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: (Control): Patients receiveinformation 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.

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-D5-Dataset.csv (dietcomposition)

Description: Dataset NCT01238172-D5-Dataset.csv (dietcomposition) is one of 5 datasets associated with PubMed ID 31935026. This dataset contains information for the dietary patterns analysis including Table 2 and the eTable.

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).

The data in variables vj, vj1, and vj2 are furthered cleaned/QCed since the analyses performed in the corresponding publication (31935026) and they represent the most accurate values.

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

All dietary parameters are continuous.

NCT01238172-D5-Dataset.csv (dietcomposition) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
De-identified patient ID	patid		
Intervention group	intgrp	47=Intervention, 48=Control	
Dark green vegetables, servings/d (baseline)	greenv		
Deep yellow vegetables, servings/d (baseline)	yellowv		
Tomatoes, servings/d (baseline)	tomato		
Legumes, servings/d (baseline)	legumes		
Other vegetables, servings/d (baseline)	otherveg		
Total vegetables, servings/d (baseline)	tveg		
Cruciferous, servings/d (baseline)	crucsv		
Cruciferous, g/d (baseline)	crucgm		
Red meat, g/d (baseline)	redmeat		
Energy, kcal/d, (baseline)	kcal		
Fat, g/d (baseline)	calsfat		
Saturated fat, g/d (baseline)	calssfa		

LABEL	NAME	ELEMENTS	COMMENTS
Lycopene, mcg/d (baseline)	lycopene		
Total carotenoids (diet), mcg/d (baseline)	tcar		
Total vegetables, servings/d (12 months)	tveg1		
Fat, g/d (12 months)	calsfat1		
Legumes, servings/d (12 months)	legumes1		
Energy, kcal/d (12 months)	kcal1		
Cruciferous, servings/d (12 months)	crucsv1		
Cruciferous, g/d (12 months)	crucgm1		
Red meat, g/d (12 months)	redmeat1		
Dark green vegetables, servings/d (12 months)	greenv1		
Deep yellow vegetables, servings/d (12 months)	yellowv1		
Tomatoes, servings/d (12 months)	tomato1		
Other vegetables, servings/d (12 months)	otherveg1		
Saturated fat, g/d (12 months)	calssfa1		
Lycopene, mcg/d (12 months)	lycopene1		
Total carotenoids (diet), mcg/d (12 months)	tcar1		
Total vegetables, servings/d (24 months)	tveg2		
Fat, g/d (24 months)	calsfat2		
Legumes, servings/d (24 months)	legumes2		
Dark green vegetables, servings/d (24 months)	greenv2		
Deep yellow vegetables, servings/d (24 months)	yellowv2		
Tomatoes, servings/d (24 months)	tomato2		
Other vegetables, servings/d (24 months)	otherveg2		

LABEL	NAME	ELEMENTS	COMMENTS
Saturated fat, g/d (24 months)	calssfa2		
Energy, kcal/d (24 months)	kcal2		
Total carotenoids (diet), mcg/d (24 months)	tcar2		
Lycopene, mcg/d (24 months)	lycopene2		
Cruciferous, servings/d (24 months)	crucsv2		
Cruciferous, g/d (24 months)	crucgm2		
Red meat, g/d (24 months)	redmeat2		
Vegetable juice, servings/d (baseline)	vj		
Vegetable juice, servings/d (12 months)	vj1		
Vegetable juice, servings/d (24 months)	vj2		