

Clinical trials of antithrombotics for cardiovascular prevention in patients at high risk

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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]

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 NOAC

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs aspirin			
COMPASS (rivaroxaban alone) <i>ongoing</i> [NCT01776424] n=27400 follow-up:	Rivaroxaban 2.5 mg twice daily alone versus aspirin 100 mg once daily	Patients With Coronary or Peripheral Artery Disease	
rivaroxaban + aspirin vs aspirin			
COMPASS (rivaroxaban + aspirin) <i>ongoing</i> [NCT01776424] n=27400 follow-up:	versus aspirin 100 mg once daily	Patients With Coronary or Peripheral Artery Disease	

References

COMPASS (rivaroxaban alone), :
COMPASS (rivaroxaban + aspirin), 0:

4 platelet aggregation inhibitors

Trial	Treatments	Patients	Trials design and methods
aspirin vs no treatment			
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			
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

References

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](#)]

Thrombosis Prevention Trial, 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 Jan 24;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](#)]

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](#)]

5 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.