

S31. Prevention of prostate cancer with selenium and vitamin E: SELECT-trial

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Prostate cancer continues to be both a major health threat, especially among African American men, and a public health burden. However, growing evidence suggests that selenium and vitamin E may decrease the risk of this disease. The Selenium and Vitamin E Cancer Prevention Trial (SELECT), a phase III randomized, placebo-controlled study, is designed to determine whether selenium and vitamin E, alone or in combination, decrease the risk of prostate cancer in healthy men.

SELECT opened to accrual on July 25, 2001 in more than 400 clinical sites across the USA, Puerto Rico and Canada; the goal was to randomize 32,400 men. Accrual was completed in June 2004, two years ahead of schedule, with a total of 35,534 men randomized.

Eligibility requirements include age of at least 55 years (African American men at least 50 years of age), and no evidence of prostate cancer as determined by a serum PSA level of no more than 4 mg/ml and a digital rectal exam (DRE) not suspicious for prostate cancer.

Participants were randomized to receive selenium (200 µg/day from L-selenomethionine) and/or vitamin E (400 IU/day of *all-rac*- δ -tocopheryl acetate) supplementation for a minimum of 7 years (maximum of 12 years). The rationale for choosing these agents was based on preclinical data as well as analyses of secondary endpoints in cancer prevention clinical trials. The primary endpoint of SELECT is prostate cancer prevention based on community standards of diagnosis. Several other non-cancer endpoints are also being explored.