# 2022-5 Problems With Single Food Ingredients

**The nine randomized_controlled clinical trials below are used by the National Cancer Institute to decide that cancer patients should not use Dietary Supplements. My observations as a Human Toxicologist. First compare the amounts given to the Recommended Daily Requirements (RDA).**

**Beta Carotene (BC)**
**Men RDA is 900 mcg and Women is 700 mcg**
**In the first study below they had 15,000 (mcg) (BC) daily.**
**In the second study below they had 20,000 (mcg) (BC) daily.**
**In the third study below they had 15,000 (mcg) (BC) daily.**
**In the fourth study below 50,000 (mcg) (BC) given every other day.**
**In the fifth study below they had 6,000 (mcg) (BC) daily.**

**Vitamin E (RDA) 15 mg or 22.5 IU daily for adults.**
**In the first study below 30 mg Vitamin E daily.**
**In the sixth study below 100 mg daily.**
**In the seventh study 400 IU daily**
**In the eighth study 400 IU daily**

**Selenium (RDA) is 55 (mcg) per day for adults.**
**In the first study below 50 (mcg) daily.**
**In the sixth study below 30 (mcg) daily.**
**In the seventh study 200 (mcg) daily**

**Vitamin C (RDA) is 90 mg for men and 70 mg for women per day.**
**In the sixth study below120 mg daily.**
**In the ninth study below 500 mg daily.**

## Problems with the studies:

**A. The antioxidant dosages were often MANY times greater, or less, than the RDA.**

1. As much as 55.5 times the RDA of Beta Carotene for men and 71.4 times the RDA for women.
2. As much as 17.8 times the RDA of Vitamin E for men and women.
3. As much as 5.6 times the RDA of Vitamin C for men and 7.1 times the RDA for women.

**B. Only two of the studies had both water- and fat-soluble antioxidants, but not at the correct ratios. See last US Patent No. 7,999,003,903 B2 Antioxidant Compositions And Method Thereto Aug. 16, 2011. The last document.**

**1.** You must balance the water-soluble and fat-soluble antioxidants to be effective. Plant food does that naturally so plant food can neutralize free radicals.
2. Albert Szent-Györgyi (September 16, 1893 – October 22, 1986) was a Hungarian biochemist who won the Nobel Prize in Physiology or Medicine in 1937. He is credited with first isolating vitamin C complex. He showed that ascorbic acid did nothing for scurvy without the complex of bioflavonoids that come with it in food. But he was ignored.
3. See the US Patent No. 7,999,003,903 B2 Antioxidant Compositions And Method Thereto Aug. 16, 2011. At the last of this document.
4. The Oxygen Radical Absorption Capacity (ORAC) of blood is all that matters. Many of the potentially strong antioxidants (as tested by themself in the laboratory) are inactivated in the stomach before they get to the blood. Only then can the plant antioxidants help by entering cells and neutralizing the oxygen free radicals made by the mitochondria.
5. Potatoes have the vitamin C complex. Thank goodness for McDonalds french fries, or many of us would have scurvy…if we relied on ascorbic acid only (sold as vitamin C), which is only part of the vitamin C complex, and is ineffective by itself.

**C. Today, we know that too much of an antioxidant can become a pro-oxidant (proven by the nine NCI Randomized Clinical Trials below). In the 1st abstract below lung cancer and gastric cancer increased at doses of 20-30 mg of beta carotene per day, in smokers and asbestos workers. In the 2nd review article dietary supplementation with vitamin E significantly increased the risk of prostate cancer among healthy men.**

# Antioxidants and Cancer Prevention

## By The National Cancer Institute

Randomized controlled clinical trials, however, lack most of the biases that limit the reliability of observational studies. Therefore, randomized trials are considered to provide the strongest and most reliable evidence of the benefit and/or harm of a health-related intervention. To date, nine randomized controlled trials of dietary antioxidant supplements for cancer prevention have been conducted worldwide. Many of the trials were sponsored by the National Cancer Institute. The results of these nine trials are summarized below.

| Trial name, country reference | Intervention | Study subjects | Results |
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| **Linxian General Population Nutrition Intervention Trial, China (6, 7)** | 15 milligrams (mg) beta-carotene, 30 mg alpha-tocopherol, and 50 micrograms (*μ*g) selenium daily for 5 years | Healthy men and women at increased risk of developing esophageal cancer and gastric cancer | Initial: no effect on risk of developing either cancer; decreased risk of dying from gastric cancer only Later: no effect on risk of dying from gastric cancer<br>Later: no effect on risk of dying from gastric cancer |

