

Clinical trials of pravastatin

TrialResults-center www.trialresultscenter.org

1 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
pravastatin vs placebo			
CARE , 1996 n=2081/2078 follow-up: 5 years	pravastatin 40 mg/d versus placebo	men and women with myocardial infarction who had plasma totalcholesterol levels below 240 mg per deciliter (mean,209) and low-density lipoprotein (LDL) cholesterollevels of 115 to 174 mg per deciliter	Parallel groups double blind USA, Canada
LIPID , 1998 n=4512/4502 follow-up: 6.1 years	pravastatin 40 mg/d versus placebo	patients with previous myocardial infarction or unstable angina and a baseline plasma cholesterol concentration of 4.0-7.0 mmol/L	Parallel groups double blind Australie et Nouvelle Zlande
PACT , 2004 n=1710/1689 follow-up: 30 days	pravastatin initiated within 24 hours of onset of symptoms and for 4 weeks versus placebo	patients with unstable angina, non-ST-segment elevation myocardial infarction, or ST-segment elevation myocardial infarction <24 hours	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for post myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q45>

References

CARE, 1996:

Sacks FM, Pfeffer MA, Moye LA, Rouleau JL, Rutherford JD, Cole TG, Brown L, Warnica JW, Arnold JM, Wun CC, Davis BR, Braunwald E, The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels. Cholesterol and Recurrent Events Trial investigators. N Engl J Med 1996; 335:1001-9 [8801446]

Plehn JF, Davis BR, Sacks FM, Rouleau JL, Pfeffer MA, Bernstein V, Cuddy TE, Moy LA, Piller LB, Rutherford J, Simpson LM, Braunwald E Reduction of stroke incidence after myocardial infarction with pravastatin: the Cholesterol and Recurrent Events (CARE) study. The Care Investigators. Circulation 1999;99:216-23 [9892586]

LIPID, 1998:

, Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group. N Engl J Med 1998; 339:1349-57 [9841303]

, Long-term effectiveness and safety of pravastatin in 9014 patients with coronary heart disease and average cholesterol concentrations: the LIPID trial follow-up. Lancet 2002; 359:1379-87 [11978335]

Design features and baseline characteristics of the LIPID (Long-Term Intervention with Pravastatin in Ischemic Disease) Study: a randomized trial in patients with previous acute myocardial infarction and/or unstable angina pectoris. Am J Cardiol 1995;76:474-9 [7653447]

PACT, 2004:

Thompson PL, Meredith I, Amerena J, Campbell TJ, Sloman JG, Harris PJ Effect of pravastatin compared with placebo initiated within 24 hours of onset of acute myocardial infarction or unstable angina: the Pravastatin in Acute Coronary Treatment (PACT) trial. Am Heart J 2004;148:e2 [15215811]

2 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
pravastatin vs control			
FAST Fukuoka pravastatin , 2002 n=83/81 follow-up: 2 years	pravastatin 10 mg/day versus control group (diet alone)	asymptomatic hypercholesterolemic patients	open Japan
MEGA , 2006 [NCT00211705] n=3866/3966 follow-up: 5.3 y	pravastatin 10 mg daily (20 mg per day if the total cholesterol concentration did not decrease to 569 mmol/L or less) versus control	patients with hypercholesterolaemia (total cholesterol 569698 mmol/L) and no history of coronary heart disease or stroke	Parallel groups open, blind assessment Japan
pravastatin vs placebo			
LAMIL , 1997 n=36/33 follow-up: 1 and 3 months	Pravastatin, 10-20 mg (starting at D3) versus Placebo	patients suffering an acute myocardial infarction	Parallel groups double blind Belgium
RECIFE , 1999 n=30/30 follow-up: 1.5 months	Pravastatin, 40 mg versus Placebo	Patients with acute myocardial infarction or unstable angina and total cholesterol levels at admission ≥ 5.2 mmol/L or LDL ≥ 3.4 mmol/L	Parallel groups double blind Canada
CARE (elderly subgroup) , 1998 n=640/643 follow-up: 5.0y	-	MI 320 months, subgroup of age 65-75 y	parallel groups double blind
LIPID (elderly sub group) , 2001 n=1741/1773 follow-up: 6.1y	-	MI or unstable angina, subgroup of age 65-75 y	parallel groups double blind

