

Study finds selenium, vitamin E do not prevent prostate cancer

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Findings from one of the largest cancer chemoprevention trials ever conducted have concluded that selenium and vitamin E taken alone or in combination for an average of five and a half years did not prevent prostate cancer, according to a team of researchers coordinated by the Southwest Oncology Group (SWOG) and led by scientists at The University of Texas M. D. Anderson Cancer Center and Cleveland Clinic.

Data and analysis gathered through Oct. 23, 2008, from the Selenium and Vitamin E Cancer Prevention Trial (SELECT) were published in the Dec. 9 issue of the *Journal of the American Medical Association (JAMA)* by Scott M. Lippman, M.D., professor and chair of Thoracic/Head and Neck Medical Oncology at M. D. Anderson, Eric A. Klein, M.D., of the Cleveland Clinic Lerner College of Medicine, and 30 coauthors from the United States, Puerto Rico and Canada.

Funded by the National Cancer Institute (NCI) with some additional contribution from the National Center for Complementary and Alternative Medicine, the Phase III trial began recruitment in August 2001 and aimed to determine whether selenium, vitamin E, or both could prevent prostate cancer and other diseases in relatively healthy men. The study followed 35,533 participants from 427 sites in the United States, Canada and Puerto Rico. The randomized, placebo-controlled and double-blind trial divided the participants into four intervention groups: selenium, vitamin E, both selenium and vitamin E, and placebos.

The study found no evidence of benefit from selenium, vitamin E, or both. Additionally, the data showed two statistically non-significant findings of concern: slightly increased risks of prostate cancer in the vitamin E group and type two diabetes mellitus in the selenium group. Both trends may be due to chance and were not observed in the group taking selenium and vitamin E together.

An independent data and safety monitoring committee reached the same conclusion and recommended supplementation be discontinued Oct. 23 for lack of evidence of benefit.

"SELECT presented a unique opportunity to improve the lives of men from every social and ethnic background through chemoprevention," said Lippman, who serves as a national study coordinator. "Although supplementation has been discontinued, we will continue to follow these men and monitor their health for approximately three more years, conducting regular prostate screening tests and questioning them about diabetes and other health issues. Doing so is critical not only to determine any possible long-term effects of the selenium and vitamin E, but also in order to gain a better understanding of prostate and other cancers and age-related disease."

Prostate cancer is the most common male cancer in the U.S. and the second leading cause of cancer deaths overall. The American Cancer Society estimates that more than 180,000 American men will be diagnosed with prostate cancer this year and nearly 29,000 will die from the disease. African-American men have a 60 percent higher incidence rate of prostate cancer and are two times more likely to die from the disease compared with Caucasian men.

Elise Cook, M.D., an associate professor in M. D. Anderson's Department of Clinical Cancer Prevention and the location's principal investigator, served as the chair of SELECT's Minority and Medically

Underserved Subcommittee. "Our site has placed a strong emphasis on recruiting African-American men to participate. Of the 387 men we follow, 101 of those are African-American. It is important we continue to follow these men to determine long-term effects and complete the ancillary studies in which many participate," said Cook.

SELECT was based upon the secondary outcomes from two previous cancer prevention trials. The first, a 1996 study of selenium versus placebo to prevent non-melanoma skin cancer, showed that although the supplement did not reduce the risk of skin cancer, selenium did reduce prostate cancer by two-thirds; and in the second, a 1998 study conducted by Finnish researchers determined that although vitamin E did not prevent lung cancer in more than 29,000 male smokers, it did result in 32 percent fewer prostate cancers in men taking the supplement.

"Preliminary data suggesting benefits - no matter how promising - cannot reliably result in new clinical recommendations until they've been tested in definitive trials," said Ernest T. Hawk, M.D., vice president and division head of M. D. Anderson's Cancer Prevention and Population Sciences.

Although the SELECT trial did not turn out as we'd hoped - identifying a new way to reduce men's risk of prostate cancer - it was nevertheless extremely valuable by generating definitive evidence. Cancer prevention advances by rigorous science."

Identity of SELECT participants will remain blinded to prevent the introduction of any unintentional bias, however, they may be unblinded upon request. The sub-studies, funded and conducted by the National Institutes of Health's National Heart, Lung and Blood Institute, the National Institute of Aging, the National Eye Institute and the NCI, will continue without the participants taking any supplementation. These ancillary studies were evaluating the effects of selenium and vitamin E

on chronic obstructive pulmonary disease, the development of Alzheimer's disease, the development of age-related macular degeneration and cataracts, and the development of colon polyps.

Lippman commented, "We are grateful to each of the 387 Houston-area men who committed to participating in this study through M. D. Anderson. Prevention trials are an important direction for the future of cancer research. SELECT played an important role in the study of the prevention of prostate cancer and we hope to learn more about why these supplements didn't do more to prevent prostate cancer as the study continues."

Source: University of Texas M. D. Anderson Cancer Center

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