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Multivitamins in the prevention of cancer in men: the Physicians' Health Study II randomized controlled trial.

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Abstract

CONTEXT:

Multivitamin preparations are the most common dietary supplement, taken by at least one-third of all US adults. Observational studies have not provided evidence regarding associations of multivitamin use with total and site-specific cancer incidence or mortality.

OBJECTIVE:

To determine whether long-term multivitamin supplementation decreases the risk of total and site-specific cancer events among men.

DESIGN, SETTING, AND PARTICIPANTS:

A large-scale, randomized, double-blind, placebo controlled trial (Physicians" Health Study II) of **14 641 male** US physicians initially aged 50 years or older (mean [SD] age, 64.3 [9.2] years), including **1312 men with a history of cancer at randomization**, enrolled in a common multivitamin study that began in **1997 with treatment and follow-up through June 1, 2011**.

INTERVENTION:

Daily multivitamin or placebo.

MAIN OUTCOME MEASURES:

Total cancer (excluding nonmelanoma skin cancer), with prostate, colorectal, and other site-specific cancers among the secondary end points.

RESULTS:

During a median (interquartile range) follow-up of 11.2 (10.7-13.3) years, there were 2669 men with confirmed cancer, including 1373 cases of prostate cancer and 210 cases of colorectal cancer. Compared with placebo, men taking a daily multivitamin had a statistically significant reduction in the incidence of total cancer (multivitamin and placebo groups, 17.0 and 18.3 events, respectively, per 1000 person-years; hazard ratio [HR], 0.92; 95% CI, 0.86-0.998; P=.04). There was no significant effect of a daily multivitamin on prostate cancer (multivitamin and placebo groups, 9.1 and 9.2 events, respectively, per 1000 person-years; HR, 0.98; 95% CI, 0.88-1.09; P=.76), colorectal cancer (multivitamin and placebo groups, 1.2 and 1.4 events, respectively, per 1000 person-years; HR, 0.89; 95% CI, 0.68-1.17; P=.39), or other site-specific cancers. There was no significant difference in the risk of cancer mortality (multivitamin and placebo groups, 4.9 and 5.6 events, respectively, per 1000 person-years; HR, 0.88; 95% CI, 0.77-1.01; P=.07). Daily multivitamin use was associated with a reduction in total cancer among 1312 men with a baseline history of cancer (HR, 0.73; 95% CI, 0.56-0.96; P=.02), but this did not differ significantly from that among 13 329 men initially without cancer (HR, 0.94; 95% CI, 0.87-1.02; P=.15; P for interaction=.07). Conclusion In this large prevention trial of male physicians, daily multivitamin supplementation modestly but significantly reduced the risk of total cancer.