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Trial	Treatments	Patients	Trials design and methods
PROSPER diabetic (sub group) , 2002 n=320/303 follow-up: 3.2y mean	pravastatin 40mg daily versus placebo	men and women aged 70-82 years with a history of, or risk factors for, vascular disease	Parallel groups double blind
LIPID (diabetic sub group) , 1998 n=396/386 follow-up: mean 6.1y	pravastatin 40 mg daily versus placebo	patients with a history of myocardial infarction or hospitalization for unstable angina and initial plasma total cholesterol levels of 155 to 271 mg per deciliter	Parallel groups double blind Australia, New Zealand
CARE (diabetic sub group) , 1998 n=282/304 follow-up:	pravastatin versus placebo	men and postmenopausal women between 21 to 75 years of age, with MI between 3 and 20 months before randomization and plasma total cholesterol values <240mg/dL, LDL-C levels between 115 and 174mg/dL, and triglycerides <350mg/dL	Parallel groups
WOSCOPS (diabetic sub group) , 1996 n=70 follow-up: mean 4.9y	pravastatin 40 mg daily versus placebo	men aged 45-64 years with no history of myocardial infarction and plasma total cholesterol concentrations of 6.5-8.0 mmol/L at initial screening	double blind
PAIS , 2001 n=50/49 follow-up: 1 and 3 months	Pravastatin, 40 mg (initiated within 48 hours of hospital admission) versus Placebo	patients with acute coronary syndromes	Parallel groups double blind The Netherlands
PLAC I (elderly sub group) , 1995 n=42/52 follow-up: 2.3y	-	Angiographic CAD or recent MI, subgroup of age 65-75 y	parallel groups double blind
PACT , 2004 n=1710/1698 follow-up: 1 months	Pravastatin, 20-40 mg within 24 hours of the onset of symptoms in versus Placebo	patients with unstable angina, non-ST-segment elevation myocardial infarction, or ST-segment elevation myocardial infarction within 24 hours of the onset of symptoms	Parallel groups double blind Australia
REGRESS (elderly subgroup) , 1995 n=75/63 follow-up: 2.0y	-	Angiographic CAD, subgroup of age 65-70 y	parallel groups double blind
CAIUS , 1996 n=151/154 follow-up: 3 years	pravastatin 40mg/d versus placebo	asymptomatic patients with hypercholesterolemia and at least one 1.3 <IMT <3.5 mm in the carotid arteries	Parallel groups double blind Italy

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Trial	Treatments	Patients	Trials design and methods
CARE , 1996 n=2081/2078 follow-up: 5 years	pravastatin 40 mg/d versus placebo	men and women with myocardial infarction who had plasma totalcholesterol levels below 240 mg per deciliter (mean,209) and low-density lipoprotein (LDL) cholesterollevels of 115 to 174 mg per deciliter	Parallel groups double blind USA, Canada
KAPS , 1995 n=224/223 follow-up: 3 years	pravastatin 40mg/d versus placebo	Hypercholesterolemics men with serum LDL-C \geq 4.0 mmol/L and total cholesterol $<$ 7.5 mmol/L	Parallel groups double blind Finland
LIPID , 1998 n=4512/4502 follow-up: 6.1 years	pravastatin 40 mg/d versus placebo	patients with previous myocardial infarction or unstable angina and a baseline plasma cholesterol concentration of 4.0-7.0 mmol/L	Parallel groups double blind Australie et Nouvelle Zlande
PACT , 2004 n=1710/1689 follow-up: 30 days	pravastatin initiated within 24 hours of onset of symptoms and for 4 weeks versus placebo	patients with unstable angina, non-ST-segment elevation myocardial infarction, or ST-segment elevation myocardial infarction $<$ 24 hours	Parallel groups double blind
PHYLLIS , 2004 n=508 follow-up: 2.6 y	pravastatin (40 mg per day) versus placebo	hypertensive, hypercholesterolemic patients with asymptomatic carotid atherosclerosis	Factorial plan double-blind Italy
PLAC I , 1995 n=206/202 follow-up: 3 y	pravastatin 40mg daily versus placebo	men and women with coronary artery disease and mild to moderate elevations in cholesterol levels	Parallel groups double blind United States
PLAC II , 1995 n=75/76 follow-up: 3 y	pravastatin 20-40mg daily versus placebo	coronary patients (men and women)	Parallel groups double blind United States
PMSG , 1993 n=530/532 follow-up: 26 weeks	pravastatin 20 mg once daily versus placebo	patients with hypercholesterolemia(serum total cholesterol concentrations of 5.2 to 7.8 mmol/liter) and \geq 2 additional risk factors for atherosclerotic coronary artery disease	Parallel groups double blind
PREVEND IT , 2004 n=433/431 follow-up: 46 months	pravastatin 40 mg daily versus placebo	subjects with microalbuminuria	Factorial plan double blind the Netherlands

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Trial	Treatments	Patients	Trials design and methods
PROSPER , 2002 n=2891/2913 follow-up: 3.2 years	pravastatin 40mg daily versus placebo	men and women aged 70-82 years with a history of, or risk factors for, vascular disease	Parallel groups double blind Ecosse, Irlande, Pays bas
PROSPER (primary prevention subgroup) , 2002 n=1584/1654 follow-up: 3.2 years	pravastatin 40mg/d versus placebo	men and women aged 70-82 years with a history of, or risk factors for, vascular disease; primary prevention subgroup	Parallel groups double blind Ecosse, Irlande, Pays bas
REGRESS , 1995 n=450/435 follow-up: 2 years	pravastatin 40 mg daily versus placebo	symptomatic men with normal to moderately elevated serum cholesterol levels	Parallel groups double blind Netherlands
WOSCOPS , 1995 n=3302/3293 follow-up: 4.9 years	pravastatine 40 mg daily versus placebo	men aged 45-64 yr with no history of myocardial infarction and with raised plasma cholesterol levels (LDL cholesterol of at least 155 mg/dL, total cholesterol of at least 252 mg/dL)	Parallel groups double blind Scotland
ALLHAT (women subgroup) , 2002 n=2511/2540 follow-up: 4.8 y	Pravastatin 40 mg daily versus control	Ambulatory persons, aged 55 years or older, with low-density lipoprotein cholesterol (LDL-C) of 120 to 189 mg/dL (100 to 129 mg/dL if known CHD) and triglycerides lower than 350 mg/dL- subgroup of women	Parallel groups open US
MEGA (women subgroup) , 2006 n=2638/2718 follow-up: 5.3 y	Pravastatin 1020 mg daily versus control	patients with hypercholesterolaemia (total cholesterol 5.69-6.98 mmol/L) and no history of coronary heart disease or stroke- subgroup of women	Parallel groups open Japan
pravastatin vs usual care			
L-CAD , 2000 n=70/56 follow-up: 1, 4, and 6 months	Pravastatin, 20-40 mg (strating on average at D6) versus Usual care	patients with acute coronary syndrome	Parallel groups open Germany
GISSI P (diabetic subgroup) , 2000 n=NA follow-up: median 24.3 months	pravastatin 20 mg daily versus usual care	recent acute myocardial infarction patients (<or = 6 months) with total blood cholesterol >or = 200 mg/dl	open

