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

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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 (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,
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

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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			
HOPE 3 , 2016 [NCT00468923] n=6361/6344 follow-up: 5.6 years	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

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Trial	Treatments	Patients	Trials design and methods
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	aged 55 years or 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

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2 About TrialResults-center.org

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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.

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