

Abstract

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

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CONTEXT: Although multivitamins are used to prevent vitamin and mineral deficiency, there is a perception that multivitamins may prevent cardiovascular disease (CVD). Observational studies have shown inconsistent associations between regular multivitamin use and CVD, with no long-term clinical trials of multivitamin use.

OBJECTIVE: To determine whether long-term multivitamin supplementation decreases the risk of major cardiovascular events among men.

DESIGN, SETTING, AND PARTICIPANTS: The Physicians' Health Study II, a randomized, double-blind, placebo-controlled trial of a common daily multivitamin, began in 1997 with continued treatment and follow-up through June 1, 2011. A total of 14,641 male US physicians initially aged 50 years or older (mean, 64.3 [SD, 9.2] years), including 754 men with a history of CVD at randomization, were enrolled.

INTERVENTION: Daily multivitamin or placebo.

MAIN OUTCOME MEASURES: Composite end point of major cardiovascular events, including nonfatal myocardial infarction (MI), nonfatal stroke, and CVD mortality. Secondary outcomes included MI and stroke individually.

RESULTS: During a median follow-up of 11.2 (interquartile range, 10.7-13.3) years, there were 1732 confirmed major cardiovascular events. Compared with placebo, there was no significant effect of a daily multivitamin on major cardiovascular events (11.0 and 10.8 events per 1000 person-years for multivitamin vs placebo, respectively; hazard ratio [HR], 1.01; 95% CI, 0.91-1.10; $P = .91$). Further, a daily multivitamin had no effect on total MI (3.9 and 4.2 events per 1000 person-years; HR, 0.93; 95% CI, 0.80-1.09; $P = .39$), total stroke (4.1 and 3.9 events per 1000 person-years; HR, 1.06; 95% CI, 0.91-1.23; $P = .48$), or CVD mortality (5.0 and 5.1 events per 1000 person-years; HR, 0.95; 95% CI, 0.83-1.09; $P = .47$). A daily multivitamin was also not significantly associated with total mortality (HR, 0.94; 95% CI, 0.88-1.02; $P = .13$). The effect of a daily multivitamin on major cardiovascular events did not differ between men with or without a baseline history of CVD ($P = .62$ for interaction).

CONCLUSION: Among this population of US male physicians, taking a daily multivitamin did not reduce major cardiovascular events, MI, stroke, and CVD mortality after more than a decade of treatment and follow-up.

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Abstract

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Vitamin C status and perception of effort during exercise in obese adults adhering to a calorie-reduced diet.

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OBJECTIVE: Moderate energy restriction and exercise are recommended for effective weight loss. Obese individuals oxidize less fat and report a higher perceived exertion during exercise, characteristics that may negatively influence exercise behavior. Because vitamin C status has been linked to fatigability, we compared the effects of vitamin C supplementation on self-reported fatigue and on the respiratory exchange ratio and the Ratings of Perceived Exertion scale during moderate exercise in healthy obese adults adhering to a hypocaloric diet.

METHODS: Twenty adults (4 men and 16 women) were stratified and randomly assigned to receive 500 mg of vitamin C (VC) or placebo (CON) daily for 4 wk while adhering to a vitamin C-controlled, calorie-restricted diet. Feelings of general fatigue as assessed by the Profile of Mood States questionnaire were recorded on a separate day from the exercise session at weeks 0 and 4. Participants walked on a treadmill at an intensity of 50% predicted maximal oxygen consumption for 60 min at weeks 0 and 4, and heart rate, respiratory exchange ratio, and Ratings of Perceived Exertion were recorded.

RESULTS: After 4 wk, the two groups lost similar amounts of weight (~4 kg), and the respiratory exchange ratio was not altered by group. Heart rate and the Ratings of Perceived Exertion during exercise were significantly decreased in the VC versus the CON group (-11 versus -3 beats/min, $P = 0.022$, and -1.3 versus +0.1 U, $P = 0.001$, respectively), and the general fatigue score was decreased 5.9 U for the VC group versus a 1.9U increase for the CON group ($P = 0.001$).

CONCLUSION: These data provide preliminary evidence that vitamin C status may influence fatigue, heart rate, and perceptions of exertion during moderate exercise in obese individuals.

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Abstract

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Effect of high-dose vs standard-dose multivitamin supplementation at the initiation of HAART on HIV disease progression and mortality in Tanzania: a randomized controlled trial.

