

Additional file 1: References to Excluded and Included studies

Excluded study	Reason for exclusion
Bakker-Arkema RG, Davidson MH, Goldstein RJ et al. Efficacy and safety of a new HMG-CoA reductase inhibitor, atorvastatin, in patients with hypertriglyceridemia. <i>JAMA</i> 1996; 275:128-33.	Exclude - duration less than 12 weeks
Adamska-Dyniewska H & chojnowska-Jeziarska J. [Effect of one-year treatment with low simvastatin doses on lipids and Lp(a) in patients with significant hypercholesterolaemia] (Polish). <i>Pol Arch Med Wewn</i> 1998; 99(5): 366-72.	Exclude - Unable to obtain from British Library. No UK location
Aengevaeren WR, Kroon AA, Stalenhoef AF, Uijen GJ, van der Werf T. Low density lipoprotein apheresis improves regional myocardial perfusion in patients with hypercholesterolemia and extensive coronary artery disease. LDL-Apheresis Atherosclerosis Regression Study (LAARS). <i>J Am Coll Cardiol</i> 1996; 28:1696-704.	Exclude - patients underwent cardiac catheterisation immediately before randomisation
Aengevaeren WR, Uijen GJ, Jukema JW, Brusckhe AV, van der Werf T. Functional evaluation of lipid-lowering therapy by pravastatin in the Regression Growth Evaluation Statin Study (REGRESS). <i>Circulation</i> 1997; 96(2):429-35.	Exclude - REGRESS trial; substudy
Aggressive lipid lowering in postcoronary angioplasty patients with elevated cholesterol (the lovastatin restenosis trial). <i>Am J Cardiol</i> 1998; 81: 633-635.	Exclude - Patients had an angioplasty after randomisation
Agheli N, Jacotot B. Effect of simvastatin and fenofibrate on the fatty acid composition of hypercholesterolaemic patients. <i>Br J Clin Pharmacol</i> 1991; 32:423-8.	Exclude - Fewer than 20 patients per treatment group
Aguilar-Salinas CA et al. A familial combined hyperlipidemic kindred with impaired apolipoprotein B catabolism: Kinetics of apolipoprotein B during placebo and pravastatin therapy. <i>Arterioscler Thromb Vasc Biol</i> 1997; 17:72-82.	Exclude - Familial hypercholesterolaemia
Alaupovic et al. Effects of lovastatin on Apo-A and Apo-Bcontaining lipoproteins. Families in a subpopulation of patients participating in the Monitored Atherosclerosis Regression Study (MARS). <i>Thrombosis & Thrombolysis</i> 1994; 14(12): 1906-1913	Exclude - MARS study. No relevant lipid data
Albert MA, Staggers J, Chew P, Ridker PM. The pravastatin inflammation CRP evaluation (PRINCE): rationale and design. <i>Am Heart J</i> 2001; 141(6):893-8.	Exclude - duplicated data PRINCE study. Data extracted from [Albert et al, 2001a]
Ambrosi P, Aillaud MF, Habib G et al. Fluvastatin decreases soluble thrombomodulin in cardiac transplant recipients. <i>Thrombosis & Haemostasis</i> 2000; 83:46-8.	Exclude - Patients entered in the study had recent heart transplantation.
Andrews TC, Ballantyne CM, Hsia JA, Kramer JH. Achieving and maintaining national cholesterol education program low-density lipoprotein cholesterol goals with five statins. <i>Am J Med</i> 2001; 111(3):185-91.	Exclude - open label
Anonymous. A coronary primary intervention study of Japanese men: study design, implementation and baseline data. The Kyushu Lipid Intervention Study Group. <i>J Atheroscler Thromb</i> 1996; 3(2):95-104.	Exclude - unsuccessful randomisation

Excluded study	Reason for exclusion
Anonymous. [Pravastatin in patients with cardiac risk factors. Effects of pravastatin in patients with total serum cholesterol concentrations of 200 to 300 mg/dl (5.2 to 7.8 mmol/l) and two additional atherosclerosis risk factors. Pravastatin Multinational Study Group for Cardiac Risk Patients]. [German]. Fortschr Med 1994; 112:57-64.	Exclude - duplicated patient information from [Pravastatin Multicentre Study Group for cardiac risk Factors 1993]
Anonymous. A multicentre comparison of lovastatin & cholestyramine therapy for severe primary hypercholesterolaemia. JAMA 1988; 260:359-366	Exclude - not properly double blinded. Must be a cross-over
Anonymous. Baseline serum cholesterol and treatment effect in the Scandinavian Simvastatin Survival Study (4S) [see comments]. Lancet 1995; 345:1274-5.	Exclude - 4S study. Data extracted from other reports
Anonymous. Comparative efficacy and safety of pravastatin and cholestyramine alone and combined in patients with hypercholesterolemia. Pravastatin Multicenter Study Group II. Arch Intern Med 1993; 153:1321-9.	Exclude - Blinding was broken and placebo patients reassigned to active treatment after 8 weeks.
