

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

ClinicalTrial.gov Identifier: NCT01238172

Study Background

Trial Description

RATIONALE: Eating a diet high in vegetables may slow down disease progression in patients with prostate cancer.

PURPOSE: This randomized clinical trial is studying how well diet works in altering disease progression in patients with prostate cancer on active surveillance.

Arms:

Arm A - MEAL Program Intervention: (Experimental): Patients will receive dietary education and telephone counseling sessions over 24 months.

Arm B - Prostate Cancer Foundation Booklet: (Experimental): Patients receive information about diet, nutrition, exercise and cancer. Patients also receive regularly scheduled newsletters.

Objectives:

Primary

- To determine if a telephone-based dietary intervention compared to no intervention will decrease clinical progression in AS patients.

Secondary

- To compare the incidence of active treatment (surgery, irradiation, local ablation, or androgen deprivation) in AS patients receiving dietary intervention compared to no intervention.
- To compare prostate cancer-related anxiety in AS patients receiving dietary intervention compared to no intervention.
- To compare health-related quality of life in AS patients receiving dietary intervention compared to no intervention.
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OUTLINE: This is a multicenter study. Patients are stratified according to age (≤ 70 years vs > 70 years), race (black or african american vs other), and baseline prostate

biopsy (0-12 months before registration vs > 12-24 months before registration).
Patients are randomized to 1 of 2 treatment arms.

Study Milestones:

Primary Completion Date: November 18, 2017

Publication Information:

Analysis Type: Primary

Pubmed ID: 31935026

Citation: JK. Parsons. Effect of a Behavioral Intervention to Increase Vegetable Consumption on Cancer Progression Among Men With Early-Stage Prostate Cancer: The MEAL Randomized Clinical Trial. JAMA 2020. 140-148

Associated Datasets:

NCT01238172-D1-Dataset.csv (baseline),

NCT01238172-D2-Dataset.csv (consort_out),

NCT01238172-D3-Dataset.csv (figout),

NCT01238172-D4-Dataset.csv (offtreat)

NCT01238172-D5-Dataset.csv (dietcomposition)

Dataset Information:

Dataset Name: NCT01238172-D2-Dataset.csv (consort_out)

Description: Dataset NCT01238172-D2-Dataset.csv (consort_out) is one of 5 datasets associated with PubMed ID 31935026. This dataset contains information that will allow you to reproduce the consort diagram.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT01238172-D2-Dataset.csv (consort_out) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
De-identified patient reference	patid		
Treatment Arm	arm	MEAL Intervention, PCF Booklet	
Randomized	rand	Yes	
Did not meet inclusion criteria based on retrospective eligibility review	inelig_retro	Yes	
Excluded	exclud	Yes	
Did not receive intervention as randomized	refuseprior	Yes	
Excluded from the analysis	centexclud	Yes	
Did not meet inclusion criteria based on central pathology review	inelig_pro	Yes	