Clinical trials of cholesterol lowering intervention for cardiovascular prevention in diabetic patients

TrialResults-center www.trialresultscenter.org

1 fibrates

Trial	Treatments	Patients	Trials design and methods
bezafibrate vs placebo			
SENDCAP , 1998 n=81/83 follow-up: 3.0 years	bezafibrate 400 mg daily versus placebo	type 2 diabetic subjects without a history of clinical cardiovascular	Parallel groups double blind UK
clofibrate vs placebo			
Hanefeld , 1991 n=379/382 follow-up: 5 years	clofibric acid 1.6 g/day versus placebo	newly diagnosed middle-aged (30- to 55-yr-old) patients with non-insulin-dependent diabetes mellitus	Parallel groups double-blind Germany
Harrold , 1969 n=30/33 follow-up: 1 years	clofibrate versus placebo	diabetic retinopathy	Parallel groups double-blind
etofibrate vs placebo			
Emmerich , 2009 n=NA follow-up: 12 months	etofibrate 1g/j versus placebo	patients with type 2 diabetes mellitus and concomitant diabetic retinopathy	Parallel groups double-blind Germany
fenofibrate vs placebo			
FIELD , 2005 [ISRCTN64783481] n=4895/4900 follow-up: 5y	fenofibrate 200 mg daily versus placebo	aged 50-75 years, with type 2 diabetes mellitus, and not taking statin therapy at study entry	
DAIS , 2001 n=207/211 follow-up: 3.3 years	fenofibrate 200 mg/day versus placebo	men and women with type 2 diabetes and coronary atherosclerosis	Parallel groups double-blind Canada, Finland, France, Sweden
gemfibrozil vs placebo			
HHS (diabetic sub group) , 1987 n=135 follow-up:	gemfibrozil 600mg twice daily versus placebo	asymptomatic middle-aged men (40 to 55 years of age) with primary dyslipidemia (non-HDL cholesterol greater than or equal to 200 mg per deciliter	double blind

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Trial	Treatments	Patients	Trials design and methods
VA-HIT (diabetic sub group) , 1999 n=309/318 follow-up: 5.1 y	gemfibrozil 1200 mg per day versus placebo	men with coronary heart disease, an HDL cholesterol level of 40 mg per deciliter (1.0 mmol per liter) or less, and an LDL cholesterol level of 140 mg per deciliter (3.6 mmol per liter) or less.	Parallel groups double blind
fenofibrate vs placebo (on top simvastatine)			
ACCORD lipid , 2010 [NCT00000620] n=2765/2753 follow-up: 4.7y	fenofibrate on top simvastatin versus placebo (on top simvastatine)	high-risk patients with type 2 diabetes	Factorial plan double-blind United States and Canada
ACCORD lipid (subgroup Eye study) , 2010 [NCT00000620] n=806/787 follow-up: 4.7y	fenofibrate on top simvastatin versus placebo (on top simvastatine)	high-risk patients with type 2 diabetes	Factorial plan double-blind United States and Canada

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VA-HIT (diabetic sub group), 1999:

ACCORD lipid, 2010:

ACCORD lipid (subgroup Eye study), 2010:

2 statins

Trial	Treatments	Patients	Trials design and methods
atorvastatin vs placebo			
ASCOT (diabetics sub group) , 2003 n=1258/1274 follow-up:	10 mg atorvastatin versus placebo	hypertensive patients with no history of coronary heart disease (CHD) but at least three cardiovascular risk factors	
Deutsche Diabetes Dialyse Studie (4D) , 2005 n=619/636 follow-up: 4 y (median)	atorvastatin 20mg daily versus matching placebo	patients with type 2 diabetes mellitus on maintenance hemodialysis	Parallel groups double blind
ASPEN , 2006 n=1211/1199 follow-up: 4y	atorvastatin 10mg daily versus placebo	patients s with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets	Parallel groups double blind
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
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
fluvastatin vs placebo			
LIPS (diabetic sub group) , 2002 n=120/82 follow-up: 3.9y	fluvastatin 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 135 and 270 mg/dL	Parallel groups double blind
ALERT (diabetic sub group) , 2003 n=197/199 follow-up:	fluvastatin versus placebo	renal transplant recipients with total cholesterol 4090 mmol/L	Parallel groups double blind
lovastatin vs placebo			
AFCAPS/TexCAPS (diabetic sub group) , 1998 n=84/71 follow-up:	lovastatin 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
pravastatin vs placebo			
PROSPER diabetic (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

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Trial	Treatments	Patients	Trials design and methods
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
simvastatin vs placebo			
HPS (diabetic sub group) , 2002 n=2978/2985 follow-up:	simvastatin 40mg daily versus placebo	Men and women diabetes aged about 4080 years with non-fasting blood total cholesterol concentrations of at least 35 mmol/L (135 mg/dL)	Parallel groups double blind
4S (diabetic sub group) , 1999 n=251/232 follow-up: 5.4y	simvastatin versus placebo	diabetic men and women aged 35 to 70 years with previous MI or active, stable angina pectoris and with serum total cholesterol level between 5.5 to 8.0 mmol/L and serum triglyceride level <=2.5 mmol/L	Parallel groups double blind Denmark, Finland, Iceland, Norway, and Sweden
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			
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
atorvastatin high dose vs atorvastatin			
TNT (diabetic sub group) , 2006 n=748/753 follow-up: 4.9 y	atorvastatin 80 mg daily versus atorvastatin 10 mg daily	patients with stable coronary heart disease	double blind
aggressive cholesterol-lowering vs moderate cholesterol-lowering			

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Trial	Treatments	Patients	Trials design and methods
Post CABG (diabetic sub group) , 1999 n=116 follow-up:	aggressive cholesterol-lowering versus moderate cholesterol-lowering	patients 1-11 years after CABG	double blind
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

References

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ASPEN, 2006:
ASPEN, 2006:
CARDS, 2004:
LIPS (diabetic sub group), 2002:
ALERT (diabetic sub group), 2003:
AFCAPS/TexCAPS (diabetic sub group), 1998:
PROSPER diabetic (sub group), 2002:
LIPID (diabetic sub group), 1998:
CARE (diabetic sub group), 1998:
WOSCOPS (diabetic sub group), 1996:
HPS (diabetic sub group), 2002:
4S (diabetic sub group), 1999:
HPS (diabetic primary prevention sub group), 2003:
GISSI P (diabetic sub group), 2000:
ALLHAT-LLT (diabetic sub group), 2002:
TNT (diabetic sub group), 2006:
Post CABG (diabetic sub group), 1999:
PROVE IT TIMI 22 (diabetic sub group), 2006:

3 strategy

Trial	Treatments	Patients	Trials design and methods
aggressive treatment vs standard teatment			

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Trial	Treatments	Patients	Trials design and methods
SANDS , 2008 [NCT00047424] n=252/247 follow-up: 3 years	aggressive targets of LDL-C of 70 mg/dL or lower and SBP of 115 mm Hg or lower versus standard targets of LDL-C of 100 mg/dL or lower and SBP of 130 mm Hg or lower	adults with type 2 diabetes	Parallel groups open US

References

SANDS, 2008:

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.

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.

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