Clinical trials of antioxydants for cardiovascular prevention in all type of patients

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1 antioxydant

Trial	Treatments	Patients	Trials design and methods
vitamin E vs control			
GISSI , 1999 n=5660/5664 follow-up: 3.5y	vitamin E 300mg/d versus no vitamine E	patients with recent (3 months) myocardial infarction	Factorial plan open Italy
PPP , 2001 n=2231/2264 follow-up: 3.6y	vitamin E (300 mg/day) versus no vitamin E	men and women aged 50 years or greater, with at least one of the major recognised cardiovascular risk factors	Factorial plan open Italy
acetylcysteine vs placebo			
Tepel , 2003 n=64/70 follow-up: 14.5 y	acetylcysteine 600 mg twice daily versus placebo	patients undergoing maintenance hemodialysis for a minimum of 3 months 3 times weekly in an ambulatory center	Parallel groups double-blind Germany
beta carotene vs placebo			
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

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Trial	Treatments	Patients	Trials design and methods
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
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
combination vs placebo			
PHS II (multivitamin) , 2012 [NCT00270647] n=7317/7324 follow-up: 11.2y (median)	Daily multivitamin versus placebo	male US physicians initially aged 50 years or older	Parallel groups double-blind USA
POPADAD (antioxydant) , 2008 [ISRCTN53295293] n=640/636 follow-up:	antioxidant capsule containing (alpha-tocopherol 200 mg, ascorbic acid 100 mg, pyridoxine hydrochloride 25 mg, zinc sulphate 10 mg, nicotinamide 10 mg, lecithin 9.4 mg, and sodium selenite 0.8 mg) versus placebo	patients with diabetes mellitus and asymptomatic peripheral arterial disease	Factorial plan double blind Scotland
HATS , 2001 n=84/76 follow-up:	antioxidant-therapy (vitamins) versus placebo	patients with coronary disease, low HDL cholesterol levels and normal LDL cholesterol	Factorial plan double-blind USA, Canada
MVP , 1997 n=158/159 follow-up: 6 montsh	multivitamins (30,000 IU of beta carotene, 500 mg of vitamin C, and 700 IU of vitamin E) for four weeks before and six months after angioplasty versus placebo	patient undergoing angioplasty	Factorial plan double-blind Canada
HPS antioxidant , 2002 n=10269/10267 follow-up: jul 1994 - may 1997	antioxidant vitamin supplementation (600 mg vitamin E, 250 mg vitamin C, and 20 mg -carotene daily) versus matching placebo	UK adults (aged 4080) with coronary disease, other occlusive arterial disease, or diabetes	Factorial plan double-blind UK
PHS II beta carotene , 2003 [NCT00270647] n=2967/2989 follow-up: 8 years	400 IU of vitamin E every other day and 500 mg of vitamin C daily versus placebo	US male physicians enrolled, aged 50 years or older	Factorial plan double-blind
SUVIMAX , 2005 n=6481/6536 follow-up: 7.5 years	single daily capsule of combination of antioxydants: 120 mg of ascorbic acid, 30 mg of vitamin E, 6 mg of beta carotene, 100 g of selenium, and 20 mg of zinc versus matched placebo	women aged 35-60 years and men aged 45-60 years	Parallel groups double-blind France

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Trial	Treatments	Patients	Trials design and methods
WAVE (Waters) , 2002 n=212/211 follow-up: 2.8 years	400 IU of vitamin E twice daily plus 500 mg of vitamin C twice daily versus placebo	postmenopausal women with at least one 15% to 75% coronary stenosis	Factorial plan double-blind US, Canada
succinobucol vs placebo			
ARISE , 2008 [NCT00066898] n=3078/3066 follow-up: 24 mo (range 12-36 mo)	succinobucol 300 mg once daily versus placebo	patients with recent (14-365 days) acute coronary syndromes already managed with conventional treatments	Parallel groups double blind Canada, US, UK, South Africa
vitamin C vs placebo			
PHS II vitamin C , 2008 [NCT00270647] n=7329/7312 follow-up: 8 years (mean)	vitamin C 500mg daily versus placebo	US male physicians aged 50 years or older	Factorial plan double blind US
WACS vitamin C , 2007 [NCT00000541] n=4087/4084 follow-up: 9.4 years	vitamin C (ascorbic acid) 500 mg/d versus placebo	female health professionals at increased risk (40 years or older with a history of CVD or 3 or more CVD risk factors)	double blind US
vitamin E vs placebo			
CHAOS , 1996 n=1035/967 follow-up: 1.5y	vitamin E 400-800UI/d (alpha tocopherol) versus identical placebo	patients with angiographically proven coronary atherosclerosis	Parallel groups double-blind UK
HOPE , 2000 n=4761/4780 follow-up: 4.5y	vitamin E 400IU/d from natural sources versus matching placebo	women and men 55 years of age or older who were at high risk for cardiovascular events because they had cardiovascular disease or diabetes in addition to one other risk factor.	Factorial plan double-blind Multinational: Canada, USA, Europe, South America
ATBC vitamin E , 1994 n=14564/14569 follow-up: 6.1 median (range 5-8y)	vitamin E (alpha-tocopherol) 50mg/d versus placebo	male smokers 50 to 69 years of age from southwestern Finland	Factorial plan double-blind Southwestern Finland
WACS vitamin E , 2007 [NCT00000541] n=4083/4088 follow-up: 9.4 years	vitamin E (600IU 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 US
WHS vitamin E , 2005 [NCT00000479] n=19937/19939 follow-up: 10.1 y	vitamin E 600 IU every other day (-tocopherol) versus placebo	apparently healthy US women aged at least 45 years	Factorial plan double-blind US
PHS II vitamin E , 2008 [NCT00270647] n=7315/7326 follow-up: 8 years (mean)	vitamin E 400IU every two days versus placebo	US male physicians aged 50 years or older	double blind US

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Trial	Treatments	Patients	Trials design and methods
ASAP , 2000 n=260/260 follow-up: 3 years	d-alpha-tocopherol 91 mg (136 IU) twice daily versus placebo	smoking and nonsmoking men and postmenopausal women aged 45-69 years with serum cholesterol >= 5.0 mmol/l	Factorial plan double-blind Finland
AREDS , 2001 n=2370/2387 follow-up: 6.3 y	daily supplementation of antioxidants (500 mg of vitamin C, 400 IU of vitamin E, and 15 mg of beta carotene) versus placebo	patients with age-related lens opacities and visual acuity loss	Factorial plan double-blind USA
Linxian , 1993 n=14792/14792 follow-up: 5y	-	Apparently healthy Individuals of ages 40-69	

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2 About TrialResults-center.org

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