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Trial	Treatments	Patients	Trials design and methods
ALLHAT-LLT (diabetic sub group) , 2002 n=1855/1783 follow-up:	pravastatin versus usual care	Ambulatory persons aged 55 years or older, with lowdensity lipoprotein cholesterol (LDL-C) of 120 to 189 mg/dL (100 to 129 mg/dL if known CHD) and triglycerides lower than 350 mg/dL	Parallel groups open
PTT , 2002 n=79/85 follow-up: 1 and 6 months	Pravastatin, 40 mg versus Usual care	patients who underwent coronary balloon angioplasty of the infarct-related artery during the first month of acute myocardial infarction	Parallel groups open Turkey
ALLHAT , 2002 [NCT00000542] n=5170/5185 follow-up: 4.8 years	pravastatin 40mg/d versus usual care	aged 55 years or older, moderately hypercholesterolemic, hypertensive participants with at least 1 additional CHD risk factor	Factorial plan open USA, Puerto Rico, Canada
OACIS-LIPID , 2008 n=176/177 follow-up: 9 months	pravastatin 10 mg/daily versus no pravastatin	patients with AMI who had plasma total cholesterol levels of 200-250 mg/dl and triglyceride levels <300 mg/dl	Parallel groups open
GISSI Prevenzione , 2000 n=2138/2133 follow-up: 23 months (mean)	low-dose pravastatin regimen 20 mg daily versus control	recent acute myocardial infarction patients (<= 6 months) with total blood cholesterol >= 200 mg/dl and <250 mg/dl and after a period of 36 months showed plasma cholesterol levels >=200 mg/ dL despite adequate dietary recommendations	Parallel groups open Italy
KLIS , 2000 n=3061/2579 follow-up: 5 years	pravastatin 10-20 mg/day versus conventional treatment	Japanese men aged 45-74 years with serum total cholesterol of >or = 220 mg/dl (5.69 mmol/l), primary prevention	Parallel groups open Japan
pravastatin high dose vs pravastatin			
PROVE IT TIMI 22 (diabetic sub group) , 2006 n=373/361 follow-up: 24 months mean	pravastatin 80mg daily versus pravastatin 40mg daily	patients hospitalized for an acute coronary syndrome within the preceding 10 days	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for cardiovascular prevention in patients with LDL elevation and without CHD at <http://www.trialresultscenter.org/go-Q5>
- cholesterol lowering intervention for cardiovascular prevention in diabetic patients at <http://www.trialresultscenter.org/go-Q6>
- cholesterol lowering intervention for cardiovascular prevention in elderly at <http://www.trialresultscenter.org/go-Q7>

- cholesterol lowering intervention for cardiovascular prevention in high risk patients with or without LDL cholesterol elevation at <http://www.trialresultscenter.org/go-Q11>
- cholesterol lowering intervention for cardiovascular prevention in patients with prior MI or with CHD at <http://www.trialresultscenter.org/go-Q12>
- cholesterol lowering intervention for cardiovascular prevention in patients with other atherosclerotic localisation at <http://www.trialresultscenter.org/go-Q126>
- cholesterol lowering intervention for cardiovascular prevention in patient with related disease at <http://www.trialresultscenter.org/go-Q137>
- cholesterol lowering intervention for cardiovascular prevention in all chronical situations at <http://www.trialresultscenter.org/go-Q154>
- cholesterol lowering intervention for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q241>
- cholesterol lowering intervention for cardiovascular prevention in women at <http://www.trialresultscenter.org/go-Q435>
- statins for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q688>
- statins for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q689>
- statins for cardiovascular prevention in diabetic patients at <http://www.trialresultscenter.org/go-Q694>
- statins for cardiovascular prevention in hypertensive patients at <http://www.trialresultscenter.org/go-Q695>

References

FAST Fukuoka pravastatin, 2002:

Sawayama Y, Shimizu C, Maeda N, Tatsukawa M, Kinukawa N, Koyanagi S, Kashiwagi S, Hayashi J Effects of probucol and pravastatin on common carotid atherosclerosis in patients with asymptomatic hypercholesterolemia. Fukuoka Atherosclerosis Trial (FAST). J Am Coll Cardiol 2002;39:610-6 [11849859]

MEGA, 2006:

Nakamura H, Arakawa K, Itakura H, Kitabatake A, Goto Y, Toyota T, Nakaya N, Nishimoto S, Muranaka M, Yamamoto A, Mizuno K, Ohashi Y Primary prevention of cardiovascular disease with pravastatin in Japan (MEGA Study): a prospective randomised controlled trial. Lancet 2006 Sep 30;368:1155-63 [17011942]

Nakamura H [Primary prevention trial by lowering hyperlipidemia on the cardiovascular disease (MEGA Study)] Nippon Ronen Igakkai Zasshi 2009;46:18-21 [19246826]

