Clinical trials of antithrombotics for cardiovascular prevention in primary prevention

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1 anticoagulant

Trial	Treatments	Patients	Trials design and methods
warfarin vs placebo			
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
warfarin + aspirin vs placebo			
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]

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3 platelet aggregation inhibitors

Trial	Treatments	Patients	Trials design and methods
error vs error			
JPPP *ongoing* [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
aspirin vs no treatment			
British Doctors Trial , 1988 n=3429/1710 follow-up: 5.5 years	aspirin 500 mg/d versus no aspirin	apparently healthy male doctors	Parallel groups open UK
Primary Prevention Project , 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
aspirin vs placebo			
Physicians Health Study , 1989 [NCT00000500] n=11037/11034 follow-up: 60.2 months	aspirin 325 mg every other day versus placebo	Healthy men	Parallel groups double blind
Thrombosis Prevention Trial , 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
HOT , 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
Womens Health Study , 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, :

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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]

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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]

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4 About TrialResults-center.org

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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.