

# Clinical trials of antioxidants for cardiovascular prevention in secondary prevention

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## 1 antioxidant

| Trial  | Treatments   | Patients  | Trials design and methods                     |
|--|--|---|---|
| <b>vitamin E vs control</b>  |  |   |   |
| <b>GISSI , 1999</b><br>n=5660/5664<br>follow-up: 3.5y                                    | vitamin E 300mg/d<br>versus<br>no vitamin E  | patients with recent (3 months) myocardial infarction   | Factorial plan<br>open<br>Italy               |
| <b>beta carotene vs placebo</b>  |  |   |   |
| <b>ATBC 2nd prev subgroup (beta carotene) , 1998</b><br>n=876/919<br>follow-up: 3.79 y   | synthetic beta carotene 20 mg daily<br>versus<br>placebo   | patients enrolled in the ATBC trial and who had angina pectoris in the Rose chest pain questionnaire at baseline      | Factorial plan<br>double-blind<br>Finland     |
| <b>WACS beta-carotene , 2007</b><br>[NCT00000541]<br>n=4084/4087<br>follow-up: 9.4 years | beta carotene (Lurotin) 50 mg every two days<br>versus<br>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<br>double blind                |
| <b>combination vs placebo</b>  |  |   |   |
| <b>HATS , 2001</b><br>n=84/76<br>follow-up:  | antioxidant-therapy (vitamins)<br>versus<br>placebo  | patients with coronary disease, low HDL cholesterol levels and normal LDL cholesterol                                 | Factorial plan<br>double-blind<br>USA, Canada |
| <b>MVP , 1997</b><br>n=158/159<br>follow-up: 6 monthsh                                   | 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<br>versus<br>placebo | patient undergoing angioplasty  | Factorial plan<br>double-blind<br>Canada      |
| <b>HPS antioxidant , 2002</b><br>n=10269/10267<br>follow-up: jul 1994 - may 1997         | antioxidant vitamin supplementation (600 mg vitamin E, 250 mg vitamin C, and 20 mg -carotene daily)<br>versus<br>matching placebo                                    | UK adults (aged 4080) with coronary disease, other occlusive arterial disease, or diabetes                            | Factorial plan<br>double-blind<br>UK          |
| <b>WAVE (Waters) , 2002</b><br>n=212/211<br>follow-up: 2.8 years                         | 400 IU of vitamin E twice daily plus 500 mg of vitamin C twice daily<br>versus<br>placebo  | postmenopausal women with at least one 15% to 75% coronary stenosis   | Factorial plan<br>double-blind<br>US, Canada  |
| <b>vitamin C vs placebo</b>  |  |   |   |

continued...

| <b>Trial</b>   | <b>Treatments</b>   | <b>Patients</b>   | <b>Trials design and methods</b>   |
|--|---|---|--|
| <b>WACS vitamin C , 2007</b><br>[NCT00000541]<br>n=4087/4084<br>follow-up: 9.4 years   | vitamin C (ascorbic acid) 500 mg/d<br>versus<br>placebo                 | female health professionals at increased risk<br>(40 years or older with a history of CVD or 3<br>or more CVD risk factors)   | double blind<br>US   |
| <b>vitamin E vs placebo</b>  |   |   |  |
| <b>CHAOS , 1996</b><br>n=1035/967<br>follow-up: 1.5y                                   | vitamin E 400-800IU/d (alpha tocopherol)<br>versus<br>identical placebo | patients with angiographically proven<br>coronary atherosclerosis   | Parallel groups<br>double-blind<br>UK  |
| <b>SPACE , 2000</b><br>n=97/99<br>follow-up: 1.42 years                                | vitamin E 800 IU daily<br>versus<br>matching placebo                    | Haemodialysis patients aged 40-75 years with<br>pre-existing cardiovascular disease   | Parallel groups<br>double -blind<br>Israel   |
| <b>HOPE , 2000</b><br>n=4761/4780<br>follow-up: 4.5y                                   | vitamin E 400IU/d from natural sources<br>versus<br>matching placebo    | women and men 55 years of age or older who<br>were at high risk for cardiovascular events<br>because they had cardiovascular disease or<br>diabetes in addition to one other risk factor. | Factorial plan<br>double-blind<br>Multinational: Canada, USA, Europe, South<br>America |
| <b>WACS vitamin E , 2007</b><br>[NCT00000541]<br>n=4083/4088<br>follow-up: 9.4 years   | vitamin E (600IU every two days)<br>versus<br>placebo                   | female health professionals at increased risk<br>(40 years or older with a history of CVD or 3<br>or more CVD risk factors)   | Factorial plan<br>double blind<br>US   |
| <b>HOPE renal insufficiency<br/>subgroup , 2004</b><br>n=499/494<br>follow-up: 4.5y    | vitamin E 400 IU/day, natural<br>versus<br>placebo                      | patients with either known cardiovascular<br>disease or diabetes and at least one additional<br>coronary risk factor and renal insufficiency<br>(sub group)                               | Factorial plan<br>double-blind<br>North and South America, Europe                      |
| <b>ATBC 2nd prev subgroup<br/>(vitamin E) , 1998</b><br>n=916/879<br>follow-up: 3.79 y | alpha tocopherol (vitamin E) 50 mg/day<br>versus<br>placebo             | patients enrolled in the ATBC trial and who<br>had angina pectoris in the Rose chest pain<br>questionnaire at baseline  | Factorial plan<br>double-blind<br>Finland  |

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## 2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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