CALGB 70807: The Men’s Eating and Living (MEAL) Study: A Randomized Trial of Diet to Alter Disease Progression in Prostate Cancer Patients on Active Surveillance

Fast Facts

Preregistration Eligibility

1. **Histologic Documentation:** The initial biopsy showing diagnosis of prostate cancer should be used for the purposes of determining eligibility. However, if a subsequent biopsy performed before patient enrollment shows that the patient is ineligible, he may not be enrolled to the study. Eligible patients must meet all of the following criteria:
   - Biopsy-proven (consisting of ≥ 10 tissue cores) adenocarcinoma of the prostate diagnosed within 24 months prior to presentation.
   - < 25% of biopsy tissue cores positive for cancer.
   - ≤ 50% of any one biopsy tissue core positive for cancer.
   - Clinical stage ≤T2a.
   - Patients who have prostate cancer with distant metastases are not eligible.


NOTE: If a patient undergoes a transurethral resection of the prostate (TURP) for benign prostatic hyperplasia (BPH), and prostate cancer is diagnosed incidentally from the TURP specimen, eligibility for CALGB 70807 cannot be determined from the TURP specimen. However, if the patient subsequently undergoes a minimum 10-core prostate biopsy within 2 years of prostate cancer diagnosis from the TURP, and prostate cancer is detected in the biopsy specimen and meets the requirements above, the patient is eligible for this study. If prostate cancer is not detected in the biopsy specimen, the patient is not eligible.

2. **Prior Treatment:** Patients who have had prior treatment for prostate cancer by surgery, irradiation, local ablative (i.e. cryosurgery or high-intensity focused ultrasound) or androgen deprivation therapy are not eligible.

3. **Patients who have had a history of non-cutaneous malignancy (other than non-melanoma skin cancer) in the previous 5 years are not eligible.**

4. **Language:** Patients must be able to read and comprehend English language text and be able to understand spoken English over the phone.

5. **Life expectancy of at least 3 years.**

6. **Patients who are currently taking vitamin supplements including lycopene and beta-carotene are eligible.**

7. **Patients receiving treatment with 5-alpha reductase inhibitors (e.g., finasteride, dutasteride) within 90 days prior to preregistration are not eligible. Treatment with these agents during the protocol intervention is not permitted.**

8. **Patients who are currently taking coumadin are not eligible.**

9. **Participants will be men aged 50 to 80 years.**

10. **For men ≤ 70 years, biopsy Gleason score ≤ 6; for men > 70 years, biopsy Gleason score ≤ (3 + 4) = 7.**

Required Initial Laboratory Values

- Serum PSA < 10 ng/mL

   NOTE: Baseline PSA for determination of eligibility must be measured after discontinuation of any 5-alpha reductase inhibitors.

Registration Eligibility

1. **Successful completion of three 24-hour dietary recalls during the run-in period.**

2. **Patients consuming ≥ 6 servings per day of fruits and vegetables (not including juices), as determined by the run-in dietary recalls are not eligible.**

Sub-study CALGB 151105 must be offered to all patients enrolled on CALGB 70807 (although patients may opt not to participate).
PREREGISTER

Run In: Diet Recall

REGISTER

Arm A: MEAL Program Intervention with dietary education and telephone counseling sessions over 24 months

Arm B: Prostate Cancer Foundation booklet