# Clinical trials of cholesterol lowering intervention for cardiovascular prevention in high risk patients with or without LDL cholesterol elevation

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## 1 ezetimibe

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **ezetimibe vs niacin** | | | |
| ARBITER-HALTS 6 , 2010<br>n=NA<br>follow-up: 14 months | addition of ezetimibe (10 mg/daily) to statin therapy<br>versus<br>extended-release niacin 2000 mg/daily | patients at high risk for vascular disease but with LDL-cholesterol levels <100 mg/dL and moderately low HDL-cholesterol levels (<50 mg/dL) | Parallel groups<br>open |

### References


**ARBITER-HALTS 6, 2010:**

10.1016/j.jacc.2010.03.017




## 2 statins

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **atorvastatin vs placebo** | | | |
| ASCOT , 2003<br>n=5168/5137<br>follow-up: 3.3 years | atorvastatin 10mg/d<br>versus<br>placebo | hypertensive patients aged 40-79 years with at least three other cardiovascular risk factors | Parallel groups<br>double blind<br>UK et Scandinavie |
| **pravastatin vs placebo** | | | |
| PMSG , 1993<br>n=530/532<br>follow-up: 26 weeks | pravastatin 20 mg once daily<br>versus<br>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<br>double blind |
| PROSPER , 2002<br>n=2891/2913<br>follow-up: 3.2 years | pravastatin 40mg daily<br>versus<br>placebo | men and women aged 70-82 years with a history of, or risk factors for, vascular disease | Parallel groups<br>double blind<br>Ecosse, Irelande, Pays bas |
| REGRESS , 1995<br>n=450/435<br>follow-up: 2 years | pravastatin 40 mg daily<br>versus<br>placebo | symptomatic men with normal to moderately elevated serum cholesterol levels | Parallel groups<br>double blind<br>Netherlands |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **rosuvastatin vs placebo** | | | |
| JUPITER , 2008<br>[NCT00239681]<br>n=8901/8901<br>follow-up: median 1.9 year | rosuvastatin 20 mg daily<br>versus<br>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<br>double blind<br>26 countries |
| **simvastatin vs placebo** | | | |
| HPS , 2002<br>n=10269/10267<br>follow-up: 5 years | simvastatin 40 mg/d<br>versus<br>placebo | adults (aged 40-80 years) with coronary disease, other occlusive arterial disease, or diabete | Factorial plan<br>double blind<br>UK |
| **pravastatin vs usual care** | | | |
| ALLHAT , 2002<br>[NCT00000542]<br>n=5170/5185<br>follow-up: 4.8 years | pravastatin 40mg/d<br>versus<br>usual care | aged 55 years or older, moderately hypercholesterolemic, hypertensive participants with at least 1 additional CHD risk factor | Factorial plan<br>open<br>USA, Puerto Rico, Canada |

## References


**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]

**PMSG, 1993:**

Effects of pravastatin in patients with serum total cholesterol levels from 5.2 to 7.8 mmol/liter (200 to 300 mg/dl) plus two additional atherosclerotic risk factors. The Pravastatin Multinational Study Group for Cardiac Risk Patients. Am J Cardiol 1993;72:1031-7 [8213583]

**PROSPER, 2002:**

Shepherd J, Blauw GJ, Murphy MB, Bollen EL, Buckley BM, Cobbe SM, Ford I, Gaw A, Hyland M, Jukema JW, Kamper AM, Macfarlane PW, Meinders AE, Norrie J, Packard CJ, Perry IJ, Stott DJ, Sweeney BJ, Twomey C, Westendorp RG, Pravastatin in elderly individuals at risk of vascular disease (PROSPER): a randomised controlled trial. Lancet 2002; 360:1623-30 [12457784]

**REGRESS, 1995:**

Jukema JW, Bruschke AV, van Boven AJ, Reiber JH, Bal ET, Zwinderman AH, Jansen H, Boerma GJ, van Rappard FM, Lie KI Effects of lipid lowering by pravastatin on progression and regression of coronary artery disease in symptomatic men with normal to moderately elevated serum cholesterol levels. The Regression Growth Evaluation Statin Study (REGRESS). Circulation 1995;91:2528-40 [7743614]

van Boven AJ, Jukema JW, Zwinderman AH, Crijns HJ, Lie KI, Bruschke AV Reduction of transient myocardial ischemia with pravastatin in addition to the conventional treatment in patients with angina pectoris. REGRESS Study Group. Circulation 1996;94:1503-5 [8840836]

**JUPITER, 2008:**

Ridker PM, Danielson E, Fonseca FA, Genest J, Gotto AM Jr, Kastelein JJ, Koenig W, Libby P, Lorenzatti AJ, Macfadyen JG, Nordestgaard BG, Shepherd J, Willerson JT, Glynn RJ Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein. N Engl J Med 2008 Nov 9;: [18997196]

**HPS, 2002:**

, MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002; 360:7-22 [12114036]

Armitage J, Collins R Need for large scale randomised evidence about lowering LDL cholesterol in people with diabetes mellitus: MRC/BHF heart protection study and other major trials. Heart 2000;84:357-60 [10995396]

MRC/BHF Heart Protection Study of cholesterol-lowering therapy and of antioxidant vitamin supplementation in a wide range of patients at increased risk of coronary heart disease death: early safety and efficacy experience. Eur Heart J 1999;20:725-41 [10329064]

**ALLHAT, 2002:**

, Major outcomes in moderately hypercholesterolemic, hypertensive patients randomized to pravastatin vs usual care: The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT-LLT). JAMA 2002; 288:2998-3007 [12479764]

# 3 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.

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.