LAMIL, 1997:

Kesteloot H, Claeys G, Blanckaert N, Lesaffre E Time course of serum lipids and apolipoproteins after acute myocardial infarction: modification by pravastatin. Acta Cardiol 1997;52:107-16 [9187418]

RECIFE, 1999:

Dupuis J, Tardif JC, Cernacek P, Throux P Cholesterol reduction rapidly improves endothelial function after acute coronary syndromes. The RECIFE (reduction of cholesterol in ischemia and function of the endothelium) trial. *Circulation* 1999;99:3227-33 [[10385495](#)]

CARE (elderly subgroup), 1998:

Lewis SJ, Moye LA, Sacks FM, Johnstone DE, Timmis G, Mitchell J, Limacher M, Kell S, Glasser SP, Grant J, Davis BR, Pfeffer MA, Braunwald E Effect of pravastatin on cardiovascular events in older patients with myocardial infarction and cholesterol levels in the average range. Results of the Cholesterol and Recurrent Events (CARE) trial. *Ann Intern Med* 1998;129:681-9 [[9841599](#)]

LIPID (elderly sub group), 2001:

Hunt D, Young P, Simes J, Hague W, Mann S, Owensby D, Lane G, Tonkin A Benefits of pravastatin on cardiovascular events and mortality in older patients with coronary heart disease are equal to or exceed those seen in younger patients: Results from the LIPID trial. *Ann Intern Med* 2001;134:931-40 [[11352694](#)]

PROSPER diabetic (sub group), 2002:

Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, Gaw A, Hyland M, Jukema JW, Kamper AM, Macfarlane PW, Meinders AE, Norrie J, Packard CJ, Perry IJ, Stott DJ, Sweeney BJ, Twomey C, Westendorp RG *Lancet* 2002;360:1623-30 [[12457784](#)]

LIPID (diabetic sub group), 1998:

N Engl J Med 1998;339:1349-57 [[9841303](#)]

CARE (diabetic sub group), 1998:

Goldberg RB, Mellies MJ, Sacks FM, Moy LA, Howard BV, Howard WJ, Davis BR, Cole TG, Pfeffer MA, Braunwald E Cardiovascular events and their reduction with pravastatin in diabetic and glucose-intolerant myocardial infarction survivors with average cholesterol levels: subgroup analyses in the cholesterol and recurrent events (CARE) trial. The Care Investigators. *Circulation* 1998;98:2513-9 [[9843456](#)]

WOSCOPS (diabetic sub group), 1996:

West of Scotland Coronary Prevention Study: identification of high-risk groups and comparison with other cardiovascular intervention trials. *Lancet* 1996 Nov 16;348:1339-42 [[8918276](#)]

Shepherd J, Cobbe SM, Ford I, Isles CG, Lorimer AR, MacFarlane PW, McKillop JH, Packard CJ *N Engl J Med* 1995;333:1301-7 [[7566020](#)]

PAIS, 2001:

Den Hartog FR, Van Kalmthout PM, Van Loenhout TT, Schaafsma HJ, Rila H, Verheugt FW Pravastatin in acute ischaemic syndromes: results of a randomised placebo-controlled trial. *Int J Clin Pract* 2001;55:300-4 [[11452676](#)]

PLAC I (elderly sub group), 1995:

Pitt B, Mancini GB, Ellis SG, Rosman HS, Park JS, McGovern ME Pravastatin limitation of atherosclerosis in the coronary arteries (PLAC I): reduction in atherosclerosis progression and clinical events. PLAC I investigation. *J Am Coll Cardiol* 1995;26:1133-9 [[7594023](#)]

PACT, 2004:

Thompson PL, Meredith I, Amerena J, et al. Effect of pravastatin compared with placebo initiated within 24 hours of onset of acute myocardial infarction or unstable angina: the Pravastatin in Acute Coronary Treatment (PACT) trial *Am Heart J*. 2004;148:e2

Thompson PL, Meredith I, Amerena J, Campbell TJ, Sloman JG, Harris PJ Effect of pravastatin compared with placebo initiated within 24 hours of onset of acute myocardial infarction or unstable angina: the Pravastatin in Acute Coronary Treatment (PACT) trial. *Am Heart J* 2004;148:e2 [[15215811](#)]

REGRESS (elderly subgroup), 1995:

Jukema JW, Bruschke AV, van Boven AJ, Reiber JH, Bal ET, Zwinderman AH, Jansen H, Boerma GJ, van Rappard FM, Lie KI Effects of lipid lowering by pravastatin on progression and regression of coronary artery disease in symptomatic men with normal to moderately elevated serum cholesterol levels. The Regression

Growth Evaluation Statin Study (REGRESS). *Circulation* 1995;91:2528-40 [7743614]

CAIUS, 1996:

Mercuri M, Bond MG, Sirtori CR, Veglia F, Crepaldi G, Feruglio FS, Descovich G, Ricci G, Rubba P, Mancini M, Gallus G, Bianchi G, D'Al G, Ventura A Pravastatin reduces carotid intima-media thickness progression in an asymptomatic hypercholesterolemic mediterranean population: the Carotid Atherosclerosis Italian Ultrasound Study. *Am J Med* 1996;101:627-34 [9003110]

CARE, 1996:

Sacks FM, Pfeffer MA, Moye LA, Rouleau JL, Rutherford JD, Cole TG, Brown L, Warnica JW, Arnold JM, Wun CC, Davis BR, Braunwald E, The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels. Cholesterol and Recurrent Events Trial investigators. *N Engl J Med* 1996; 335:1001-9 [8801446]

