Clinical trials of cholesterol lowering intervention for cardiovascular prevention in primary prevention

TrialResults-center www.trialresultscenter.org

1 statins

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
atorvastatin vs placebo			
ASCOT , 2003 n=5168/5137 follow-up: 3.3 years	atorvastatin 10mg/d versus placebo	hypertensive patients aged 40-79 years with at least three other cardiovascular risk factors	Parallel groups double blind UK et Scandinavie
ASPEN , 2006 n=1211/1199 follow-up: 4 year	atorvastatin 10mg versus placebo	subjects with type 2 diabetes and LDL cholesterol levels below contemporaryguideline targets	Parallel groups double blind 14 countries
ASPEN (primary prevention sub group) , 2006 n=959/947 follow-up: 4 year	atorvastatin 10mg versus placebo	subjects with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets; primary prevention subgroup	Parallel groups double blind 14 countries
CARDS , 2004 [NCT00327418] n=1429/1412 follow-up: 3.9 years	atorvastatin 10mg/d versus placebo	patients with type 2 diabetes without high concentrations of LDL-cholesterol and at least one of the following: retinopathy, albuminuria, current smoking, or hypertension.	Parallel groups double blind UK, Irelande
Mohler , 2003 n=NA follow-up: 12 months	atorvastatin (10 mg per day) versus placebo	patients with intermittent claudication	double blind
fluvastatin vs placebo			
ALERT , 2003 n=1050/1052 follow-up: 5.1 years	fluvastatin 40 mg daily versus placebo	renal transplant recipients with total cholesterol 4.0-9.0 mmol/L	Parallel groups double-blind Belgium, Denmark, Finland, Germany, Norway,

continued...

Trial	Treatments	Patients	Trials design and methods
BCAPS , 2001 n=395/398 follow-up: 3.0 years	fluvastatin 40 mg once daily versus placebo	subjects who had carotid plaque but no symptoms of carotid artery disease	Factorial plan double-blind Sweden
HYRIM , 2005 n=283/285 follow-up: 4 year	fluvastatin 40 mg daily versus placebo	drug-treated hypertensive men aged 40-74 years with total cholesterol 4.5-8.0 mmol/L, triglycerides <4.5 mmol/L, body mass index 25-35 kg/m2, and a sedentary lifestyle	Factorial plan double blind Norway
lovastatin vs placebo			
ACAPS , 1994 [NCT00000469] n=460/459 follow-up: 2.8 years	lovastatin 20mg daily versus placebo	men and women, 40 to 79 years old, with early carotid atherosclerosis and moderately elevated LDL cholesterol.	Factorial plan double blind USA
AFCAPS/TexCAPS , 1998 n=3304/3301 follow-up: 5.2 years	lovastatin 20-40 mg/d versus placebo	men and women without clinically evident atherosclerotic cardiovascular disease with average total cholesterol (TC) and LDL-C levels and below-average high-density lipoprotein cholesterol (HDL-C) levels	Parallel groups double blind USA
pravastatin vs placebo			
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
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
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
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
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
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
rosuvastatin vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
HOPE 3 , 2016 [NCT00468923] n=6361/6344 follow-up:	rosuvastatin 10 mg per day versus placebo	subjects who did not have cardiovascular disease and were at intermediate risk	Factorial plan double-blind 21 countries
JUPITER , 2008 [NCT00239681] n=8901/8901 follow-up: median 1.9 year	rosuvastatin 20 mg daily versus placebo	apparently healthy individuals with low LDL-cholesterol levels of less than 130 mg per deciliter but elevated C-reactive-protein (high-sensitivity C-reactive protein levels of 2.0 mg per liter or higher)	Parallel groups double blind 26 countries
simvastatin vs placebo			
HPS (diabetic primary prevention sub group) , 2003 n=1455/1457 follow-up: 5 years	simvastatin 40 mg/d versus placebo	adults (aged 40-80 years) with diabetes (primary prevention subgroup)	Parallel groups double blind UK
pravastatin vs usual care			
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
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

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]

ASCOT, 2003:

Sever PS, Dahlof B, Poulter NR, Wedel H, Beevers G, Caulfield M, Collins R, Kjeldsen SE, Kristinsson A, McInnes GT, Mehlsen J, Nieminen M, O'Brien E, Ostergren J, Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial–Lipid Lowering Arm (ASCOT-LLA): a multicentre randomised controlled trial. Lancet 2003; 361:1149-58 [12686036]

ASPEN, 2006:

Knopp RH, d'Emden M, Smilde JG, Pocock SJ Efficacy and safety of atorvastatin in the prevention of cardiovascular end points in subjects with type 2 diabetes: the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in non-insulin-dependent diabetes mellitus (ASPEN). Diabetes Care 2006;29:1478-85 [16801565]

ASPEN (primary prevention sub group), 2006:

Knopp RH, d'Emden M, Smilde JG, Pocock SJ Efficacy and safety of atorvastatin in the prevention of cardiovascular end points in subjects with type 2 diabetes: the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in non-insulin-dependent diabetes mellitus (ASPEN). Diabetes Care 2006;29:1478-85 [16801565] 10.2337/dc05-2415

CARDS, 2004:

Colhoun HM, Betteridge DJ, Durrington PN, Hitman GA, Neil HA, Livingstone SJ, Thomason MJ, Mackness MI, Charlton-Menys V, Fuller JH Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. Lancet 2004 Aug 21;364:685-96 [15325833]

Mohler, 2003:

Mohler ER 3rd, Hiatt WR, Creager MA Cholesterol reduction with atorvastatin improves walking distance in patients with peripheral arterial disease. Circulation 2003;108:1481-6 [12952839]

ALERT, 2003:

Holdaas H, Fellstrm B, Jardine AG, Holme I, Nyberg G, Fauchald P, Grnhagen-Riska C, Madsen S, Neumayer HH, Cole E, Maes B, Ambhl P, Olsson AG, Hartmann A, Solbu DO, Pedersen TR Effect of fluvastatin on cardiac outcomes in renal transplant recipients: a multicentre, randomised, placebo-controlled trial. Lancet 2003;361:2024-31 [12814712]

BCAPS, 2001:

Hedblad B, Wikstrand J, Janzon L, Wedel H, Berglund G Low-dose metoprolol CR/XL and fluvastatin slow progression of carotid intima-media thickness: Main results from the Beta-Blocker Cholesterol-Lowering Asymptomatic Plaque Study (BCAPS). Circulation 2001;103:1721-6 [11282901]

HYRIM, 2005:

ACAPS, 1994:

AFCAPS/TexCAPS, 1998:

CAIUS, 1996:

KAPS, 1995:

PHYLLIS, 2004:

PMSG, 1993:

PROSPER (primary prevention subgroup), 2002:

WOSCOPS, 1995:

HOPE 3, 2016:

JUPITER, 2008:

HPS (diabetic primary prevention sub group), 2003:

ALLHAT, 2002:

KLIS, 2000:

2 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.