

Abstract

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Effects of long-term vitamin E supplementation on cardiovascular events and cancer: a randomized controlled trial.

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CONTEXT: Experimental and epidemiological data suggest that vitamin E supplementation may prevent cancer and cardiovascular events. Clinical trials have generally failed to confirm benefits, possibly due to their relatively short duration.

OBJECTIVE: To evaluate whether long-term supplementation with vitamin E decreases the risk of cancer, cancer death, and major cardiovascular events.

DESIGN, SETTING, AND PATIENTS: A randomized, double-blind, placebo-controlled international trial (the initial Heart Outcomes Prevention Evaluation [HOPE] trial conducted between December 21, 1993, and April 15, 1999) of patients at least 55 years old with vascular disease or diabetes mellitus was extended (HOPE-The Ongoing Outcomes [HOPE-TOO]) between April 16, 1999, and May 26, 2003. Of the initial 267 HOPE centers that had enrolled 9541 patients, 174 centers participated in the HOPE-TOO trial. Of 7030 patients enrolled at these centers, 916 were deceased at the beginning of the extension, 1382 refused participation, 3994 continued to take the study intervention, and 738 agreed to passive follow-up. Median duration of follow-up was 7.0 years.

INTERVENTION AND MAIN OUTCOME MEASURES: Daily dose of natural source vitamin E (400 IU) or matching placebo. Primary outcomes included cancer incidence, cancer deaths, and major cardiovascular events (myocardial infarction, stroke, and cardiovascular death). Secondary outcomes included heart failure, unstable angina, and revascularizations.

RESULTS: Among all HOPE patients, there were no significant differences in the primary analysis: for cancer incidence, there were 552 patients (11.6%) in the vitamin E group vs 586 (12.3%) in the placebo group (relative risk [RR], 0.94; 95% confidence interval [CI], 0.84-1.06; $P = .30$); for cancer deaths, 156 (3.3%) vs 178 (3.7%), respectively (RR, 0.88; 95% CI, 0.71-1.09; $P = .24$); and for major cardiovascular events, 1022 (21.5%) vs 985 (20.6%), respectively (RR, 1.04; 95% CI, 0.96-1.14; $P = .34$). Patients in the vitamin E group had a higher risk of heart failure (RR, 1.13; 95% CI, 1.01-1.26; $P = .03$) and hospitalization for heart failure (RR, 1.21; 95% CI, 1.00-1.47; $P = .045$). Similarly, among patients enrolled at the centers participating in the HOPE-TOO trial, there were no differences in cancer incidence, cancer deaths, and major cardiovascular events, but higher rates of heart failure and hospitalizations for heart failure.

CONCLUSION: In patients with vascular disease or diabetes mellitus, long-term vitamin E supplementation does not prevent cancer or major cardiovascular events and may increase the risk for heart failure.

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