

# Clinical trials of vitamin E

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## 1 cardiovascular prevention

| 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 vitamine E                               | patients with recent (3 months)<br>myocardial infarction   | Factorial plan<br>open<br>Italy  |
| <b>PPP , 2001</b><br>n=2231/2264<br>follow-up: 3.6y                                    | vitamin E (300 mg/day)<br>versus<br>no vitamin E                           | men and women aged 50 years or greater,<br>with at least one of the major recognised<br>cardiovascular risk factors  | Factorial plan<br>open<br>Italy  |
| <b>vitamin E vs placebo</b>  |  |  |  |
| <b>CHAOS , 1996</b><br>n=1035/967<br>follow-up: 1.5y                                   | vitamin E 400-800UI/d (alpha<br>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<br>with 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<br>who were at high risk for cardiovascular<br>events because they had cardiovascular<br>disease or diabetes in addition to one<br>other risk factor. | Factorial plan<br>double-blind<br>Multinational: Canada, USA, Europe,<br>South America |
| <b>ATBC vitamin E , 1994</b><br>n=14564/14569<br>follow-up: 6.1 median<br>(range 5-8y) | vitamin E (alpha-tocopherol) 50mg/d<br>versus<br>placebo                   | male smokers 50 to 69 years of age from<br>southwestern Finland  | Factorial plan<br>double-blind<br>Southwestern Finland                                 |
| <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<br>risk (40 years or older with a history of<br>CVD or 3 or more CVD risk factors)  | Factorial plan<br>double blind<br>US   |

continued...

| <b>Trial</b>  | <b>Treatments</b>   | <b>Patients</b>   | <b>Trials design and methods</b>                                  |
|---|---|---|---|
| <b>WHS vitamin E , 2005</b><br>[NCT00000479]<br>n=19937/19939<br>follow-up: 10.1 y          | vitamin E 600 IU every other day<br>(-tocopherol)<br>versus<br>placebo  | apparently healthy US women aged at<br>least 45 years   | Factorial plan<br>double-blind<br>US                              |
| <b>PHS II vitamin E , 2008</b><br>[NCT00270647]<br>n=7315/7326<br>follow-up: 8 years (mean) | vitamin E 400IU every two days<br>versus<br>placebo   | US male physicians aged 50 years or older   | 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<br>additional coronary risk factor and renal<br>insufficiency (sub group) | Factorial plan<br>double-blind<br>North and South America, Europe |
| <b>ASAP , 2000</b><br>n=260/260<br>follow-up: 3 years                                       | d-alpha-tocopherol 91 mg (136 IU) twice<br>daily<br>versus<br>placebo   | smoking and nonsmoking men and<br>postmenopausal women aged 45-69 years<br>with serum cholesterol $\geq$ 5.0 mmol/l   | Factorial plan<br>double-blind<br>Finland                         |
| <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 enroled in the ATBC trial and<br>who had angina pectoris in the Rose chest<br>pain questionnaire at baseline                                       | Factorial plan<br>double-blind<br>Finland                         |
| <b>AREDS , 2001</b><br>n=2370/2387<br>follow-up: 6.3 y                                      | daily supplementation of antioxidants<br>(500 mg of vitamin C, 400 IU of vitamin<br>E, and 15 mg of beta carotene)<br>versus<br>placebo | patients with age-related lens opacities<br>and visual acuity loss  | Factorial plan<br>double-blind<br>USA                             |
| <b>Linxian , 1993</b><br>n=14792/14792<br>follow-up: 5y                                     | -   | Apparently healthy Individuals of ages<br>40-69   |   |

More details and results :

- antioxydants for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/godirect.asp?q=131>
- antioxydants for cardiovascular prevention in patients with renal disease at <http://www.trialresultscenter.org/godirect.asp?q=432>
- antioxydants for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/godirect.asp?q=433>
- antioxydants for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/godirect.asp?q=434>

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Entry terms: vitamin e