CALGB-70806

Vitamin D and Breast Cancer Biomarkers

ClinicalTrials.gov Identifier: NCT01224678

Study Background

Trial Description

RATIONALE: Vitamin D may help prevent breast cancer.

PURPOSE: This randomized clinical trial is studying vitamin D and breast cancer biomarkers in female patients.

Arms:

Placebo: (Placebo Comparator): Patients receive oral placebo once daily for 12 months.

Vitamin D: (Experimental): Patients receive oral vitamin D (2000 IU) once daily for 12 months.

Objectives:

- OBJECTIVES:
  - Primary
    - To evaluate change in mammographic density using the Boyd method after one year of vitamin D supplementation compared to placebo in premenopausal women.
  - Secondary
    - To explore changes in the serum biomarker IGF1 in response to one year of vitamin D or placebo supplementation in premenopausal women.
    - To explore changes in cellular proliferation (atypia and Ki67) in response to one year of vitamin D or placebo supplementation in premenopausal women.
    - To explore correlations between change in breast cancer biomarkers (density, IGF1, atypia, and Ki67) with each other and with change in vitamin D levels.
    - To compare methods of mammographic density analysis.
    - To validate a recently developed sunlight questionnaire.
- OUTLINE: This is a multicenter study. Patients are stratified according to baseline vitamin D (sufficient [≥ 30 ng/mL or ≥ 75 mmol/L] vs insufficient [< 30 ng/mL or < 75 mmol/L]) and institutional random periareolar fine-needle aspiration (RPFNA) status (performs RPFNA vs does not perform RPFNA). Patients are randomized to 1 of 2 treatment arms.

- Arm I: Patients receive oral placebo once daily for 12 months.
- Arm II: Patients receive oral vitamin D (2000 IU) once daily for 12 months. Tissue and blood samples are collected at baseline and at 12 months for laboratory biomarker analysis. Patients also complete questionnaires at baseline and at 12 months.

Study Milestones:

Start date: October 2010

Primary Completion Date: December 2014

Publication Information:

Analysis Type: Primary

PubMed ID: 33849913

Citation: Wood ME, Liu H, Storrick E, Zahrieh D, Le-Petross HC, Jung SH, Zekan P, Kemeny MM, Charlamb JR, Wang LX, Unzeitig GW, Johnson CS, Garber JE, Marshall JR, Bedrosian I. The Influence of Vitamin D on Mammographic Density: Results from CALGB 70806 (Alliance) a Randomized Clinical Trial. Cancer Prev Res (Phila). 2021 Jul;14(7):753-762. doi: 10.1158/1940-6207.CAPR-20-0581. Epub 2021 Apr 13. PMID: 33849913; PMCID: PMC8449513.

Associated Datasets: NCT01224678-D1-Dataset.csv (rand), NCT01224678-D2-Dataset.csv (aedat)

Dataset Information:

Dataset Name: NCT01224678-D1-Dataset.csv (rand)

Description: Dataset NCT01224678-D1-Dataset.csv (rand) is one of 2 datasets associated with PubMed ID 33849913. This dataset contains data presented in the publication other than the safety analyses.

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.

NCT01224678-D1-Dataset.csv (rand) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient identifier	patid		
Cumulus: Baseline Density (%)	basedenssemi		
Cumulus: Month 12 Density (%)	m12denssemi		
Cumulus: Change in breast density (%)	denschange		
Region	region	Midwest, Northeast, South, West	
Ethnicity	ETHNIC_ID	Hispanic, Non-Hispanic, Not reported, Unknown	
Race	RACE_ID	Asian, Black or African American, Not Reported, Other, White	Data in RACE_ID with frequencies of 5 or fewer have been combined into an "Other" category in order to protect patient confidentiality.

LABEL	NAME	ELEMENTS	COMMENTS
Treatment Assigned	TREAT_ASSIGNED	Placebo, Vitamin D	
Age (years)	age		
Body Mass Index (BMI) (kg/m2)	BMI		
Baseline: Locally Reviewed Vitamin D (ng/mL)	VITDLEVEL		
Off treatment reason	OFFTRTREAS	Adverse event/side effect, Alternative therapy, Death on study, Ineligible, Lost to follow-up, Non- Compliant, Patient withdrawal/refusal after beginning therapy, Patient withdrawal/refusal prior to beginning therapy, Pregnancy, Treatment completed per protocol	
Baseline: Centrally Reviewed Vitamin D (ng/mL)	baseoh25d		
Month 12: Centrally Reviewed Vitamin D (ng/mL)	m12oh25d		
Vitamin D Change from Baseline to Month 12 (ng/mL)	oh25dchng		
BI-RADS density	basacr	2, 3, 4	The data in the dataset have been updated following the publication and are the most up-to-date data.
Evaluable for Adverse Events	eval_ae	Yes	
Complete case	eval_prim_endpoint	Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Baseline image data available	bsl_image_data_avail	Yes	