Clinical trials of statins for cardiovascular prevention in secondary prevention

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1 diet

Trial	Treatments	Patients	Trials design and methods
diet vs usual diet			
DART (Burr) , 1989 n=NA follow-up: 2 years	diet advice versus usual diet	men who had recovered from MI	Factorial plan open, blind assessment

References

DART (Burr), 1989:

Burr ML, Fehily AM, Gilbert JF, Rogers S, Holliday RM, Sweetnam PM, Elwood PC, Deadman NM Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial (DART). Lancet 1989;2:757-61 [2571009]

2 statins

Trial	Treatments	Patients	Trials design and methods
atorvastatin vs placebo			
Mohler , 2003 n=NA follow-up: 12 months	atorvastatin (10 mg per day) versus placebo	patients with intermittent claudication	double blind
fluvastatin vs placebo			
FLARE , 1999 n=409/425 follow-up: 40 weeks	fluvastatin 40 mg twice daily versus placebo	successful coronary balloon angioplasty	Parallel groups double blind
LCAS , 1997 n=164/157 follow-up: 2.5 years	fluvastatin 20 mg twice daily versus placebo	men and women aged 35 to 75 years with angiographic CHD and mean low-density lipoprotein (LDL) cholesterol of 115 to 190 mg/dl despite diet	Parallel groups double-blind
LIPS , 2002 n=844/833 follow-up: 3.9 years	fluvastatin, 80 mg/d versus placebo	patients (aged 18-80 years) with stable or unstable angina or silent ischemia following successful completion of their first PCI who had baseline total cholesterol levels between 3.5-7.0 mmol/L and with fasting triglyceride levels of less than 4.5 mmol/L	Parallel groups double blind Europe, Canada, and Brazil
Riegger et al. , 1999 n=187/178 follow-up: 1.0 years	fluvastatin 40 mg (o.a.d. or b.i.d.) versus placebo	hyperlipidaemic patients with symptomatic, clinically-diagnosed (exercise-ECG) coronary heart disease	Parallel groups double blind

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Trial	Treatments	Patients	Trials design and methods
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
CCAIT , 1994 n=165/166 follow-up: 2 years	lovastatin begun at 20 mg/d and titrated to 40 and 80 mg during the first 16 weeks to attain a fasting low-density lipoprotein (LDL) cholesterol <or = 130 mg/dL versus placebo	patients with diffuse but not necessarily severe coronary atherosclerosis documented on a recent arteriogram and with fasting serum cholesterol between 220 and 300 mg/dL	Parallel groups double-blind Canada
MARS , 1993 [NCT00116870] n=123/124 follow-up: 2.0y	lovastatin 80 mg/day versus placebo	patients, 37 to 67 years old, with total cholesterol ranging from 4.92 to 7.64 mmol/L (190 to 295 mg/dL) and angiographically defined coronary artery disease	Parallel groups double blind
Weintraub , 1994 n=203/201 follow-up: 0.5 years	lovastatin 40 mg orally twice daily versus placebo	patients undergoing PTCA	Parallel groups double blind
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
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

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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
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
simvastatin vs placebo			
4S , 1994 n=2221/2223 follow-up: 5.4 years	simvastatin 20 or 40 mg/d, target CT between 3 et 5.2 mmol/l versus placebo	patients with angina pectoris or previous myocardial infarction and serum cholesterol 5.5-8.0 mmol/L on a lipid-lowering diet	Parallel groups double blind Scandinavia
CIS , 1997 n=129/125 follow-up: 2.3 years	simvastatin 40 mg versus placebo	men with documented coronary artery disease and hypercholesterolaemia	Parallel groups double blind
HPS , 2002 n=10269/10267 follow-up: 5 years	simvastatin 40 mg/d versus placebo	adults (aged 40-80 years) with coronary disease, other occlusive arterial disease, or diabete	Factorial plan double blind UK
MAAS , 1994 n=193/188 follow-up: 4 y	simvastatin 20 mg daily versus placebo	patients with coronary heart disease	Parallel groups double blind
atorvastatin vs usual care			
GREACE , 2002 n=800/800 follow-up: 3 years mean	atorvastatin 10-80 mg/d versus usual care	patients with established coronary heart disease	Parallel groups open
lovastatin vs usual care			
CLAPT , 1999 n=112/114 follow-up: 2.0 years	lovastatin begun at 20 mg daily and tritrated up to 80 mg daily versus usual care	patients underwenting PTCA	Parallel groups open (blind assessement)
Sahni , 1991 n=79/78 follow-up: 2 years	lovastatin 20-40mg/d versus conventional therapy alone	patients undergoing successful PTCA	Parallel groups open
pravastatin vs usual care			
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

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GISSI Prevenzione, 2000:

3 statins high dose

Trial	Treatments	Patients	Trials design and methods
atorvastatin high dose vs angioplasty			
AVERT , 1999 n=164/177 follow-up: 1.5 years	atorvastatin 80 mg/d versus recommended percutaneous revascularization procedure(angioplasty) followed by usual care, whichcould include lipid-lowering treatment	patients referred for percutaneous revascularization, with stable coronary artery disease, relatively normal left ventricular function, asymptomatic or mild-to-moderate angina, and a serum level of low-density lipoprotein (LDL) cholesterol of at least 115 mg per deciliter (3.0 mmol per liter)	Parallel groups open US, Europe
atorvastatin high dose vs atorvastatin			
TNT , 2005 [NCT00327691] n=4995/5006 follow-up: 4.9 years	80 mg of atorvastatin daily versus 10 mg of atorvastatin daily	Chronic coronary artery disease LDL cholesterol <3.4 mmol/L	Parallel groups double blind 14 countries
atorvastatin high dose vs lovastatin			

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Trial	Treatments	Patients	Trials design and methods
Vascular basis , 2005 n=197/103 follow-up: 1 year	atorvastatin (80 mg) with or without vitamin C and E versus low dose lovastatin (5 mg)	Chronic coronary artery disease	Parallel groups double blind
atorvastatin high dose vs pravastatin			
REVERSAL , 2004 n=327/327 follow-up: 1.5 years	atorvastatin 80 mg daily versus Pravastatin(40 mg)	Chronic coronary artery disease	Parallel groups double blind
SAGE , 2007 n=446/445 follow-up: 1 years	atorvastatin 80 mg daily versus pravastatin(40 mg)	Chronic coronary artery disease	Parallel groups double blind
atorvastatin high dose vs simvastatin			
IDEAL , 2005 [NCT00159835] n=4439/4449 follow-up: 4.8 years	atorvastatin 80mg daily versus simvastatine 20mg/j	Men and women aged 80 years or younger with a history of a definite myocardial infarction and who qualified for statin therapy according to national guidelines	Parallel groups open Denmark, Finland, Iceland, Netherlands, Norway, Sweden
simvastatin high dose vs simvastatin			
SEARCH , 2010 [NCT00124072] n=6031/6033 follow-up: 6.7 years (mean)	simvastatin 80 mg daily versus simvastatin 20mg daily	MI survivors	Parallel groups

References

AVERT, 1999:
TNT, 2005:
Vascular basis, 2005:
REVERSAL, 2004:
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IDEAL, 2005:
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4 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.

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