

Clinical trials of cholesterol lowering intervention for cardiovascular prevention in women

TrialResults-center www.trialresultscenter.org

1 statins

Trial	Treatments	Patients	Trials design and methods
Atorvastatin vs placebo			
ASCOT (women subgroup) , 2003 n=979/963 follow-up: 3.3 y	Atorvastatin 10 mg daily versus placebo	hypertensive patients (aged 40-79 years with at least three other cardiovascular risk factors) - subgroup of women	Parallel groups double-blind Europe
Lovastatin vs placebo			
65279;AFCAPS (women subgroup) , 1998 n=499/498 follow-up: 5.2 y	Lovastatin 2040 mg daily versus placebo	men and postmenopausal women without clinical evidence of cardiovascular disease (CVD) who had average low-density lipoprotein cholesterol and below average high-density lipoprotein cholesterol - subgroup of women	Parallel groups double blind US
Pravastatin vs placebo			
ALLHAT (women subgroup) , 2002 n=2511/2540 follow-up: 4.8 y	Pravastatin 40 mg daily versus control	Ambulatory persons, aged 55 years or older, with low-density 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- subgroup of women	Parallel groups open US
MEGA (women subgroup) , 2006 n=2638/2718 follow-up: 5.3 y	Pravastatin 1020 mg daily versus control	patients with hypercholesterolaemia (total cholesterol 5.69-6.98 mmol/L) and no history of coronary heart disease or stroke- subgroup of women	Parallel groups open Japan
Rosuvastatin vs placebo			
JUPITER (women subgroup) , 2008 n=3426/3375 follow-up: 1.9 y	Rosuvastatin 20 mg daily versus placebo	apparently healthy men and women with low-density lipoprotein cholesterol levels of less than 130 mg/dL and high-sensitivity C-reactive protein levels of 2.0 mg/L or higher - subgroup of women	Parallel groups double-blind 26 countries
Simvastatin vs placebo			
HPS (women subgroup) , 2002 n=914/902 follow-up: 5 y	Simvastatin 40 mg versus placebo	UK adults (aged 40-80 years) with coronary disease, other occlusive arterial disease, or diabetes - subgroup of women without CHD	Parallel groups double blind UK

References

ASCOT (women subgroup) , 2003:

Sever PS, Dahlf 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](#)] [10.1016/S0140-6736\(03\)12948-0](#)

65279;AFCAPS (women subgroup) , 1998:

Downs JR, Clearfield M, Weis S, Whitney E, Shapiro DR, Beere PA, Langendorfer A, Stein EA, Kruyer W, Gotto AM Jr Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels: results of AFCAPS/TexCAPS. Air Force/Texas Coronary Atherosclerosis Prevention Study. *JAMA* 1998;279:1615-22 [[9613910](#)]

Clearfield M, Downs JR, Weis S, Whitney EJ, Kruyer W, Shapiro DR, Stein EA, Langendorfer A, Beere PA, Gotto AM Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS): efficacy and tolerability of long-term treatment with lovastatin in women. *J Womens Health Gend Based Med* 2001;10:971-81 [[11788107](#)] [10.1089/152460901317193549](#)

ALLHAT (women subgroup) , 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](#)]

MEGA (women subgroup) , 2006:

Nakamura H, Arakawa K, Itakura H, Kitabatake A, Goto Y, Toyota T, Nakaya N, Nishimoto S, Muranaka M, Yamamoto A, Mizuno K, Ohashi Y Primary prevention of cardiovascular disease with pravastatin in Japan (MEGA Study): a prospective randomised controlled trial. *Lancet* 2006;368:1155-63 [[17011942](#)] [10.1016/S0140-6736\(06\)69472-5](#)

JUPITER (women subgroup) , 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;359:2195-207 [[18997196](#)] [10.1056/NEJMoa0807646](#)

HPS (women subgroup) , 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](#)] [10.1016/S0140-6736\(02\)09327-3](#)

2 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.