

Abstract

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Vitamin E and the risk of prostate cancer: the Selenium and Vitamin E Cancer Prevention Trial (SELECT).

Klein EA, Thompson IM Jr, Tangen CM, Crowley JJ, Lucia MS, Goodman PJ, Minasian LM, Ford LG, Parnes HL, Gaziano JM, Karp DD, Lieber MM, Walther PJ, Klotz L, Parsons JK, Chin JL, Darke AK, Lippman SM, Goodman GE, Meyskens FL Jr, Baker LH.

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CONTEXT: The initial report of the Selenium and Vitamin E Cancer Prevention Trial (SELECT) found no reduction in risk of prostate cancer with either selenium or vitamin E supplements but a statistically nonsignificant increase in prostate cancer risk with vitamin E. Longer follow-up and more prostate cancer events provide further insight into the relationship of vitamin E and prostate cancer.

OBJECTIVE: To determine the long-term effect of vitamin E and selenium on risk of prostate cancer in relatively healthy men.

DESIGN, SETTING, AND PARTICIPANTS: A total of 35,533 men from 427 study sites in the United States, Canada, and Puerto Rico were randomized between August 22, 2001, and June 24, 2004. Eligibility criteria included a prostate-specific antigen (PSA) of 4.0 ng/mL or less, a digital rectal examination not suspicious for prostate cancer, and age 50 years or older for black men and 55 years or older for all others. The primary analysis included 34,887 men who were randomly assigned to 1 of 4 treatment groups: 8752 to receive selenium; 8737, vitamin E; 8702, both agents, and 8696, placebo. Analysis reflect the final data collected by the study sites on their participants through July 5, 2011.

INTERVENTIONS: Oral selenium (200 µg/d from L-selenomethionine) with matched vitamin E placebo, vitamin E (400 IU/d of all *rac*- α -tocopheryl acetate) with matched selenium placebo, both agents, or both matched placebos for a planned follow-up of a minimum of 7 and maximum of 12 years.

MAIN OUTCOME MEASURES: Prostate cancer incidence.

RESULTS: This report includes 54,464 additional person-years of follow-up and 521 additional cases of prostate cancer since the primary report. Compared with the placebo (referent group) in which 529 men developed prostate cancer, 620 men in the vitamin E group developed prostate cancer (hazard ratio [HR], 1.17; 99% CI, 1.004-1.36, $P = .008$); as did 575 in the selenium group (HR, 1.09; 99% CI, 0.93-1.27; $P = .18$), and 555 in the selenium plus vitamin E group (HR, 1.05; 99% CI, 0.89-1.22, $P = .46$). Compared with placebo, the absolute increase in risk of prostate cancer per 1000 person-years was 1.6 for vitamin E, 0.8 for selenium, and 0.4 for the combination.

CONCLUSION: Dietary supplementation with vitamin E significantly increased the risk of prostate cancer among healthy men.

TRIAL REGISTRATION: Clinicaltrials.gov Identifier: NCT00006392.

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