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CONTEXT: Large randomized trials have previously shown that high-dose micronutrient supplementation can increase CD4 counts and reduce human immunodeficiency virus (HIV) disease progression and mortality among individuals not receiving highly active antiretroviral therapy (HAART); however, the safety and efficacy of such supplementation has not been established in the context of HAART.

OBJECTIVE: To test the hypothesis that high-dose multivitamin supplementation vs standard-dose multivitamin supplementation decreases the risk of HIV disease progression or death and improves immunological, virological, and nutritional parameters in patients with HIV initiating HAART.

DESIGN, SETTING, AND PARTICIPANTS: A randomized, double-blind, controlled trial of high-dose vs standard-dose multivitamin supplementation for 24 months in 3418 patients with HIV initiating HAART between November 2006 and November 2008 in 7 clinics in Dar es Salaam, Tanzania. **INTERVENTION** The provision of daily oral supplements of vitamin B complex, vitamin C, and vitamin E at high levels or standard levels of the recommended dietary allowance.

MAIN OUTCOME MEASURE: The composite of HIV disease progression or death from any cause.

RESULTS: The study was stopped early in March 2009 because of evidence of increased levels of alanine transaminase (ALT) in patients receiving the high-dose multivitamin supplement. At the time of stopping, 3418 patients were enrolled (median follow-up, 15 months), and there were 2374 HIV disease progression events and 453 observed deaths (2460 total combined events). Compared with standard-dose multivitamin supplementation, high-dose supplementation did not reduce the risk of HIV disease progression or death. The absolute risk of HIV progression or death was 72% in the high-dose group vs 72% in the standard-dose group (risk ratio [RR], 1.00; 95% CI, 0.96-1.04). High-dose supplementation had no effect on CD4 count, plasma viral load, body mass index, or hemoglobin level concentration, but increased the risk of ALT elevations (1239 events per 1215 person-years vs 879 events per 1236 person-years; RR, 1.44; 95% CI, 1.11-1.87) vs standard-dose supplementation.

CONCLUSION In adults receiving HAART, use of high-dose multivitamin supplements compared with standard-dose multivitamin supplements did not result in a decrease in HIV disease progression or death but may have resulted in an increase in ALT levels.

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Abstract

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Effect of vitamin D3 supplementation on upper respiratory tract infections in healthy adults: the VIDARIS randomized controlled trial.

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CONTEXT: Observational studies have reported an inverse association between serum 25-hydroxyvitamin D (25-OHD) levels and incidence of upper respiratory tract infections (URTIs). However, results of clinical trials of vitamin D supplementation have been inconclusive.

OBJECTIVE: To determine the effect of vitamin D supplementation on incidence and severity of URTIs in healthy adults.

DESIGN, SETTING, AND PARTICIPANTS: Randomized, double-blind, placebo-controlled trial conducted among 322 healthy adults between February 2010 and November 2011 in Christchurch, New Zealand.

INTERVENTION: Participants were randomly assigned to receive an initial dose of 200,000 IU oral vitamin D3, then 200,000 IU 1 month later, then 100,000 IU monthly (n = 161), or placebo administered in an identical dosing regimen (n = 161), for a total of 18 months.

MAIN OUTCOME MEASURES: The primary end point was number of URTI episodes. Secondary end points were duration of URTI episodes, severity of URTI episodes, and number of days of missed work due to URTI episodes.

RESULTS: The mean baseline 25-OHD level of participants was 29 (SD, 9) ng/mL. Vitamin D supplementation resulted in an increase in serum 25-OHD levels that was maintained at greater than 48 ng/mL throughout the study. There were 593 URTI episodes in the vitamin D group and 611 in the placebo group, with no statistically significant differences in the number of URTIs per participant (mean, 3.7 per person in the vitamin D group and 3.8 per person in the placebo group; risk ratio, 0.97; 95% CI, 0.85-1.11), number of days of missed work as a result of URTIs (mean, 0.76 days in each group; risk ratio, 1.03; 95% CI, 0.81-1.30), duration of symptoms per episode (mean, 12 days in each group; risk ratio, 0.96; 95% CI, 0.73-1.25), or severity of URTI episodes. These findings remained unchanged when the analysis was repeated by season and by baseline 25-OHD levels.

CONCLUSION: In this trial, monthly administration of 100,000 IU of vitamin D did not reduce the incidence or severity of URTIs in healthy adults.

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