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| **Alpha-Tocopherol/Beta-Carotene Cancer Prevention Study (ATBC), Finland (8–12)** | Alpha-tocopherol (50 mg per day) and/or beta-carotene (20 mg per day) supplements for 5 to 8 years | Middle-aged male smokers | Initial: increased incidence of lung cancer for those who took beta-carotene supplements<br>Later: no effect of either supplement on incidence of urothelial, pancreatic, colorectal, renal cell, or upper aerodigestive tract cancers |

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| **Carotene and Retinol Efficacy Trial (CARET), United States (13–15)** | Daily supplementation with 15 mg beta-carotene and 25,000 International Units (IU) retinol | People at high risk of lung cancer because of a history of smoking or exposure to asbestos | Initial: increased risk of lung cancer and increased death from all causes—trial ended early<br>Later: higher risks of lung cancer and all-cause mortality persisted; no effect on risk of prostate cancer |
| **Physicians' Health Study I (PHS I), United States (16)** | Beta-carotene supplementation (50 mg every other day for 12 years) | Male physicians | No effect on cancer incidence, cancer mortality, or all-cause mortality in either smokers or nonsmokers |

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| **Women's Health Study (WHS), United States (17, 18)** | Beta-carotene supplementation (50 mg every other day), vitamin E supplementation (600 IU every other day), and aspirin (100 mg every other day) | Women ages 45 and older | Initial: no benefit or harm associated with 2 years of beta-carotene supplementation<br>Later: no benefit or harm associated with 2 years of vitamin E supplementation |

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| **Supplémentation en Vitamines et Minéraux Antioxydants (SU.VI.MAX) Study, France (19–22)** | Daily supplementation with vitamin C (120 mg), vitamin E (30 mg), beta-carotene (6 mg), and the minerals selenium (100 $\mu$g) and zinc (20 mg) for a median of 7.5 years | Men and women | Initial: lower total cancer and prostate cancer incidence and all-cause mortality among men only; increased incidence of skin cancer among women only<br>Later: no evidence of protective effects in men or harmful effects in women within 5 years of ending supplementation |

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| **Heart Outcomes Prevention Evaluation–The Ongoing Outcomes (HOPE–TOO) Study, International (23)** | Daily supplementation with alpha-tocopherol (400 IU) for a median of 7 years | People diagnosed with cardiovascular disease or diabetes | No effect on cancer incidence, death from cancer, or the incidence of major cardiovascular events |
| **Selenium and Vitamin E Cancer Prevention Trial (SELECT), United States (24, 25)** | Daily supplementation with selenium (200 $\mu$g), vitamin E (400 IU), or both | Men ages 50 and older | Initial: no reduction in incidence of prostate or other cancers—trial stopped early<br>Later: more prostate cancer cases among those who took vitamin E alone |

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| **Physicians' Health Study II (PHS II), United States (26)** | 400 IU vitamin E every other day, 500 mg vitamin C every day, or a combination of the two | Male physicians ages 50 years and older | No reduction in incidence of prostate cancer or other cancers |

Overall, these nine randomized controlled clinical trials did not provide evidence that dietary antioxidant supplements are beneficial in primary cancer prevention. In addition, a systematic review of the available evidence regarding the use of vitamin and mineral supplements for the prevention of chronic diseases, including cancer, conducted for the United States Preventive Services Task Force (USPSTF) likewise found no clear evidence of benefit in preventing cancer (27).

## 1st review article

**Review**

Int J Cancer
actions:
. 2010 Jul 1;127(1):172-84. doi: 10.1002/ijc.25008.

# Beta-carotene supplementation and cancer risk: a systematic review and metaanalysis of randomized controlled trials

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Affiliations expand

• PMID: 19876916 DOI: 10.1002/ijc.25008

**Free article**

**Abstract**

**The effect of beta-carotene supplementation on cancer incidence has been investigated in several randomized controlled trials.** The objective was to review the effect of beta-carotene supplementation on cancer incidence in randomized trials by cancer site, beta-carotene supplementation characteristics and study population. Relevant trials were retrieved by searching PubMed (up to April 2009). Authors involved in selected studies were contacted for additional information. Thirteen publications reporting results from 9 randomized controlled trials were included. Overall, no effect of beta-carotene supplementation was observed on the incidence of all cancers combined (RR, 1.01; 95% CI, 0.98-1.04), pancreatic cancer (RR, 0.99; 95% CI, 0.73-1.36), colorectal cancer (RR, 0.96; 95% CI, 0.85-1.09), prostate cancer (RR, 0.99; 95% CI, 0.91-1.07), breast cancer (RR, 0.96; 95% CI, 0.85-1.10), melanoma (RR, 0.98; 95% CI, 0.65-1.46) and non melanoma skin cancer (RR, 0.99; 95% CI, 0.93-1.05). The incidence of lung and stomach cancers were significantly increased in individuals supplemented with beta-carotene at 20-30 mg day(-1) (RR, 1.16; 95% CI, 1.06-1.27 and RR, 1.34; 95% CI, 1.06-1.70), in smokers and asbestos workers (RR, 1.20; 95% CI, 1.07-1.34 and RR, 1.54; 95% CI, 1.08-2.19) compared to the placebo group. **Beta-carotene supplementation has not been shown to have any beneficial effect on cancer prevention. Conversely, it was associated with increased risk not only of lung cancer but also of gastric cancer at doses of 20-30 mg day(-1), in smokers and asbestos workers. This study adds to the evidence that nutritional prevention of cancer through beta-carotene supplementation should not be recommended.**

