

# Serum 25-Hydroxyvitamin D in the VITamin D and Omega-3 Trial (VITAL): Clinical and Demographic Characteristics Associated With Baseline and Change With Randomized Vitamin D Treatment

## Background

- The VITamin D and Omega-3 Trial (VITAL) is a large, randomized trial that assessed the effects of vitamin D3 and omega-3 fatty acid supplements on cancer and cardiovascular disease (CVD).
- Among the overall population, no association was observed between vitamin D3 supplementation and major CVD event risk reduction.<sup>1</sup>
- However, the role of vitamin D in calcium regulation and skeletal health is well established; knowing how vitamin D levels vary by patient characteristics and seasonal changes could affect clinical treatment decisions.
- **Objective:** The investigators examined the association of baseline vitamin D levels with patient characteristics and season, and the changes in vitamin D after 1 year of treatment (vitamin D3 supplement or placebo).

## Methods

- Serum specimens were obtained from 15,804 VITAL participants at baseline (before randomization to treatment and placebo arms) and from 1,660 participants after 1 year of daily intake of 2,000 IU vitamin D3.
- Total 25(OH)D and components 25(OH)D2, and 25(OH)D3 were measured by liquid chromatography-tandem mass spectrometry; in addition, 13,149 baseline specimens and all follow-up specimens were also measured by immunoassay.
- Parathyroid hormone (iPTH), a hormone that controls calcium levels in the blood, was measured by chemiluminescence, and calcium was measured by spectrophotometry.
- Linear regression was used to evaluate the associations of baseline 25(OH)D and changes in 25(OH)D levels with patient characteristics and seasonal changes.

## Results

- Mean age of the study population was 68 years; 50.8% were women, and 15.7% were African American.
- The mean ( $\pm$ SD) total 25(OH)D at baseline was 30.8 ( $\pm$ 10.0) ng/mL.
- Total 25(OH)D correlated inversely with iPTH ( $r=-0.28$ ;  $p<0.001$ )
- Total 25(OH)D varied by season: higher in summer and lower in winter.
- After adjustment for patient factors (eg, age, sex, race, BMI) and seasonal changes, the baseline mean 25(OH)D level was lower in men than women (29.7 vs. 31.4 ng/mL,  $P<0.001$ ) and lower in African American participants than white participants (27.9 vs 32.5 ng/mL,  $P<0.001$ ). Lower levels were also associated with smoking, higher BMIs, and higher latitudes.
- After 1 year, mean 25(OH)D increased 11.9 ng/mL in the treatment arm and decreased 0.7 ng/mL in the control arm. Greater increases were seen in participants with low baseline levels and African American participants.
- iPTH levels decreased in the treatment trial arm and did not change in the control arm; calcium levels remained similar in both trial arms.

## Conclusions

- Among VITAL participants, baseline 25(OH)D levels varied with participant characteristics and seasons.
- Vitamin D supplementation increased concentrations, and participants with low baseline 25(OH)D had the greatest increases.

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### Webpage

<https://www.sciencedirect.com/science/article/pii/S1551714419305695>

### Reference

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