

# Clinical trials of antithrombotics for cardiovascular prevention in primary prevention

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## 1 anticoagulant

Trial	Treatments	Patients	Trials design and methods
<b>warfarin vs placebo</b>			
Thrombosis Prevention trial (Warfarin) , 1998 [NCT00000614] n=2762/2737 follow-up: median 6.8 y	warfarin started at 2.5mg/d adjusted for a target INR 1.5 versus placebo	men aged between 45 years and 69 years at high risk of IHD	Factorial plan double blind UK

## References

### Thrombosis Prevention trial (Warfarin), 1998:

Thrombosis prevention trial: randomised trial of low-intensity oral anticoagulation with warfarin and low-dose aspirin in the primary prevention of ischaemic heart disease in men at increased risk. The Medical Research Council's General Practice Research Framework. Lancet 1998;351:233-41 [9457092]

Meade TW, Wilkes HC, Stirling Y, Brennan PJ, Kelleher C, Browne W Randomized controlled trial of low dose warfarin in the primary prevention of ischaemic heart disease in men at high risk: design and pilot study. Eur Heart J 1988;9:836-43 [3053176]

Meade TW, Roderick PJ, Brennan PJ, Wilkes HC, Kelleher CC Extra-cranial bleeding and other symptoms due to low dose aspirin and low intensity oral anticoagulation. Thromb Haemost 1992;68:1-6 [1514166]

## 2 anticoagulant + antiplatelet

Trial	Treatments	Patients	Trials design and methods
<b>warfarin + aspirin vs placebo</b>			
Thrombosis Prevention trial (W plus A) , 1998 [NCT00000614] n=1277/1272 follow-up: median 6.8 y	warfarin adjusted dose for INR of 1.5 + aspirin 75 mg daily versus placebo	men aged between 45 years and 69 years at high risk of IHD	NA double blind UK

## References

### Thrombosis Prevention trial (W plus A), 1998:

Thrombosis prevention trial: randomised trial of low-intensity oral anticoagulation with warfarin and low-dose aspirin in the primary prevention of ischaemic heart disease in men at increased risk. The Medical Research Council's General Practice Research Framework. Lancet 1998;351:233-41 [9457092]

Meade TW, Wilkes HC, Stirling Y, Brennan PJ, Kelleher C, Browne W Randomized controlled trial of low dose warfarin in the primary prevention of ischaemic heart disease in men at high risk: design and pilot study. *Eur Heart J* 1988;9:836-43 [3053176]

### 3 platelet aggregation inhibitors

Trial	Treatments	Patients	Trials design and methods
<b>error vs error</b>			
<b>JPPP</b> <i>ongoing</i> [NCT00225849] n=NA follow-up:	aspirin versus no aspirin	Japanese patients aged 60 to 85 years with hypertension, dyslipidemia, or diabetes mellitus	Parallel groups open Japan
<b>aspirin vs no treatment</b>			
<b>British Doctors Trial</b> , 1988 n=3429/1710 follow-up: 5.5 years	aspirin 500 mg/d versus no aspirin	apparently healthy male doctors	Parallel groups open UK
<b>Primary Prevention Project</b> , 2001 n=2226/2269 follow-up: 3.6 y	aspirin 100 mg/d versus no aspirin (open control)	men and women aged 50 years or greater, with at least one of the major recognised cardiovascular risk factors.	Factorial plan Open Italy
<b>aspirin vs placebo</b>			
<b>Physicians Health Study</b> , 1989 [NCT00000500] n=11037/11034 follow-up: 60.2 months	aspirin 325 mg every other day versus placebo	Healthy men	Parallel groups double blind
<b>Thrombosis Prevention Trial</b> , 1998 [NCT00000614] n=2545/2540 follow-up: median 6.8y	aspirin 75 mg/d (controlled release) versus placebo	Men at high risk of CHD	Factorial plan double blind UK
<b>HOT</b> , 1998 n=9399/9391 follow-up: mean 3.8 y (range 3.3-4.9y)	aspirin 75 mg daily versus placebo	patients aged 50-80 with hypertension and diastolic blood pressure between 100 mmHG and 115 mmHG	Factorial plan Double blind Europe, North and South America, and Asia
<b>Womens Health Study</b> , 2005 n=19934/19942 follow-up: 10.1 y mean (range 8.2 to 10.9)	aspirin 100mg daily versus placebo	initially healthy women 45 years of age or older	Factorial plan Double blind

### References

**JPPP** , :

Teramoto T, Shimada K, Uchiyama S, Sugawara M, Goto Y, Yamada N, Oikawa S, Ando K, Ishizuka N, Yamazaki T, Yokoyama K, Murata M, Ikeda Y Rationale, design, and

baseline data of the Japanese Primary Prevention Project (JPPP)-a randomized, open-label, controlled trial of aspirin versus no aspirin in patients with multiple risk factors for vascular events. *Am Heart J* 2010;159:361-369.e4 [20211296] [10.1016/j.ahj.2009.11.030](https://doi.org/10.1016/j.ahj.2009.11.030)

#### **British Doctors Trial, 1988:**

Peto R, Gray R, Collins R, Wheatley K, Hennekens C, Jamrozik K, Warlow C, Hafner B, Thompson E, Norton S Randomised trial of prophylactic daily aspirin in British male doctors. *Br Med J (Clin Res Ed)* 1988 Jan 30;296:313-6 [3125882]

#### **Primary Prevention Project, 2001:**

de Gaetano G Low-dose aspirin and vitamin E in people at cardiovascular risk: a randomised trial in general practice. Collaborative Group of the Primary Prevention Project. *Lancet* 2001 Jan 13;357:89-95 [11197445]

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#### **Thrombosis Prevention Trial, 1998:**

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Meade TW, Wilkes HC, Stirling Y, Brennan PJ, Kelleher C, Browne W Randomized controlled trial of low dose warfarin in the primary prevention of ischaemic heart disease in men at high risk: design and pilot study. *Eur Heart J* 1988;9:836-43 [3053176]

#### **HOT, 1998:**

Hansson L, Zanchetti A, Carruthers SG, Dahlof B, Elmfeldt D, Julius S, Menard J, Rahn KH, Wedel H, Westerling S Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial. HOT Study Group. *Lancet* 1998 Jun 13;351:1755-62 [9635947]

Hansson L, Zanchetti A The Hypertension Optimal Treatment (HOT) Study-patient characteristics: randomization, risk profiles, and early blood pressure results. *Blood Press* 1994;3:322-7 [7866597]

#### **Womens Health Study, 2005:**

Ridker PM, Cook NR, Lee IM, Gordon D, Gaziano JM, Manson JE, Hennekens CH, Buring JE A randomized trial of low-dose aspirin in the primary prevention of cardiovascular disease in women. *N Engl J Med* 2005 Mar 31;352:1293-304 [15753114]

Rexrode KM, Lee IM, Cook NR, Hennekens CH, Buring JE Baseline characteristics of participants in the Women's Health Study. *J Womens Health Gend Based Med* 2000;9:19-27 [10718501] [10.1089/152460900318911](https://doi.org/10.1089/152460900318911)

## 4 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.

TrialResults-center is non-profit and self-funded.