Abstract

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Effect of selenium and vitamin E on risk of prostate cancer and other cancers: the Selenium and Vitamin E Cancer Prevention Trial (SELECT).


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CONTEXT: Secondary analyses of 2 randomized controlled trials and supportive epidemiologic and preclinical data indicated the potential of selenium and vitamin E for preventing prostate cancer.

OBJECTIVE: To determine whether selenium, vitamin E, or both could prevent prostate cancer and other diseases with little or no toxicity in relatively healthy men.

DESIGN, SETTING, AND PARTICIPANTS: A randomized, placebo-controlled trial (Selenium and Vitamin E Cancer Prevention Trial [SELECT]) of 35,533 men from 427 participating sites in the United States, Canada, and Puerto Rico randomly assigned to 4 groups (selenium, vitamin E, selenium + vitamin E, and placebo) in a double-blind fashion between August 22, 2001, and June 24, 2004. Baseline eligibility included age 50 years or older (African American men) or 55 years or older (all other men), a serum prostate-specific antigen level of 4 ng/mL or less, and a digital rectal examination not suspicious for prostate cancer.

INTERVENTIONS: Oral selenium (200 microg/d from L-selenomethionine) and matched vitamin E placebo, vitamin E (400 IU/d of all rac-alpha-tocopheryl acetate) and matched selenium placebo, selenium + vitamin E, or placebo + placebo for a planned follow-up of minimum of 7 years and a maximum of 12 years.

MAIN OUTCOME MEASURES: Prostate cancer and prespecified secondary outcomes, including lung, colorectal, and overall primary cancer.

RESULTS: As of October 23, 2008, median overall follow-up was 5.46 years (range, 4.17-7.33 years). Hazard ratios (99% confidence intervals [CIs]) for prostate cancer were 1.13 (99% CI, 0.95-1.35; n = 473) for vitamin E, 1.04 (99% CI, 0.87-1.24; n = 432) for selenium, and 1.05 (99% CI, 0.88-1.25; n = 437) for selenium + vitamin E vs 1.00 (n = 416) for placebo. There were no significant differences (all P>.15) in any other prespecified cancer end points. There were statistically nonsignificant increased risks of prostate cancer in the vitamin E group (P = .06) and type 2 diabetes mellitus in the selenium group (relative risk, 1.07; 99% CI, 0.94-1.22; P = .16) but not in the selenium + vitamin E group.

CONCLUSION: Selenium or vitamin E, alone or in combination at the doses and formulations used, did not prevent prostate cancer in this population of relatively healthy men.

TRIAL REGISTRATION: clinicaltrials.gov identifier: NCT00006392.

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