Anonymous. Design and baseline results of the Scandinavian Simvastatin Survival Study of patients with stable angina and/or previous myocardial infarction. Am J Cardiol 1993; 71:393-400.	Exclude - Duplicated information for 4S study. Data extracted from [Pedersen et al, 1998]
Anonymous. Design features and baseline characteristics of the LIPID (Long-Term Intervention with Pravastatin in Ischemic Disease) Study: a randomized trial in patients with previous acute myocardial infarction and/or unstable angina pectoris. Am J Cardiol 1995; 76:474-9.	Exclude - LIPID study. Lipid data extracted from substudy [MacMahon et al, 1998]
Anonymous. Plaque Hypertension Lipid-Lowering Italian Study (PHYLLIS): a protocol for non-invasive evaluation of carotid atherosclerosis in hypercholesterolaemic hypertensive subjects. J Hypertens Suppl 1993; 11 Suppl 5:S314-5.	Exclude - combination therapy; PHYLLIS study
Anonymous. Pravastatin use and risk of coronary events and cerebral infarction in Japanese men with moderate hypercholesterolemia: the Kyushu Lipid Intervention Study. J Atheroscler Thromb 2000; 7(2): 110-21.	Exclude - randomisation was unsuccessful
Anonymous. Pravastatin use and risk of coronary events and cerebral infarction in Japanese men with moderate hypercholesterolemia: The Kyushu Lipid Intervention Study. J Atheroscler Thromb 2000; 7(2):110-21.	Exclude - randomisation was stated as being unsuccessful. Used a protocol-based analysis with adjustment for coronary risk factors.
Anonymous. Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group [see comments]. N Engl J Med 1998; 339:1349-57.	Exclude - LIPID study. No lipid data for entire population. Lipid data extracted from substudy [MacMahon et al, 1998]
Anonymous. Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group [see comments]. N Engl J Med 1998; 339:1349-57.	Exclude - LIPID study. No lipid data for entire population. Lipid data extracted from substudy [MacMahon et al, 1998]
Anonymous. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S) [see comments]. Lancet 1994; 344:1383-9.	Exclude - 4S study. Data extracted from other reports
Anonymous. Screening experience and baseline characteristics in the West of Scotland Coronary Prevention Study. The WOSCOPS Study Group. West of Scotland Coronary Prevention Study. Am J Cardiol 1995; 76:485-91.	Exclude - WOSCOPS study. Duplicates data in [Shepherd et al, 1995]

Excluded study	Reason for exclusion
Anonymous. The effects of pravastatin on hospital admission in hypercholesterolemic middle-aged men: West of Scotland Coronary Prevention Study. <i>J Am Coll Cardiol</i> 1999; 33:909-15.	Exclude - WOSCOPS study. Duplicates data in [Shepherd et al, 1995]
Anonymous. Therapeutic response to lovastatin (Mevinolin) in nonfamilial hypercholesterolaemia. <i>JAMA</i> 1986; 256:2829-34.	Exclude - number of patients per group not stated other than between 17-20
Aquilani R, Tramarin R, Pedretti RF et al. Despite good compliance, very low fat diet alone does not achieve recommended cholesterol goals in outpatients with coronary heart disease [see comments]. <i>Eur Heart J</i> 1999; 20:1020-9.	Exclude - open label
Arntz et al. [Effectiveness of pravastatin and bezafibrate in primary hypercholesterolemia] ORIGINAL TITLE: Wirksamkeit von Pravastatin und Bezafibrat bei primärer Hypercholesterinämie. <i>Dtsch-Med-Wochenschr</i> 1991; 116:7-12.	Exclude - Duplicate of [Arntz 1999]
Athanasios G et al. Effects of simvastatin and ciprofibrate alone and in combination on lipid profile, plasma fibrinogen and low density lipoprotein particle structure and distribution in patients with familial combined hyperlipidaemia and coronary artery disease. <i>Coronary Artery disease</i> 1996;7:843-850.	Exclude - Familial hypercholesterolaemia
