

# Clinical trials of cholesterol lowering intervention for cardiovascular prevention in patients with LDL elevation and without CHD

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## 1 diet

Trial	Treatments	Patients	Trials design and methods
<b>diet vs usual diet</b>			
<b>Finnish Mental Hospital (Miettinen) , 1985</b> n=612/610 follow-up: 6.0 years	cholesterol-lowering diet (low in saturated fats and cholesterol and relatively high in polyunsaturated fats) versus usual diet	middle-aged institutionalized women without CHD	Cluster-randomized cross-over open, blind assessment Finland
<b>Goteborg , 1986</b> n=10004/20028 follow-up: 10 years	multifactorial intervention programme versus no intervention	men, 47-55 years old at entry	Parallel groups open Sweden
<b>Hjermann , 1981</b> n=604/628 follow-up: 6.5 years	diet versus usual diet	healthy, normotensive men at high risk of coronary heart disease	Parallel groups open Sweden
<b>MRFIT , 1982</b> n=6428/6438 follow-up: 6.5 y	multifactor intervention program versus usual diet	high-risk men aged 35 to 57 years	Parallel groups open
<b>Veterans Ad. (Dayton) , 1969</b> n=424/422 follow-up: 3.6 and 8 y	cholesterol lowering diet versus usual diet	men in domiciliary care, age>55, with or without CHD	Parallel groups double blind USA
<b>WHO Collaborative , 1986</b> n=30489/26971 follow-up: 5.5 years	multifactorial prevention versus usual diet	middle-aged men	Parallel groups open Belgium, Italy, Poland, UK

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## 2 fibrates

Trial	Treatments	Patients	Trials design and methods
<b>clofibrate vs placebo</b>			
<a href="#">Cullen , 1974</a> n=20/20 follow-up: 2 years	clofibrate versus placebo		Parallel groups
<a href="#">WHO clofibrate , 1978</a> n=5331/5296 follow-up: 5.3 years	clofibrate 1.6 g daily versus olive oil	primary prevention, Hommes, de 30 59 ans	Parallel groups double blind Scotland, Hungary, Czech Republic
<b>gemfibrozil vs placebo</b>			
<a href="#">Helsinki (HHS) , 1987</a> n=2046/2035 follow-up: 5 years	gemfibrozil 1,2 g/d 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 [ <a href="#">5.2 mmol per liter</a> ])	Parallel groups double blind Finland

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### 3 inhibitor of lipoprotein-associated phospholipase

Trial	Treatments	Patients	Trials design and methods
<b>darapladib vs placebo</b>			
<b>SOLID-TIMI 52</b> [NCT01000727] n=NA follow-up:	-	-	

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### 4 Probucol

Trial	Treatments	Patients	Trials design and methods
<b>probucol vs control</b>			
<b>FATS Fukosawa (probucol), 2002</b> n=82/81 follow-up: 2 years	probucol 500 mg/day versus diet alone	asymptomatic patients with hypercholesterolemia	Parallel groups open Japan

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### 5 resins

Trial	Treatments	Patients	Trials design and methods
<b>cholestyramine vs placebo</b>			

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Trial	Treatments	Patients	Trials design and methods
<b>LRC , 1984</b> n=1906/1900 follow-up: 7.4 years	cholestyramine 24 g daily versus placebo	asymptomatic middle-aged men with primary hypercholesterolemia (type II hyperlipoproteinemia)	Parallel groups double blind USA
<b>colestipol vs placebo</b>			
<b>Gundersen , 1976</b> n=36/30 follow-up: 0.8 years	colestipol 10g twice daily versus placebo	hypercholesterolemic patients	Parallel groups double-blind
<b>Ruoff , 1978</b> n=21/19 follow-up: 3.2 years	colestipol versus placebo	hypercholesterolemic patients	Parallel groups
<b>Ryan , 1974</b> n=44/48 follow-up: 3.0 years	colestipol15 g/day versus placebo	patients with hypercholesterolemia	Parallel groups
<b>UCS (Dorr) , 1978</b> n=1149/1129 follow-up: 1.9 years	colestipol hydrochloride 32 mg/dl versus placebo	Hommes et femmes, >18 ans	Parallel groups double blind

