

# Abstract

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## Vitamin E in the primary prevention of cardiovascular disease and cancer: the Women's Health Study: a randomized controlled trial.

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**CONTEXT:** Basic research provides plausible mechanisms and observational studies suggest that apparently healthy persons, who self-select for high intakes of vitamin E through diet or supplements, have decreased risks of cardiovascular disease and cancer. Randomized trials do not generally support benefits of vitamin E, but there are few trials of long duration among initially healthy persons.

**OBJECTIVE:** To test whether vitamin E supplementation decreases risks of cardiovascular disease and cancer among healthy women.

**DESIGN, SETTING, AND PARTICIPANTS:** In the Women's Health Study conducted between 1992 and 2004, 39 876 apparently healthy US women aged at least 45 years were randomly assigned to receive vitamin E or placebo and aspirin or placebo, using a 2 x 2 factorial design, and were followed up for an average of 10.1 years.

**INTERVENTION AND MAIN OUTCOME MEASURES:** Administration of 600 IU of natural-source vitamin E on alternate days. Primary outcomes were a composite end point of first major cardiovascular event (nonfatal myocardial infarction, nonfatal stroke, or cardiovascular death) and total invasive cancer.

**RESULTS:** During follow-up, there were 482 major cardiovascular events in the vitamin E group and 517 in the placebo group, a nonsignificant 7% risk reduction (relative risk [RR], 0.93; 95% confidence interval [CI], 0.82-1.05; P = .26). There were no significant effects on the incidences of myocardial infarction (RR, 1.01; 95% CI, 0.82-1.23; P = .96) or stroke (RR, 0.98; 95% CI, 0.82-1.17; P = .82), as well as ischemic or hemorrhagic stroke. For cardiovascular death, there was a significant 24% reduction (RR, 0.76; 95% CI, 0.59-0.98; P = .03). There was no significant effect on the incidences of total cancer (1437 cases in the vitamin E group and 1428 in the placebo group; RR, 1.01; 95% CI, 0.94-1.08; P = .87) or breast (RR, 1.00; 95% CI, 0.90-1.12; P = .95), lung (RR, 1.09; 95% CI, 0.83-1.44; P = .52), or colon cancers (RR, 1.00; 95% CI, 0.77-1.31; P = .99). Cancer deaths also did not differ significantly between groups. There was no significant effect of vitamin E on total mortality (636 in the vitamin E group and 615 in the placebo group; RR, 1.04; 95% CI, 0.93-1.16; P = .53).

**CONCLUSIONS:** The data from this large trial indicated that 600 IU of natural-source vitamin E taken every other day provided no overall benefit for major cardiovascular events or cancer, did not affect total mortality, and decreased cardiovascular mortality in healthy women. These data do not support recommending vitamin E supplementation for cardiovascular disease or cancer prevention among healthy women.

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