Attanasio E, Russo P, Allen SE. Cost-minimization analysis of simvastatin versus atorvastatin for maintenance therapy in patients with coronary or peripheral vascular disease. <i>Clin Ther</i> 2001; 23(2):276-83; discussion 274-5.	Exclude - Cost analysis based on another trial with low baseline cholesterol entry criteria
Avellone G et al. Changes induced by pravastatin treatment on hemostatic and fibrinolytic patterns in patients with type IIb hyperlipoproteinemia. <i>CURR THER RES CLIN EXP</i> 1994; 55:1335-44.	Exclude - Fewer than 20 patients per treatment group
Bach LA, Cooper ME, O'Brien RC, Jerums G. The use of simvastatin, an HMG CoA reductase inhibitor, in older patients with hypercholesterolemia and atherosclerosis. <i>J Am Geriatr Soc</i> 1990; 38:10-4.	Exclude - duration less than 12 wks (double blind); fewer than 20 patients per treatment group
Badia X, Russo P, Attanasio E. A comparative economic analysis of simvastatin versus atorvastatin: results of the Surrogate Marker Cost-Efficacy (SMaC) study. <i>Clin Ther</i> 1999; 21:1788-96.	Exclude - Cost Analysis of SMaC [Dart A, et al, 1997]
Bakker-Arkema RG, Nawrocki JW, Black DM. Safety profile of atorvastatin-treated patients with low LDL-cholesterol levels. <i>Atherosclerosis</i> 2000; 149(1):123-9.	Exclude. Pooled safety analysis from 21 trials
Balestrieri GP, Maffi V, Sleiman I et al. Fish oil supplementation in patients with heterozygous familial hypercholesterolemia. <i>Recenti Prog Med</i> 1996; 87:102-5.	Exclude - Familial hypercholesterolaemia
Ballantyne Cm et al. Efficacy and safety of an extended-release formulation of fluvastatin for once-daily treatment of primary hyperchoelsterolemia. <i>Am J Cardiol</i> 2000; 86:759-63	Exclude - duration less than 12 weeks
Ballantyne CM, Herd JA, Ferlic LL et al. Influence of low HDL on progression of coronary artery disease and response to fluvastatin therapy. <i>Circulation</i> 1999; 99:736-43.	Exclude - LCAS study. Data extracted from [Herd et al, 1997]

Excluded study	Reason for exclusion
Banga JD, Jacotot B, Pfister P, Mehra M. Long-term treatment of hypercholesterolemia with fluvastatin: a 52-week multicenter safety and efficacy study. French-Dutch Fluvastatin Study Group. <i>Am J Med</i> 1994; 96:87S-93S.	Exclude - open label extension to an earlier trial of various doses of fluvastatin versus placebo.
Barbir M, Hunt BJ, Galloway D et al. A randomized pilot trial of low-dose combination lipid-lowering therapy following coronary artery bypass grafting. <i>Clin Cardiol</i> 1994; 17:59-64.	Exclude - combination of simvastatin with colestipole; fewer than 20 patients per treatment group
Bard JM, Dallongeville J, Hagen E et al. Comparison of the effect of fluvastatin, an hydroxymethyl glutaryl coenzyme A reductase inhibitor, and cholestyramine, a bile acid sequestrant, on lipoprotein particles defined by apolipoprotein composition. <i>Metabolism: Clinical & Experimental</i> 1995; 44:1447-54.	Exclude - duplicated data. Information from Hagen et al, 1994
Bard JM, Ose L, Hagen E et al. Changes in plasma apolipoprotein B-containing lipoparticle levels following therapy with fluvastatin and cholestyramine. European Fluvastatin Study Group. <i>Am J Cardiol</i> 1995; 76:65A-70A.	Exclude - combination of fluvastatin & cholestyramine at different doses. No active/inert comparator
Bard JM, Parra HJ, Camare R et al. A multicenter comparison of the effects of simvastatin and fenofibrate therapy in severe primary hypercholesterolemia, with particular emphasis on lipoproteins defined by their apolipoprotein composition. <i>Metabolism: Clinical & Experimental</i> 1992; 41:498-503.	Exclude - duration less than 12 wks
