

Physicians' Health Study

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Physicians' Health Study
<http://phs.bwh.harvard.edu/>

Welcome to the Web site of the Physicians' Health Study. This landmark study was begun in the fall of 1982 to test the benefits and risks of aspirin and beta-carotene in the primary prevention of cardiovascular disease and cancer. Twenty-four years and more than 200 published research reports later, it is still going strong.

The original randomized trial, the Physicians' Health Study-I, ended in 1995. Its finding that daily low-dose aspirin decreased the risk of a first myocardial infarction by 44% Pill packs around the globe helped focus on the role of aspirin in primary prevention. It also showed no benefit or harm from beta-carotene, a finding that allowed investigators to turn to other, more promising agents. Although that trial may be over, the physicians who took part in it continue to help advance our knowledge about the prevention of cardiovascular disease, cancer, and other chronic diseases by completing annual questionnaires. Dedicated PHS participants took the study, and their study pills, to almost every part of the globe. A second randomized trial, the Physicians' Health Study-II, is now testing the balance of benefits and risks of three other widely used, but as yet unproven, supplements for the primary prevention of cardiovascular disease, cancer, and age-related eye disease--vitamin E, vitamin C, and a multivitamin.

<http://clinicaltrials.gov/ct/show/NCT00270647>

Physicians' Health Study II: Vitamin E, Ascorbic Acid, Beta Carotene, and/or Multivitamins in Preventing Cancer and Cardiovascular Disease in Older Healthy Male Doctors

This study is no longer recruiting patients.
Sponsors and Collaborators: Dana-Farber Cancer Institute
National Cancer Institute (NCI)
Information provided by: National Cancer Institute (NCI)
ClinicalTrials.gov Identifier: NCT00270647

RATIONALE: Chemoprevention is the use of certain drugs or nutritional supplements to keep cancer from forming, growing, or coming back. The use

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of vitamin E, ascorbic acid, beta carotene, and/or multivitamins may keep cancer or other diseases, such as cardiovascular disease, from forming.

PURPOSE: This randomized clinical trial is studying vitamin E, ascorbic acid, beta carotene, and/or multivitamins to see how well they work compared to placebos in preventing prostate cancer, other cancers, or cardiovascular disease in healthy older male doctors. **NOTE:** Beta carotene was no longer given as of 3/8/2003.

Colorectal Cancer

Prostate Cancer

Unspecified Adult Solid Tumor, Protocol Specific

Drug: ascorbic acid

Drug: beta carotene

Drug: multivitamin

Drug: vitamin E

Procedure: biologically based therapies

Procedure: cancer prevention intervention

Procedure: chemoprevention of cancer

Procedure: complementary and alternative therapy

Procedure: dietary intervention

Procedure: nutritional supplementation

Study Type: Interventional

Study Design: Prevention, Randomized, Double-Blind, Placebo Control

Official Title: Physicians' Health Study II: Trial of Vitamins in the Chemoprevention of Cancer, CVD, and Eye Disease

Further study details as provided by National Cancer Institute (NCI):

OBJECTIVES:

Primary

- * Determine whether vitamin E every other day reduces the risk of developing prostate cancer in older healthy male physicians.
- * Determine whether daily ascorbic acid and/or a multivitamin reduces the risk of total cancer in these participants.
- * Determine whether vitamin E every other day, ascorbic acid daily, or a multivitamin daily reduces the risk of important vascular events in these participants (beta carotene portion of study discontinued as of 3/8/2003).

Secondary

- * Determine whether vitamin E and/or multivitamins reduce the risk of developing total cancer, colon cancer, and colon polyps in these participants.
- * Determine whether vitamin E, ascorbic acid, or multivitamins reduce the risk of myocardial infarction and stroke in these participants.

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* Determine whether vitamin E, ascorbic acid, or multivitamins reduce the risk of age-related macular degeneration or cataract in these participants.

* Determine whether vitamin E, ascorbic acid, or multivitamins reduce the risk of early cognitive decline in men aged 65 and over.

OUTLINE: This is a randomized, double-blind, placebo-controlled study.

* Pre-randomization run-in phase: Participants who did not participate in the Physicians' Health Study I (PHS I) receive vitamin E placebo once every other day, ascorbic acid placebo once daily, multivitamin placebo once daily, and beta carotene placebo once every other day for 12 weeks. Participants demonstrating compliance with pill taking proceed, along with participants who participated in PHS I, to the randomized phase. (Beta carotene portion of study discontinued as of 3/8/2003.)

* Randomized phase: Participants are randomized to receive all active supplements, all placebos, or any combination comprising oral vitamin E or placebo once every other day, oral ascorbic acid or placebo once daily, oral multivitamin or placebo once daily, and/or oral beta carotene or placebo once every other day for 4 years. (Beta carotene portion of study discontinued as of 3/8/2003.)

PROJECTED ACCRUAL: A total of 14,661 participants were accrued for this study.

* Healthy male physician practicing in the United States

* Prior participation in the Physicians' Health Study I allowed

PATIENT CHARACTERISTICS:

Age * 50 and over

* No history of other serious illness that would preclude study participation

* No history of significant adverse events (e.g., rash or allergic reaction) attributed to study agents

More Information

Clinical trial summary from the National Cancer Institute's PDQ® database
Study ID Numbers: CDR0000448630; BWH-1999-P-003315; BWH-1999-P-003318;
BWH-83-00405

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