## 2nd review article:

**Randomized Controlled Trial**

JAMA

actions:

. 2011 Oct 12;306(14):1549-56. doi: 10.1001/jama.2011.1437.

# Vitamin E and the risk of prostate cancer: the Selenium and Vitamin E Cancer Prevention Trial (SELECT)

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**Free PMC article**

## Abstract

**Context: The initial report of the Selenium and Vitamin E Cancer Prevention Trial (SELECT) found no reduction in risk of prostate cancer with either selenium or vitamin E supplements but a statistically nonsignificant increase in prostate cancer risk with vitamin E. Longer follow-up and more prostate cancer events provide further insight into the relationship of vitamin E and prostate cancer.**

**Objective:** To determine the long-term effect of vitamin E and selenium on risk of prostate cancer in relatively healthy men.

**Design, setting, and participants:** A total of 35,533 men from 427 study sites in the United States, Canada, and Puerto Rico were randomized between August 22, 2001, and June 24, 2004. Eligibility criteria included a prostate-specific antigen (PSA) of 4.0 ng/mL or less, a digital rectal examination not suspicious for prostate cancer, and age 50 years or older for black men and 55 years or older for all others. The primary analysis included 34,887 men who were randomly assigned to 1 of 4 treatment groups: 8752 to receive selenium; 8737, vitamin E; 8702, both agents, and 8696, placebo. Analysis reflect the final data collected by the study sites on their participants through July 5, 2011.

**Interventions:** Oral selenium (200 μg/d from L-selenomethionine) with matched vitamin E placebo, vitamin E (400 IU/d of all rac-α-tocopheryl acetate) with matched selenium placebo, both agents, or both matched placebos for a planned follow-up of a minimum of 7 and maximum of 12 years.
**Main outcome measures:** Prostate cancer incidence.
**Results:** This report includes 54,464 additional person-years of follow-up and 521 additional cases of prostate cancer since the primary report. Compared with the placebo (referent group) in which 529 men developed prostate cancer, 620 men in the vitamin E group developed prostate cancer (hazard ratio [HR], 1.17; 99% CI, 1.004-1.36, P = .008); as did 575 in the selenium group (HR, 1.09; 99% CI, 0.93-1.27; P = .18), and 555 in the selenium plus vitamin E group (HR, 1.05; 99% CI, 0.89-1.22, P = .46). Compared with placebo, the absolute increase in risk of prostate cancer per 1000 person-years was 1.6 for vitamin E, 0.8 for selenium, and 0.4 for the combination.
**Conclusion:** **Dietary supplementation with vitamin E significantly increased the risk of prostate cancer among healthy men.**
**Trial registration:** Clinicaltrials.gov Identifier: NCT00006392.

US007999003B2

(12) **United States Patent**
**McAnalley et al.**

(10) **Patent No.: US 7,999,003 B2**
(45) **Date of Patent: Aug. 16, 2011**

(54) **ANTIOXIDANT COMPOSITIONS AND METHODS THERETO**

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( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1158 days.

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*A61K 31/7048* (2006.01)

(52) **U.S. Cl.** ..... **514/456**; 424/729; 424/766; 514/27; 514/904; 514/458; 422/68.1

(58) **Field of Classification Search** ..... 422/68; 424/729, 766; 514/27, 456, 458, 904
See application file for complete search history.

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(57) **ABSTRACT**

The present invention provides a performance assay that measures the total antioxidant activity of a composition using oxygen uptake in contrast to prior art methods that measure antioxidant capacity by indirectly measuring degradation of a fluorescent compound by following the disappearance of fluorescence. Using the performance antioxidant assay of the present invention, an antioxidant composition having synergistic activity is provided by the present inventors that includes flavonoids such as the flavonol quercetin, mixed tocopherols or tocotrienols, grape skin extract, green tea extract and bush plum. The antioxidant activity of the present composition exceeds 6,000 micromoles Trolox equivalent units per gram using the present invention.

**16 Claims, 5 Drawing Sheets**