Plehn JF, Davis BR, Sacks FM, Rouleau JL, Pfeffer MA, Bernstein V, Cuddy TE, Moy LA, Piller LB, Rutherford J, Simpson LM, Braunwald E Reduction of stroke incidence after myocardial infarction with pravastatin: the Cholesterol and Recurrent Events (CARE) study. The Care Investigators. *Circulation* 1999;99:216-23 [9892586]

KAPS, 1995:

Salonen R, Nyssnen K, Porkkala-Sarataho E, Salonen JT The Kuopio Atherosclerosis Prevention Study (KAPS): effect of pravastatin treatment on lipids, oxidation resistance of lipoproteins, and atherosclerotic progression. *Am J Cardiol* 1995;76:34C-39C [7572684]

Salonen R, Nyssnen K, Porkkala E, Rummukainen J, Belder R, Park JS, Salonen JT Kuopio Atherosclerosis Prevention Study (KAPS). A population-based primary preventive trial of the effect of LDL lowering on atherosclerotic progression in carotid and femoral arteries. *Circulation* 1995;92:1758-64 [7671358]

LIPID, 1998:

, Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group. *N Engl J Med* 1998; 339:1349-57 [9841303]

, Long-term effectiveness and safety of pravastatin in 9014 patients with coronary heart disease and average cholesterol concentrations: the LIPID trial follow-up. *Lancet* 2002; 359:1379-87 [11978335]

Design features and baseline characteristics of the LIPID (Long-Term Intervention with Pravastatin in Ischemic Disease) Study: a randomized trial in patients with previous acute myocardial infarction and/or unstable angina pectoris. *Am J Cardiol* 1995;76:474-9 [7653447]

PACT, 2004:

Thompson PL, Meredith I, Amerena J, Campbell TJ, Sloman JG, Harris PJ Effect of pravastatin compared with placebo initiated within 24 hours of onset of acute myocardial infarction or unstable angina: the Pravastatin in Acute Coronary Treatment (PACT) trial. *Am Heart J* 2004;148:e2 [15215811]

PHYLLIS, 2004:

Zanchetti A, Crepaldi G, Bond MG, Gallus G, Veglia F, Mancia G, Ventura A, Baggio G, Sampieri L, Rubba P, Sperti G, Magni A Different effects of antihypertensive regimens based on fosinopril or hydrochlorothiazide with or without lipid lowering by pravastatin on progression of asymptomatic carotid atherosclerosis: principal results of PHYLLIS—a randomized double-blind trial. *Stroke* 2004;35:2807-12 [15514192]

J Hypertens Suppl 1993 Dec;11:S314-5 [8158402]

PLAC I, 1995:

Furberg CD, Pitt B, Byington RP, Park JS, McGovern ME Reduction in coronary events during treatment with pravastatin. PLAC I and PLAC II Investigators. Pravastatin Limitation of Atherosclerosis in the Coronary Arteries. *Am J Cardiol* 1995;76:60C-63C [7572689]

Pitt B, Ellis SG, Mancini GB, Rosman HS, McGovern ME Design and recruitment in the United States of a multicenter quantitative angiographic trial of pravastatin to limit atherosclerosis in the coronary arteries (PLAC I). *Am J Cardiol* 1993;72:31-5 [8517425]

Pitt B, Mancini GB, Ellis SG, Rosman HS, Park JS, McGovern ME Pravastatin limitation of atherosclerosis in the coronary arteries (PLAC I): reduction in atherosclerosis progression and clinical events. PLAC I investigation. *J Am Coll Cardiol* 1995;26:1133-9 [7594023]

PLAC II, 1995:

Byington RP, Furberg CD, Crouse JR 3rd, Espeland MA, Bond MG Pravastatin, Lipids, and Atherosclerosis in the Carotid Arteries (PLAC-II). *Am J Cardiol* 1995;76:54C-59C [7572688]

Crouse JR, Byington RP, Bond MG, Espeland MA, Sprinkle JW, McGovern M, Furberg CD Pravastatin, lipids, and atherosclerosis in the carotid arteries: design features of a clinical trial with carotid atherosclerosis outcome. *Control Clin Trials* 1992;13:495-506 [1334821]

Furberg CD, Byington RP, Crouse JR, Espeland MA Pravastatin, lipids, and major coronary events. *Am J Cardiol* 1994;73:1133-4 [8198043]

PMSG, 1993:

Effects of pravastatin in patients with serum total cholesterol levels from 5.2 to 7.8 mmol/liter (200 to 300 mg/dl) plus two additional atherosclerotic risk factors. The Pravastatin Multinational Study Group for Cardiac Risk Patients. *Am J Cardiol* 1993;72:1031-7 [8213583]

PREVEND IT, 2004:

Asselbergs FW, Diercks GF, Hillege HL, van Boven AJ, Janssen WM, Voors AA, de Zeeuw D, de Jong PE, van Veldhuisen DJ, van Gilst WH Effects of fosinopril and pravastatin on cardiovascular events in subjects with microalbuminuria. *Circulation* 2004;110:2809-16 [15492322]

PROSPER, 2002:

Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, Gaw A, Hyland M, Jukema JW, Kamper AM, Macfarlane PW, Meinders AE, Norrie J, Packard CJ, Perry IJ, Stott DJ, Sweeney BJ, Twomey C, Westendorp RG, Pravastatin in elderly individuals at risk of vascular disease (PROSPER): a randomised controlled trial. *Lancet* 2002; 360:1623-30 [12457784]

PROSPER (primary prevention subgroup), 2002:

Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, Gaw A, Hyland M, Jukema JW, Kamper AM, Macfarlane PW, Meinders AE, Norrie J, Packard CJ, Perry IJ, Stott DJ, Sweeney BJ, Twomey C, Westendorp RG Pravastatin in elderly individuals at risk of vascular disease (PROSPER): a randomised controlled trial. *Lancet* 2002;360:1623-30 [12457784]

REGRESS, 1995:

Jukema JW, Bruschke AV, van Boven AJ, Reiber JH, Bal ET, Zwinderman AH, Jansen H, Boerma GJ, van Rappard FM, Lie KI Effects of lipid lowering by pravastatin on progression and regression of coronary artery disease in symptomatic men with normal to moderately elevated serum cholesterol levels. The Regression Growth Evaluation Statin Study (REGRESS). *Circulation* 1995;91:2528-40 [7743614]

van Boven AJ, Jukema JW, Zwinderman AH, Crijs HJ, Lie KI, Bruschke AV Reduction of transient myocardial ischemia with pravastatin in addition to the conventional treatment in patients with angina pectoris. REGRESS Study Group. *Circulation* 1996;94:1503-5 [8840836]

WOSCOPS, 1995:

Shepherd J, Cobbe SM, Ford I, Isles CG, Lorimer AR, MacFarlane PW, McKillop JH, Packard CJ, Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. West of Scotland Coronary Prevention Study Group. *N Engl J Med* 1995; 333:1301-7 [7566020]

A coronary primary prevention study of Scottish men aged 45-64 years: trial design. The West of Scotland Coronary Prevention Study Group. *J Clin Epidemiol* 1992;45:849-60 [1624967]

ALLHAT (women subgroup) , 2002:

Major outcomes in moderately hypercholesterolemic, hypertensive patients randomized to pravastatin vs usual care: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT-LLT). JAMA 2002;288:2998-3007 [12479764]

MEGA (women subgroup) , 2006:

Nakamura H, Arakawa K, Itakura H, Kitabatake A, Goto Y, Toyota T, Nakaya N, Nishimoto S, Muranaka M, Yamamoto A, Mizuno K, Ohashi Y Primary prevention of cardiovascular disease with pravastatin in Japan (MEGA Study): a prospective randomised controlled trial. Lancet 2006;368:1155-63 [17011942] 10.1016/S0140-6736(06)69472-5

L-CAD, 2000:

Arntz HR, Agrawal R, Wunderlich W, Schnitzer L, Stern R, Fischer F, Schultheiss HP Beneficial effects of pravastatin (+/-colestyramine/niacin) initiated immediately after a coronary event (the randomized Lipid-Coronary Artery Disease [L-CAD] Study). Am J Cardiol 2000;86:1293-8 [11113401]

GISSI P (diabetic sub group), 2000:

Results of the low-dose (20 mg) pravastatin GISSI Prevenzione trial in 4271 patients with recent myocardial infarction: do stopped trials contribute to overall knowledge? GISSI Prevenzione Investigators (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico). Ital Heart J 2000;1:810-20 [11302109]

ALLHAT-LLT (diabetic sub group), 2002:

JAMA 2002;288:2998-3007 [12479764]

PTT, 2002:

Kayikioğlu M, Can L, Kltrsay H, Payzin S, Turkoglu C Early use of pravastatin in patients with acute myocardial infarction undergoing coronary angioplasty. Acta Cardiol 2002;57:295-302 [12222700]

ALLHAT, 2002:

, Major outcomes in moderately hypercholesterolemic, hypertensive patients randomized to pravastatin vs usual care: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT-LLT). JAMA 2002; 288:2998-3007 [12479764]

OACIS-LIPID, 2008:

Sato H, Kinjo K, Ito H, Hirayama A, Nanto S, Fukunami M, Nishino M, Lim YJ, Kijima Y, Koretsune Y, Nakatani D, Mizuno H, Shimizu M, Hori M Effect of early use of low-dose pravastatin on major adverse cardiac events in patients with acute myocardial infarction: the OACIS-LIPID Study. Circ J 2008;72:17-22 [18159093]

GISSI Prevenzione, 2000:

Ital Heart J 2000 Dec;1:810-20 [11302109]

Chiodini BD, Franzosi MG, Barlera S, Signorini S, Lewis CM, D'Orazio A, Mocarelli P, Nicolis E, Marchioli R, Tognoni G Eur Heart J 2007 Aug;28:1977-83 [17567623]

Dietary supplementation with n-3 polyunsaturated fatty acids and vitamin E after myocardial infarction: results of the GISSI-Prevenzione trial. Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto miocardico. Lancet 1999;354:447-55 [10465168]

KLIS, 2000:

J Atheroscler Thromb 2000;7:110-21 [11426582]

J Atheroscler Thromb 1996;3:95-104 [9226461]

Sasaki J, Arakawa K, Iwashita M, Matsushita Y, Kono S Circ J 2003 Jun;67:473-8 [12808261]

PROVE IT TIMI 22 (diabetic sub group), 2006:

Cannon CP, Braunwald E, McCabe CH, Rader DJ, Rouleau JL, Belder R, Joyal SV, Hill KA, Pfeffer MA, Skene AM N Engl J Med 2004;350:1495-504 [15007110] 10.1056/NEJMoa040583

