Version 07/21/22 (Add. #4)

NCI Community Oncology Research Program

EA8184

ECOG-ACRIN cancer research group

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 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

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

Study Chair:
Nagi B. Kumar, PhD

Study Co-Chairs:
Raymond Bergan, MD
Julio Pow-Sang, MD

Patient Enrollment

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

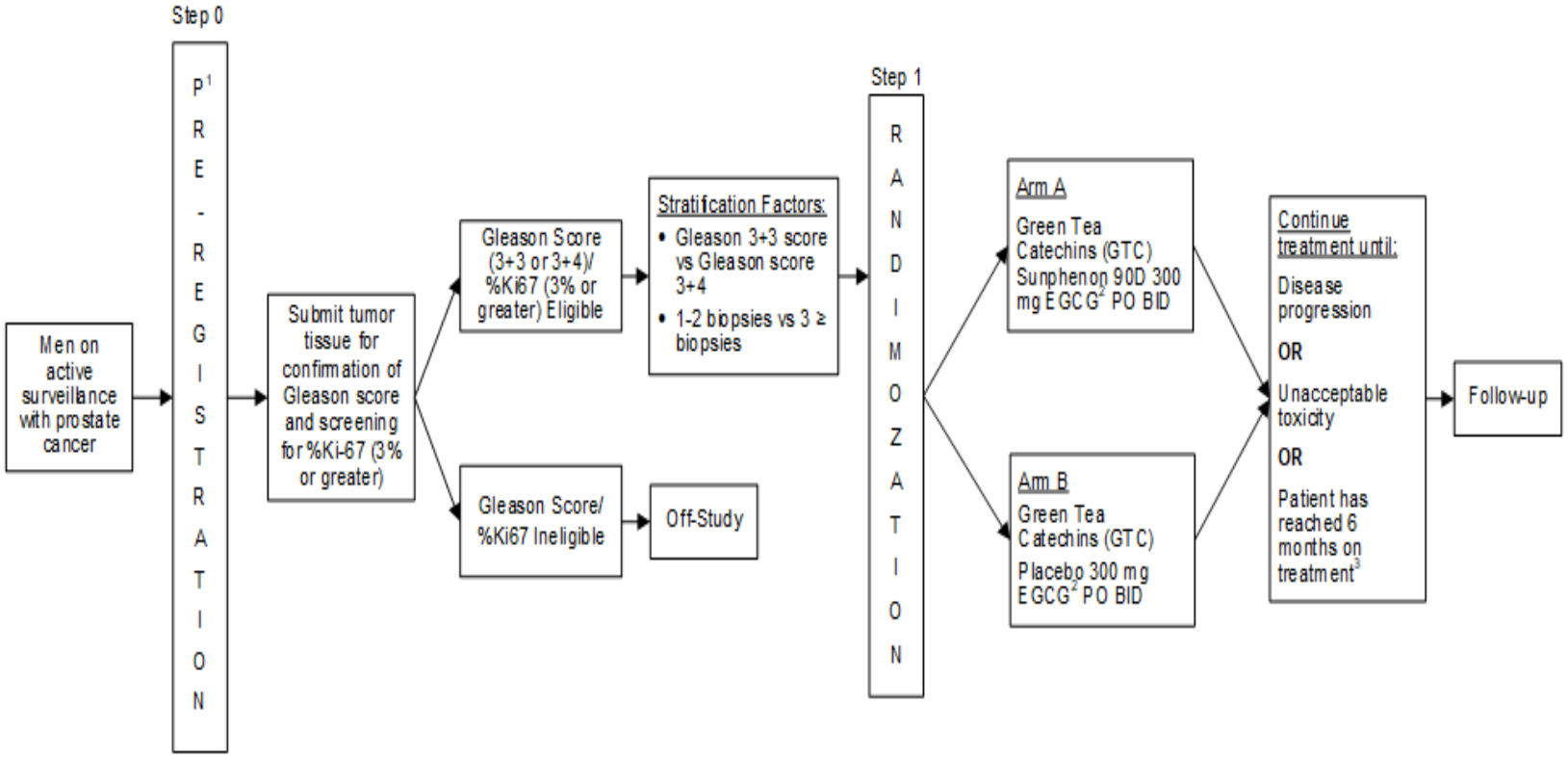
Protocol Information

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

Please Enroll Your Eligible Patients!

EA8184

Schema



Total 360 for Step 1

1. Tumor tissue must be submitted at preregistration for central review to determine patient eligibility. See Section 10 for collection and submission instructions. 720 patients will be screened in step 0.
2. EGCG: (-)-epigallocatechin-3-gallate. Each 300mg capsule of Sunphenon® 90D/Placebo contains 135mg EGCG/capsule.
3. After 6 months on treatment, there is a mandatory end-of-study (EOS) biopsy.