease progression, unacceptable toxicity, or 6 months of treatment (at which time the mandatory end of study [EOS] biopsy will be done)

Dietary Intake:
- Research staff will provide patients with dietary recall forms and instructions at the Step 1 randomization, and at 3 month intervals (month 3 and 6 or EOS)

Patient Enrollment
All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

Please Enroll Your Eligible Patients!
**STEP 0: PRE-REGISTRATION**

Submit tumor tissue for confirmation of Gleason score and screening for %Ki-67

- **Gleason Score**
  - [3+3 (GG1) or 3+4 (GG2)]
  - and %Ki-67 ≥ 3%
  - **Eligible**

- **Gleason Score is not**
  - [3+3 (GG1) or 3+4 (GG2)]
  - or %Ki-67 < 3%
  - **Ineligible**

**Stratification Factors:**
- Gleason Score 3+3 (GG1) or 3+4 (GG2)
- 1–2 biopsies vs 3 ≥ biopsies

**STEP 1: RANDOMIZATION (Note: will be indicated as “Arm X”)**

- **Arm A**
  - Green Tea Catechin (Sunphenon 90D)²
  - 300 mg PO BID

- **Arm B**
  - Placebo² 300 mg PO BID

**Continue treatment until:**
- Disease progression OR
- Unacceptable toxicity OR
- Patient has reached 6 months on treatment²

**Follow-up**

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¹Tumor tissue must be submitted at pre-registration for central review to determine patient eligibility. 720 patients will be screened at Step 0.
²EGCG: (-)-epigallocatechin-3-gallate. Each 300 mg capsule of Sunphenon 90D/placebo contains 136 mg ECGG/capsule.
³After 6 months on treatment, there is a mandatory EOS biopsy.