Abstract

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Age-Related Cataract in Men in the Selenium and Vitamin E Cancer Prevention Trial Eye Endpoints Study: A Randomized Clinical Trial.

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IMPORTANCE: Observational studies suggest a role for dietary nutrients such as vitamin E and selenium in cataract prevention. However, the results of randomized clinical trials of vitamin E supplements and cataract have been disappointing and are not yet available for selenium.

OBJECTIVE: To test whether long-term supplementation with selenium and vitamin E affects the incidence of cataract in a large cohort of men.

DESIGN, SETTING AND PARTICIPANTS: The Selenium and Vitamin E Cancer Prevention Trial (SELECT) Eye Endpoints Study was an ancillary study of the Southwest Oncology Group-coordinated SELECT, a randomized placebo-controlled 4-arm trial of selenium and vitamin E conducted among 35,533 men, 50 years and older for African American participants and 55 years and older for all other men, at 427 participating sites in the United States, Canada, and Puerto Rico. A total of 11,267 SELECT participants from 128 SELECT sites participated in the SELECT Eye Endpoints ancillary study.

INTERVENTIONS: Individual supplements of selenium (200 μg per day from L-selenomethionine) and vitamin E (400 IU per day of all rac-α-tocopheryl acetate).

MAIN OUTCOMES AND MEASURES: Incident cataract was defined as a lens opacity, age related in origin, and responsible for a reduction in best-corrected visual acuity to 20/30 or worse based on self-reports confirmed by medical record review. Cataract extraction was defined as the surgical removal of an incident cataract.

RESULTS: During a mean (SD) of 5.6 (1.2) years of treatment and follow-up, 389 cases of cataract were documented. There were 185 cataracts in the selenium group and 204 in the no selenium group (hazard ratio, 0.91; 95 % CI, 0.75-1.11; P = .37). For vitamin E, there were 197 cases in the treated group and 192 in the placebo group (hazard ratio, 1.02; 95 % CI, 0.84-1.25; P = .81). Similar results were observed for cataract extraction.

CONCLUSIONS AND RELEVANCE: These data from a large cohort of apparently healthy men indicate that long-term daily supplementation with selenium and/or vitamin E is unlikely to have a large beneficial effect on age-related cataract.

Trial Registration: ClinicalTrials.gov Identifier: NCT00784225.

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