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## 6 statins

Trial	Treatments	Patients	Trials design and methods
<b>any statin vs no statin</b>			
<b>Sakamoto , 2006</b> n=241/245 follow-up: up to 24 months	any available statin versus no statin	Japanese patients with AMI within 96 hours of AMI onset	Parallel groups open Japan

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>atorvastatin vs placebo</b>			
<b>MIRACL , 2001</b> n=1538/1548 follow-up: 1 and 4 months	Atorvastatin, 80 mg (early initiation) versus Placebo	unstable angina or nonQ-wave acute MI	Parallel groups Double blind Europe, North America, South Africa, and Australasia
<b>macin , 2005</b> n=NA follow-up: 30 days	atorvastatin 40 mg daily for 30 days versus placebo	patients admitted within 48 hours of onset of ACS with CRP levels $> \text{or} = 1.4$ mg/dL	Parallel groups double-blind
<b>fluvastatin vs placebo</b>			
<b>LIPS (sub groups) , 2002</b> n=417/407 follow-up: 1, 4, and 6 months	Fluvastatin, 80 mg versus Placebo	patients with unstable angina and successful first percutaneous coronary intervention	Parallel groups double blind Europe, Canada, and Brazil
<b>FLORIDA , 2002</b> n=265/275 follow-up: 1, 4, and 6 months	Fluvastatin, 80 mg (early initiation) versus Placebo	patients with an AMI and total cholesterol of $< 6.5$ mmol.l	Parallel groups double blind The Netherlands
<b>Czech trial ongoing</b> [NCT00171275] n=NA follow-up: 52 weeks	fluvastatin versus placebo	-	Parallel groups double blind
<b>lovastatin vs placebo</b>			
<b>AFCAPS/TexCAPS , 1998</b> 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
<b>pravastatin vs placebo</b>			
<b>LAMIL , 1997</b> 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
<b>RECIFE , 1999</b> 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 $\geq 5.2$ mmol/L or LDL $\geq 3.4$ mmol/L	Parallel groups double blind Canada
<b>PAIS , 2001</b> 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
<b>PACT , 2004</b> 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

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>WOSCOPS , 1995</b> 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
<b>simvastatin vs placebo</b>			
<b>A to Z , 2004</b> n=2265/2232 follow-up: 1 and 4 months	Simvastatin, 40-80 mg early initiation versus Placebo	patient with an acute coronary syndrome (ACS)	Parallel groups Double aveugle 41 countries
<b>Ren , 2009</b> n=NA follow-up:	simvastatin (40 mg/d for 4 weeks) versus placebo	patients with unstable angina pectoris	Parallel groups double-blind
<b>atorvastatin vs usual care</b>			
<b>Colivicchi , 2002</b> n=40/41 follow-up: 1, 3, and 6 months	Atorvastatin, 80 mg daily early initiation versus Usual care	unstable angina pectoris or non-Q-wave myocardial infarction	Parallel groups open Italy
<b>ESTABLISH , 2004</b> n=35/35 follow-up: 1, 4, and 6 months	Atorvastatin, 20 mg early initiation versus Usual care	patients with ACS undergoing emergency coronary angiography and percutaneous coronary intervention	Parallel groups open Japan
<b>pravastatin vs usual care</b>			
<b>L-CAD , 2000</b> 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
<b>PTT , 2002</b> 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
<b>OACIS-LIPID , 2008</b> 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
<b>pitavastatin vs atorvastatin</b>			
<b>JAPAN ACS , 2009</b> [NCT00242944] n=307 follow-up: 8-12 months	pitavastatin 4 mg daily versus atorvastatin 20mg daily	patients with acute coronary syndrome undergoing IVUS-guided percutaneous coronary intervention	Parallel groups open Japan
<b>atorvastatin vs pravastatin</b>			
<b>PROVE IT - TIMI 22 , 2004</b> n=2099/2063 follow-up: 24 mo (18-36 mo)	80 mg of atorvastatin daily (intensive therapy). versus 40 mg of pravastatin daily (standard therapy)	patients who had been hospitalized for an acute coronary syndrome within the preceding 10 days	Parallel groups double blind UK, US, AUstralia, Italy, France, Germany, Spain, Canada

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## 7 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.

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