3 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
pravastatin vs control			
Tveit , 2004 n=51/51 follow-up: 65279;6 weeks	pravastatin65279; 40 mg versus standard therapy	65279;AF >48 h and scheduled EC	

More details and results :

- prevention for atrial fibrillation in patient with history of atrial fibrillation at <http://www.trialresultscenter.org/go-Q328>

References

Tveit, 2004:

Tveit A, Grundtvig M, Gundersen T, Vanberg P, Semb AG, Holt E, Gullestad L Analysis of pravastatin to prevent recurrence of atrial fibrillation after electrical cardioversion. Am J Cardiol 2004;93:780-2 [[15019894](#)] [10.1016/j.amjcard.2003.12.009](#)

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4 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
pravastatin vs placebo			
LAMIL , 1997 n=36/33 follow-up: 1 and 3 months	Pravastatin, 10-20 mg (starting at D3) versus Placebo	patients suffering an acute myocardial infarction	Parallel groups double blind Belgium
RECIFE , 1999 n=30/30 follow-up: 1.5 months	Pravastatin, 40 mg versus Placebo	Patients with acute myocardial infarction or unstable angina and total cholesterol levels at admission ≥ 5.2 mmol/L or LDL ≥ 3.4 mmol/L	Parallel groups double blind Canada
PAIS , 2001 n=50/49 follow-up: 1 and 3 months	Pravastatin, 40 mg (initiated within 48 hours of hospital admission) versus Placebo	patients with acute coronary syndromes	Parallel groups double blind The Netherlands

continued...

Trial	Treatments	Patients	Trials design and methods
PACT , 2004 n=1710/1698 follow-up: 1 months	Pravastatin, 20-40 mg within 24 hours of the onset of symptoms in versus Placebo	patients with unstable angina, non-ST-segment elevation myocardial infarction, or ST-segment elevation myocardial infarction within 24 hours of the onset of symptoms	Parallel groups double blind Australia
pravastatin vs usual care			
L-CAD , 2000 n=70/56 follow-up: 1, 4, and 6 months	Pravastatin, 20-40 mg (strating on average at D6) versus Usual care	patients with acute coronary syndrome	Parallel groups open Germany
PTT , 2002 n=79/85 follow-up: 1 and 6 months	Pravastatin, 40 mg versus Usual care	patients who underwent coronary balloon angioplasty of the infarct-related artery during the first month of acute myocardial infarction	Parallel groups open Turkey

More details and results :

- cholesterol lowering intervention for acute coronary syndrome in early initiation at <http://www.trialresultscenter.org/go-Q21>

References

LAMIL, 1997:

Kesteloot H, Claeys G, Blanckaert N, Lesaffre E Time course of serum lipids and apolipoproteins after acute myocardial infarction: modification by pravastatin. *Acta Cardiol* 1997;52:107-16 [9187418]

RECIFE, 1999:

Dupuis J, Tardif JC, Cernacek P, Throux P Cholesterol reduction rapidly improves endothelial function after acute coronary syndromes. The RECIFE (reduction of cholesterol in ischemia and function of the endothelium) trial. *Circulation* 1999;99:3227-33 [10385495]

PAIS, 2001:

Den Hartog FR, Van Kalmthout PM, Van Loenhout TT, Schaafsma HJ, Rila H, Verheugt FW Pravastatin in acute ischaemic syndromes: results of a randomised placebo-controlled trial. *Int J Clin Pract* 2001;55:300-4 [11452676]

PACT, 2004:

Thompson PL, Meredith I, Amerena J, et al. Effect of pravastatin compared with placebo initiated within 24 hours of onset of acute myocardial infarction or unstable angina: the Pravastatin in Acute Coronary Treatment (PACT) trial *Am Heart J*. 2004;148:e2

Thompson PL, Meredith I, Amerena J, Campbell TJ, Sloman JG, Harris PJ Effect of pravastatin compared with placebo initiated within 24 hours of onset of acute myocardial infarction or unstable angina: the Pravastatin in Acute Coronary Treatment (PACT) trial. *Am Heart J* 2004;148:e2 [15215811]

L-CAD, 2000:

Arntz HR, Agrawal R, Wunderlich W, Schnitzer L, Stern R, Fischer F, Schultheiss HP Beneficial effects of pravastatin (+/-colestyramine/niacin) initiated immediately after a coronary event (the randomized Lipid-Coronary Artery Disease [L-CAD] Study). *Am J Cardiol* 2000;86:1293-8 [11113401]

PTT, 2002:

Kayikioglu M, Can L, Kltrsay H, Payzin S, Turkoglu C Early use of pravastatin in patients with acute myocardial infarction undergoing coronary angioplasty. Acta Cardiol 2002;57:295-302 [12222700]

