

Clinical trials of antiplatelets drug for cardiovascular prevention in all type of patients

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1 clopidogrel

Trial	Treatments	Patients	Trials design and methods
clopidogrel vs aspirin			
CAPRIE , 1996 n=9599/9586 follow-up: mean 1.91 years	clopidogrel 75 mg once daily versus aspirin 325 mg once daily	patients with atherosclerotic vascular disease manifested as either recent ischaemic stroke, recent myocardial infarction, or symptomatic peripheral arterial disease	Parallel groups Double blind 16 countries
clopidogrel vs placebo (on top aspirin)			
CHARISMA , 2006 [NCT00050817] n=7802/7801 follow-up: median 28 months	clopidogrel (75 mg per day) plus low-dose aspirin (75 to 162 mg per day) versus placebo plus low-dose aspirin	patients with either clinically evident cardiovascular disease or multiple risk factors	Parallel groups Double blind 32 countries

References

CAPRIE, 1996:

A randomised, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE). CAPRIE Steering Committee. Lancet 1996 Nov 16;348:1329-39 [[8918275](#)]

CHARISMA, 2006:

Bhatt DL, Fox KA, Hacke W, Berger PB, Black HR, Boden WE, Cacoub P, Cohen EA, Creager MA, Easton JD, Flather MD, Haffner SM, Hamm CW, Hankey GJ, Johnston SC, Mak KH, Mas JL, Montalescot G, Pearson TA, Steg PG, Steinhubl SR, Weber MA, Brennan DM, Fabry-Rib Clopidogrel and aspirin versus aspirin alone for the prevention of atherothrombotic events. N Engl J Med 2006;354:1706-17 [[16531616](#)] [10.1056/NEJMoa060989](#)

2 P2Y12 receptor-antagonist

Trial	Treatments	Patients	Trials design and methods
ticagrelor vs placebo (on top aspirin)			
PEGASUS 90mg , 2015 [NCT01225562] n=7050/7067 follow-up: 2.75 y (median)	-	patients who had had a myocardial infarction 1 to 3 years earlier	double-blind
PEGASUS 60mg , 2015 [NCT01225562] n=7045/7067 follow-up: 2.75 y (median)	ticagrelor at a dose of 60 mg twice daily versus placebo	patients who had had a myocardial infarction 1 to 3 years earlier	Parallel groups double-blind

References

PEGASUS 90mg, 2015:

Bonaca MP, Bhatt DL, Braunwald E, Cohen M, Steg PG, Storey RF, Held P, Jensen EC, Sabatine MS Design and rationale for the Prevention of Cardiovascular Events in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin-Thrombolysis in Myocardial Infarction 54 (PEGASUS-TIMI 54) trial. *Am Heart J* 2014;167:437-444.e5 [24655690]

Bonaca MP, Bhatt DL, Cohen M, Steg PG, Storey RF, Jensen EC, Magnani G, Bansilal S, Fish MP, Im K, Bengtsson O, Ophuis TO, Budaj A, Theroux P, Ruda M, Hamm C, Goto S, Spinar J, Nicolau JC, Kiss RG, Murphy SA, Wiviott SD, Held P, Braunwald E, Sabatine MS Long-Term Use of Ticagrelor in Patients with Prior Myocardial Infarction. *N Engl J Med* 2015 Mar 14;: [25773268] 10.1056/NEJMoa1500857

PEGASUS 60mg, 2015:

Bonaca MP, Bhatt DL, Braunwald E, Cohen M, Steg PG, Storey RF, Held P, Jensen EC, Sabatine MS Design and rationale for the Prevention of Cardiovascular Events in Patients With Prior Heart Attack Using Ticagrelor Compared to Placebo on a Background of Aspirin-Thrombolysis in Myocardial Infarction 54 (PEGASUS-TIMI 54) trial. *Am Heart J* 2014;167:437-444.e5 [24655690]

