**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

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### 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 mpMRI-Prostate or TP biopsy or TRUS biopsy
- Must be on active surveillance [local– Gleason 3+3/4] very low/low and favorable intermediate risk (NCCN)]
- Baseline biopsy must be 6-18 months prior to preregistration (schedule a follow-up prostate biopsy 6 months after the initiation of treatment on this study)
- Must be willing to abstain from consumption of 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 the past 2 years
- 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 planned prostate biopsy):**

- Gleason score (3+3) or predominant Gleason pattern 3 (3+4), ≤ 33% of biopsy cores, and ≤ 50% involvement of any biopsy core confirmed via central review

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### 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

**Dietary Intake:**

- Research staff will provide patients with dietary recall forms and instructions at the baseline, randomization, and at 3 month intervals

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**Patient Enrollment**

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

**Protocol Information**

ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

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**Please Enroll Your Eligible Patients!**