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### **NIH-funded study shows increased prostate cancer risk from vitamin E supplements**

Men who took 400 international units (I.U.) of vitamin E daily had more prostate cancers compared to men who took a placebo, according to an updated review of data from the Selenium and Vitamin E Cancer Prevention Trial (SELECT). The findings showed that, per 1,000 men, there were 76 prostate cancers in men who took only vitamin E supplements, vs. 65 in men on placebo over a seven-year period, or 11 more cases of prostate cancer per 1,000 men. This represents a 17 percent increase in prostate cancers relative to those who took a placebo. This difference was statistically significant and therefore is not likely due to chance. The results of this update appeared Oct. 12, 2011, in the Journal of the American Medical Association.

SWOG, an international network of research institutions, carried out SELECT at more than 400 clinical sites in the United States, Puerto Rico, and Canada. SELECT was funded by the National Cancer Institute (NCI) and other institutes that comprise the National Institutes of Health.

"Based on these results and the results of large cardiovascular studies using vitamin E, there is no reason for men in the general population to take the dose of vitamin E used in SELECT as the supplements have shown no benefit and some very real risks," said Eric Klein, M.D., a study co-chair for SELECT, and a physician at the Cleveland Clinic. "For now, men who were part of SELECT should continue to see their primary care physician or urologist and bring these results to their attention for further consideration."

The SELECT study began in 2001 and included over 35,000 men. It was started because earlier research had suggested that selenium or vitamin E might reduce the risk of developing prostate cancer. However, based on an independent safety monitoring review in autumn 2008, participants were told to stop taking their study supplements because it had become clear that the trial would never produce the 25 percent reduction in prostate cancer the study was designed to show with the use of these supplements. In 2010, the study sites were closed and over half of the participants consented to have their health monitored via mail questionnaires. Now, because of this latest finding, researchers are encouraging all participants to consider taking part in long-term study follow-up so investigators can continue to track outcomes.

SELECT was undertaken to substantiate earlier, separate findings from studies in which prostate cancer risk was not the primary outcome. A 1998 study of male smokers in Finland who took 50 I.U. of vitamin E daily to prevent lung cancer, showed 32 percent fewer prostate cancers in men who took the supplement. A 1996 study of men and women with a history of skin cancer who took selenium for prevention of disease recurrence showed that men who took the supplement had 52 percent fewer prostate cancers than men who did not take the supplement.

Based on these and other findings, men were recruited to participate in SELECT. They were randomly assigned to take one of four sets of supplements or placebos, with more than 8,000 men in each group. One group took both selenium and vitamin E; one took selenium and a placebo that looked similar to vitamin E; one took vitamin E and a placebo that looked similar to selenium; and the final group received placebos of both supplements. Men who took selenium alone or vitamin E and selenium together were also more likely to develop prostate cancer than men who took a placebo, but those increases were small and possibly due to chance.

"SELECT has definitively shown a lack of benefit from vitamin E and selenium supplements in the prevention of prostate cancer and has shown there is the potential for harm," said Lori Minasian, M.D., study co-author and acting director of NCI's Division of Cancer Prevention. "Nevertheless, this type of research has been critically important to understanding

the potential benefits and risks from supplements."

SELECT researchers are now measuring the amount of vitamin E, selenium, and other nutrients in the blood of participants when they joined the trial, to see if the effect of the supplements depended upon this baseline level of micronutrient. Other researchers are looking at single nucleotide polymorphisms, which are DNA changes known as SNPs, to see if a change in one or more genes could affect cancer risk or perhaps increase a man's risk of developing prostate cancer while taking vitamin E.

The participant samples come from the study biorepository of blood and toe nail clippings which, when coupled with the extensive clinical information on participants, is a vital resource for further study. "SWOG is soliciting proposals from researchers nationwide to use the SELECT biorepository to help answer the biological question of why vitamin E increased risk instead of decreasing it," said Laurence Baker, D.O., study co-author and chairman of SWOG. "There are many more questions raised by these study results than we have answers for, and thus the need for further investigation."

Except for skin cancer, prostate cancer is the most common type of cancer in men in the United States. The current lifetime risk of prostate cancer for American men is 16 percent. In 2011, there will be an estimated 240,890 new cases of prostate cancer and 33,720 deaths from this disease in the United States.

SELECT has been funded by NCI with additional monies from the National Center for Complementary and Alternative Medicine, and with sub-studies funded and conducted by the National Heart, Lung, and Blood Institute; the National Institute of Aging; and the National Eye Institute at NIH.

For an updated Q&A on SELECT [available upon request prior to 10/11/2011], please go to <http://www.cancer.gov/newscenter/qa/2008/selectqa>.

For a Spanish version of the release and Q&A, please go to <http://www.cancer.gov/espanol/noticias/SELECT2011Spanish>.

To view a schematic drawing of the prostate, a microscopic view of the crystal structure of vitamin E, and photos of the pills that were provided to the SELECT participants, please go to <http://www.cancer.gov/newscenter/pressreleases/2001/select>.

SWOG (formerly the Southwest Oncology Group) is a network of more than 4,000 researchers at more than 500 institutions that designs and conducts clinical trials to improve the practice of medicine in preventing, detecting, and treating cancer and to enhance the quality of life for cancer survivors. For more information, go to <http://www.crab.org/select>.

NCI leads the National Cancer Program and the NIH effort to dramatically reduce the burden of cancer and improve the lives of cancer patients and their families, through research into prevention and cancer biology, the development of new interventions, and the training and mentoring of new researchers. For more information about cancer, please visit the NCI Web site at [www.cancer.gov](http://www.cancer.gov) or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).

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**Reference:** EA Klein, IM Thompson, CM Tangen, JJ Crowley, MS Lucia, PJ Goodman, L Minasian, LG Ford, HL Parnes, JM Gaziano, DD Karp, MM Lieber, PJ Walther, L Klotz, JK Parsons, JL Chin, A Darke, SM Lippman, GE Goodman, FL Meyskens, and LH Baker. Vitamin E and the Risk of Prostate Cancer: Results of The Selenium and Vitamin E Cancer Prevention Trial (SELECT). JAMA. October 12, 2011. 306(14) 1549-1556.

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