Bonaca MP, Bhatt DL, Cohen M, Steg PG, Storey RF, Jensen EC, Magnani G, Bansilal S, Fish MP, Im K, Bengtsson O, Ophuis TO, Budaj A, Theroux P, Ruda M, Hamm C, Goto S, Spinar J, Nicolau JC, Kiss RG, Murphy SA, Wiviott SD, Held P, Braunwald E, Sabatine MS Long-Term Use of Ticagrelor in Patients with Prior Myocardial Infarction. *N Engl J Med* 2015 Mar 14;: [25773268] 10.1056/NEJMoa1500857

3 platelet aggregation inhibitors

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Trial	Treatments	Patients	Trials design and methods
error vs error			
JPPP <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
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			
AAA , 2009 [ISRCTN66587262] n=1675/1675 follow-up: 8.2 y (mean)	aspirin 100mg daily versus placebo	men and women aged 50 to 80 years with asymptomatic atherosclerosis detected by low ankle brachial index (<=0.95)	Parallel groups double blind UK, Scotland

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Trial	Treatments	Patients	Trials design and methods
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, :

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]

AAA, 2009:

Fowkes FG, Price JF, Stewart MC, Butcher I, Leng GC, Pell AC, Sandercock PA, Fox KA, Lowe GD, Murray GD Aspirin for prevention of cardiovascular events in a general population screened for a low ankle brachial index: a randomized controlled trial. *JAMA* 2010 Mar 3;303:841-8 [20197530] [10.1001/jama.2010.221](https://doi.org/10.1001/jama.2010.221)

Physicians Health Study, 1989:

Final report on the aspirin component of the ongoing Physicians' Health Study. Steering Committee of the Physicians' Health Study Research Group. *N Engl J Med* 1989 Jul 20;321:129-35 [2664509]

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. *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](#)

4 selective PAR-1 thrombin receptor antagonist

Trial	Treatments	Patients	Trials design and methods
vorapaxar vs placebo (on top aspirin)			
TRA-2P TIMI 50 , 2012 [NCT00526474] n=13225/13244 follow-up: 2.5 y (median)	vorapaxar (SCH 530348) 2.5-mg daily versus placebo (added to the existing standard of care for preventing heart attack and stroke (eg, aspirin, clopidogrel)	patients with a known history of atherosclerosis (MI, ischemic stroke, or peripheral vascular disease)	Parallel groups double-blind

References

TRA-2P TIMI 50, 2012:

Morrow DA, Scirica BM, Fox KA, Berman G, Strony J, Veltri E, Bonaca MP, Fish P, McCabe CH, Braunwald E Evaluation of a novel antiplatelet agent for secondary prevention in patients with a history of atherosclerotic disease: design and rationale for the Thrombin-Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events (TRA 2 degrees P)-TIMI 50 trial. *Am Heart J* 2009 Sep;158:335-341.e3 [[19699854](#)]

Morrow DA, Braunwald E, Bonaca MP, Ameriso SF, Dalby AJ, Fish MP, Fox KA, Lipka LJ, Liu X, Nicolau JC, Oude Ophuis AJ, Paolasso E, Scirica BM, Spinar J, Theroux P, Wiviott SD, Strony J, Murphy SA Vorapaxar in the Secondary Prevention of Atherothrombotic Events. *N Engl J Med* 2012 Mar 24;: [[22443427](#)] [10.1056/NEJMoa1200933](#)

Scirica BM, Bonaca MP, Braunwald E, De Ferrari GM, Isaza D, Lewis BS, Mehrhof F, Merlini PA, Murphy SA, Sabatine MS, Tendera M, Van de Werf F, Wilcox R, Morrow DA Vorapaxar for secondary prevention of thrombotic events for patients with previous myocardial infarction: a prespecified subgroup analysis of the TRA 2P-TIMI 50 trial. *Lancet* 2012;380:1317-24 [[22932716](#)]

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.

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