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 synmptoms 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

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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 cholesterolconcentration 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 (subgroup) , 1998 n=640/643 follow-up: 5.0y	-	MI 320 months, subgroup of age 65-75 y	parallel groups double blind
LIPID (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 (sub group) , 2002 n=320/303 follow-up: 3.2y mean	pravastatin 40mg daily versus placebo	mena and women aged 7082 years with a history of, or risk factors for, vascular disease	Parallel groups double blind
LIPID (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 (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 (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 (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 (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 >or = 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 synmptoms 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 >or = 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, Irelande, 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, Irelande, 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 (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

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Trial	Treatments	Patients	Trials design and methods
ALLHAT-LLT (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	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 prevenion	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
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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

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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

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5 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
pravastatin vs placebo			
PROSPER (sub group) , 2002 n=320/303 follow-up: 3.2y mean	pravastatin 40mg daily versus placebo	mena and women aged 7082 years with a history of, or risk factors for, vascular disease	Parallel groups double blind
LIPID (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 (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 (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 (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 (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 withour hypercholesterolemia at http://www.trialresultscenter.org/go-Q85

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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

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