

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

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 ezetimibe

Trial	Treatments	Patients	Trials design and methods
<b>ezetimibe vs niacin</b>			
<b>ARBITER-HALTS 6 , 2010</b> n=NA follow-up: 14 months	addition of ezetimibe (10 mg/daily) to statin therapy versus 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 open

## References

**ARBITER-HALTS 6, 2010:**

[10.1016/j.jacc.2010.03.017](https://doi.org/10.1016/j.jacc.2010.03.017)

## 2 statins

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
<b>ASCOT , 2003</b> 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
<b>pravastatin vs placebo</b>			
<b>PMSG , 1993</b> 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 ≥ 2 additional risk factors for atherosclerotic coronary artery disease	Parallel groups double blind
<b>PROSPER , 2002</b> 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, Irlande, Pays bas
<b>REGRESS , 1995</b> 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

continued...

Trial	Treatments	Patients	Trials design and methods
<b>rosuvastatin vs placebo</b>			
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
<b>simvastatin vs placebo</b>			
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
<b>pravastatin vs usual care</b>			
ALLHAT , 2002 [NCT00000542] n=5170/5185 follow-up: 4.8 years	pravastatin 40mg/d versus usual care	older, moderately hypercholesterolemic, hypertensive participants with at least 1 additional CHD risk factor	Factorial plan open 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, Crijs 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

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.

TrialResults-center is non-profit and self-funded.