

Clinical trials of beta carotene

TrialResults-center www.trialresultscenter.org

1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
beta carotene vs placebo			
ATBC 2nd prev subgroup (b carotene) , 1998 n=876/919 follow-up: 3.79 y	synthetic beta carotene 20 mg daily versus placebo	patients enrolled in the ATBC trial and who had angina pectoris in the Rose chest pain questionnaire at baseline	Factorial plan double-blind Finland
ATBC beta carotene , 1994 n=14560/14573 follow-up: 6.1 median (range 5-8y)	beta carotene 20mg four times daily versus placebo	male smokers 50 to 69 years of age from southwestern Finland	Factorial plan double-blind Southwestern Finland
CARET beta carotene , 1996 n=9420/8894 follow-up: 4 y	combination of 30 mg of beta carotene per day and 25,000 IU of retinol (vitamin A) in the form of retinyl palmitate per day versus placebo	smokers, former smokers, and workers exposed to asbestos	Parallel groups double-blind USA
NSCP (Green) beta carotene , 1999 n=820/801 follow-up: 4.5 y	beta carotene 30mg four times daily versus placebo	residents of Nambour	Factorial plan double-blind Queensland, Australia
PHS beta carotene , 1996 n=11036/1035 follow-up: 12 y	beta carotene 50 mg on alternate days versus placebo	male physicians, 40 to 84 years of age with no history of cancer (except nonmelanoma skin cancer), myocardial infarction, stroke, or transient cerebral ischemia	Factorial plan double-blind USA
SCP beta carotene , 1990 n=913/892 follow-up: 4.02 years	beta carotene 50mg four times daily versus placebo	Age <85 years (most <65 years); previous non-melanoma skin cancer; 69% male	Parallel groups double-blind USA
WACS beta-caroten , 2007 [NCT00000541] n=4084/4087 follow-up: 9.4 years	beta carotene (Lurotin) 50 mg every two days versus placebo	female health professionals at increased risk (40 years or older with a history of CVD or 3 or more CVD risk factors)	Factorial plan double blind

continued...

Trial	Treatments	Patients	Trials design and methods
WHS beta carotene , 1999 [NCT00000479] n=19939/19937 follow-up: 2.1y (range 0 - 2.72y)	beta carotene 50mg four times daily versus placebo	female health professionals, aged 45 years or older and without a history of cancer (except nonmelanoma skin cancer), coronary heart disease, or cerebrovascular disease	Factorial plan double-blind USA

More details and results :

- antioxidants for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q131>
- antioxidants for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q433>
- antioxidants for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q434>

References

ATBC 2nd prev subgroup (b carotene), 1998:

Rapola JM, Virtamo J, Ripatti S, Haukka JK, Huttunen JK, Albanes D, Taylor PR, Heinonen OP Effects of alpha tocopherol and beta carotene supplements on symptoms, progression, and prognosis of angina pectoris. *Heart* 1998;79:454-8 [9659191]

ATBC beta carotene, 1994:

The effect of vitamin E and beta carotene on the incidence of lung cancer and other cancers in male smokers. The Alpha-Tocopherol, Beta Carotene Cancer Prevention Study Group. *N Engl J Med* 1994 Apr 14;330:1029-35 [8127329]

Kataja-Tuomola MK, Kontto JP, Mnnist S, Albanes D, Virtamo JR Effect of alpha-tocopherol and beta-carotene supplementation on macrovascular complications and total mortality from diabetes: results of the ATBC Study. *Ann Med* 2010 Apr;42:178-86 [20350251]

CARET beta carotene, 1996:

Omenn GS, Goodman GE, Thornquist MD, Balmes J, Cullen MR, Glass A, Keogh JP, Meyskens FL, Valanis B, Williams JH, Barnhart S, Hammar S Effects of a combination of beta carotene and vitamin A on lung cancer and cardiovascular disease. *N Engl J Med* 1996 May 2;334:1150-5 [8602180]

Goodman GE, Thornquist MD, Balmes J, Cullen MR, Meyskens FL Jr, Omenn GS, Valanis B, Williams JH Jr The Beta-Carotene and Retinol Efficacy Trial: incidence of lung cancer and cardiovascular disease mortality during 6-year follow-up after stopping beta-carotene and retinol supplements. *J Natl Cancer Inst* 2004;96:1743-50 [15572756] [10.1093/jnci/djh320](https://doi.org/10.1093/jnci/djh320)

NSCP (Green) beta carotene, 1999:

Green A, Williams G, Neale R, Hart V, Leslie D, Parsons P, Marks GC, Gaffney P, Battistutta D, Frost C, Lang C, Russell A Daily sunscreen application and betacarotene supplementation in prevention of basal-cell and squamous-cell carcinomas of the skin: a randomised controlled trial. *Lancet* 1999 Aug 28;354:723-9 [10475183]

PHS beta carotene, 1996:

Hennekens CH, Buring JE, Manson JE, Stampfer M, Rosner B, Cook NR, Belanger C, LaMotte F, Gaziano JM, Ridker PM, Willett W, Peto R Lack of effect of long-term supplementation with beta carotene on the incidence of malignant neoplasms and cardiovascular disease. *N Engl J Med* 1996 May 2;334:1145-9 [8602179]

SCP beta carotene, 1990:

Greenberg ER, Baron JA, Stukel TA, Stevens MM, Mandel JS, Spencer SK, Elias PM, Lowe N, Nierenberg DW, Bayrd G A clinical trial of beta carotene to prevent basal-cell and squamous-cell cancers of the skin. The Skin Cancer Prevention Study Group. *N Engl J Med* 1990 Sep 20;323:789-95 [[2202901](#)]

WACS beta-carotene, 2007:

Cook NR, Albert CM, Gaziano JM, Zaharris E, MacFadyen J, Danielson E, Buring JE, Manson JE A randomized factorial trial of vitamins C and E and beta carotene in the secondary prevention of cardiovascular events in women: results from the Women's Antioxidant Cardiovascular Study. *Arch Intern Med* 2007 Aug 13-27;167:1610-8 [[17698683](#)]

Bassuk SS, Albert CM, Cook NR, Zaharris E, MacFadyen JG, Danielson E, Van Denburgh M, Buring JE, Manson JE The Women's Antioxidant Cardiovascular Study: design and baseline characteristics of participants. *J Womens Health (Larchmt)* 2004;13:99-117 [[15006283](#)] [10.1089/154099904322836519](#)

Manson JE, Gaziano JM, Spelsberg A, Ridker PM, Cook NR, Buring JE, Willett WC, Hennekens CH A secondary prevention trial of antioxidant vitamins and cardiovascular disease in women. Rationale, design, and methods. The WACS Research Group. *Ann Epidemiol* 1995;5:261-9 [[8520707](#)]

WHS beta carotene, 1999:

Lee IM, Cook NR, Manson JE, Buring JE, Hennekens CH Beta-carotene supplementation and incidence of cancer and cardiovascular disease: the Women's Health Study. *J Natl Cancer Inst* 1999 Dec 15;91:2102-6 [[10601381](#)]

Lee IM, Cook NR, Gaziano JM, Gordon D, Ridker PM, Manson JE, Hennekens CH, Buring JE Vitamin E in the primary prevention of cardiovascular disease and cancer: the Women's Health Study: a randomized controlled trial. *JAMA* 2005;294:56-65 [[15998891](#)] [10.1001/jama.294.1.56](#)

Buring JE, Hennekens CH. The WomensHealth Study: rationale and background. *J Myocardial Ischemia* 1992;4:3040