5 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
pravastatin vs placebo			
PROSPER (diabetic sub group) , 2002 n=320/303 follow-up: 3.2y mean	pravastatin 40mg daily versus placebo	men and women aged 70-82 years with a history of, or risk factors for, vascular disease	Parallel groups double blind
LIPID (diabetic sub group) , 1998 n=396/386 follow-up: mean 6.1y	pravastatin 40 mg daily versus placebo	patients with a history of myocardial infarction or hospitalization for unstable angina and initial plasma total cholesterol levels of 155 to 271 mg per deciliter	Parallel groups double blind Australia, New Zealand
CARE (diabetic sub group) , 1998 n=282/304 follow-up:	pravastatin versus placebo	men and postmenopausal women between 21 to 75 years of age, with MI between 3 and 20 months before randomization and plasma total cholesterol values <240mg/dL, LDL-C levels between 115 and 174mg/dL, and triglycerides <350mg/dL	Parallel groups
WOSCOPS (diabetic sub group) , 1996 n=70 follow-up: mean 4.9y	pravastatin 40 mg daily versus placebo	men aged 45-64 years with no history of myocardial infarction and plasma total cholesterol concentrations of 6.5-8.0 mmol/L at initial screening	double blind
pravastatin vs usual care			
GISSI P (diabetic sub group) , 2000 n=NA follow-up: median 24.3 months	pravastatin 20 mg daily versus usual care	recent acute myocardial infarction patients (<or = 6 months) with total blood cholesterol >or = 200 mg/dl	open
ALLHAT-LLT (diabetic sub group) , 2002 n=1855/1783 follow-up:	pravastatin versus usual care	Ambulatory persons aged 55 years or older, with lowdensity lipoprotein cholesterol (LDL-C) of 120 to 189 mg/dL (100 to 129 mg/dL if known CHD) and triglycerides lower than 350 mg/dL	Parallel groups open
pravastatin high dose vs pravastatin			

continued...

Trial	Treatments	Patients	Trials design and methods
PROVE IT TIMI 22 (diabetic sub group) , 2006 n=373/361 follow-up: 24 months mean	pravastatin 80mg daily versus pravastatin 40mg daily	patients hospitalized for an acute coronary syndrome within the preceding 10 days	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for diabetes type 2 in diabetic patients with or without hypercholesterolemia at <http://www.trialresultscenter.org/go-Q85>
- cholesterol lowering intervention for diabetes type 2 in primary prevention at <http://www.trialresultscenter.org/go-Q720>
- cholesterol lowering intervention for diabetes type 2 in secondary prevention at <http://www.trialresultscenter.org/go-Q721>

References

PROSPER diabetic (sub group), 2002:

Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, Gaw A, Hyland M, Jukema JW, Kamper AM, Macfarlane PW, Meinders AE, Norrie J, Packard CJ, Perry IJ, Stott DJ, Sweeney BJ, Twomey C, Westendorp RG Lancet 2002;360:1623-30 [12457784]

LIPID (diabetic sub group), 1998:

N Engl J Med 1998;339:1349-57 [9841303]

CARE (diabetic sub group), 1998:

Goldberg RB, Mellies MJ, Sacks FM, Moy LA, Howard BV, Howard WJ, Davis BR, Cole TG, Pfeffer MA, Braunwald E Cardiovascular events and their reduction with pravastatin in diabetic and glucose-intolerant myocardial infarction survivors with average cholesterol levels: subgroup analyses in the cholesterol and recurrent events (CARE) trial. The Care Investigators. Circulation 1998;98:2513-9 [9843456]

WOSCOPS (diabetic sub group), 1996:

West of Scotland Coronary Prevention Study: identification of high-risk groups and comparison with other cardiovascular intervention trials. Lancet 1996 Nov 16;348:1339-42 [8918276]

Shepherd J, Cobbe SM, Ford I, Isles CG, Lorimer AR, MacFarlane PW, McKillop JH, Packard CJ N Engl J Med 1995;333:1301-7 [7566020]

GISSI P (diabetic sub group), 2000:

Results of the low-dose (20 mg) pravastatin GISSI Prevenzione trial in 4271 patients with recent myocardial infarction: do stopped trials contribute to overall knowledge? GISSI Prevenzione Investigators (Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardico). Ital Heart J 2000;1:810-20 [11302109]

ALLHAT-LLT (diabetic sub group), 2002:

JAMA 2002;288:2998-3007 [12479764]

PROVE IT TIMI 22 (diabetic sub group), 2006:

Cannon CP, Braunwald E, McCabe CH, Rader DJ, Rouleau JL, Belder R, Joyal SV, Hill KA, Pfeffer MA, Skene AM N Engl J Med 2004;350:1495-504 [15007110]
[10.1056/NEJMoa040583](http://dx.doi.org/10.1056/NEJMoa040583)

6 percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
pravastatin vs placebo			
PREDICT , 1997 n=347/348 follow-up: 6 mo	Pravastatin 40 mg/d 1 d after PCI versus placebo	patient undergoing PCI	double blind

More details and results :

- statins for percutaneous coronary intervention in all type of patients at <http://www.trialresultscenter.org/go-Q148>

References

PREDICT, 1997:

Bertrand ME, McFadden EP, Fruchart JC, Van Belle E, Commeau P, Grollier G, Bassand JP, Machecourt J, Cassagnes J, Mossard JM, Vacheron A, Castaigne A, Danchin N, Lablanche JM Effect of pravastatin on angiographic restenosis after coronary balloon angioplasty. The PREDICT Trial Investigators. Prevention of Restenosis by Elisor after Transluminal Coronary Angioplasty. J Am Coll Cardiol 1997;30:863-9 [9316510]

Entry terms: Pravastatin, Eptastatin, Liplat, RMS-431, RMS 431, RMS431, SQ-31000, SQ 31000, SQ31000, Vasten, Bristacol, CS-514, CS 514, CS514, Lipemol, Prareduct, Mevalotin, Pravachol, Elisor, Selektine, Pravacol, Pravasin, Lipostat,