Bard JM, Parra HJ, Luc G et al. Lipoprotein particle analysis comparing simvastatin and fenofibrate. <i>Atherosclerosis</i> 1991; 91 Suppl:S29-34.	Exclude - no data to extract; apolipoprotein levels only provided. Duplicated by [Bard et al, 1992] which provides fuller details
Barter PJ & O'Brien RC. Achievement of target plasma cholesterol levels in hypercholesterolaemic patients being treated in general practice. <i>Atherosclerosis</i> 2000; 149:199-205.	Exclude - open label
Barth JD, Zonjee MM. Regression growth evaluation statin study (REGRESS): study design and baseline characteristics in 600 patients. The REGRESS Research Group. <i>Can J Cardiol</i> 1992; 8(9):925-32.	Exclude - duplicated information REGRESS study, design and baseline data
Behounek BD et al. 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. <i>AM. J. Cardiol.</i> 1993; 72:1031-7.	Exclude - duplicate publication. Data from [The pravastatin Multinational Study Group for Cardiac Risk Patients, 1993]
Benitez M et al. A comparative study of policosanol versus pravastatin in patients with type II hypercholesterolemia. <i>Curr Ther Res Clin Exp</i> 1997; 58:859-67.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Berg K, Dahlen G, Christophersen B, Cook T, Kjekshus J, Pedersen T. Lp(a) lipoprotein level predicts survival and major coronary events in the Scandinavian Simvastatin Survival Study. <i>Clin Genet</i> 1997; 52:254-61.	Exclude - 4S study. Duplicate patient information.
Berger GM, Marais AD, Seftel HC et al. Treatment of hypercholesterolemia with the HMG CoA reductase inhibitor, simvastatin. <i>Cardiovascular Drugs & Therapy</i> 1989; 3:219-27.	Exclude - duration less than 12 wks
Berioli S, Bentivoglio M, Conti R et al. [Simvastatin versus gemfibrozil in the treatment of primary hypercholesterolemia in hypertensive patients treated with hydrochlorothiazide]. [Italian]. <i>Cardiologia</i> 1990; 35:335-40.	Exclude - Fewer than 20 patients per treatment group

Excluded study	Reason for exclusion
Berlioli S, Bentivoglio M, Conti R et al. [Simvastatin versus gemfibrozil in the treatment of primary hypercholesterolemia in hypertensive patients treated with hydrochlorothiazide]. [Italian]. <i>Cardiologia</i> 1990; 35:335-40.	Exclude - not double blind
Bertrand ME et al. Effect of pravastatin on angiographic restenosis after coronary balloon angioplasty. <i>J Am Coll Cardiol</i> 1997; 30:863-9.	Exclude - All patients underwent coronary angioplasty (PTCA) in the 24 hrs of randomisation
Betteridge DJ, Durrington PN, Fairhurst GJ et al. Comparison of lipid-lowering effects of low-dose fluvastatin and conventional-dose gemfibrozil in patients with primary hypercholesterolemia. <i>Am J Med</i> 1994; 96:45S-54S.	Exclude - duration less than 12 wks
Bittner V, Simon JA, Fong J, Blumenthal RS, Newby K, Stefanick ML. Correlates of high HDL cholesterol among women with coronary heart disease. <i>Am Heart J</i> 2000; 139(2 Pt 1):288-96.	Exclude - not given specific lipid altering drugs & analysis split by cholesterol level rather than by drug
Blair SN, Capuzzi DM, Gottlieb SO, Nguyen T, Morgan JM, Cater NB. Incremental reduction of serum total cholesterol and low-density lipoprotein cholesterol with the addition of plant stanol ester-containing spread to statin therapy. <i>Am J Cardiol</i> 2000; 86(1):46-52.	Exclude - duration less than 12 wks
Blann AD et al. Influence of pravastatin on lipoproteins, and on endothelial, platelet, and inflammatory markers in subjects with peripheral artery disease. <i>Am J Cardiol</i> 2001; 88: 89-92.	Exclude - fewer than 20 patients per treatment group
Bradford RH et al. Expanded Clinical Evaluation of Lovastatin (EXCEL) study results: two-year efficacy and safety follow-up. <i>Am J Cardiol</i> . 1994 Oct 1; 74(7):667-673	Exclude- EXCEL study - 2 yr follow-up of 25% of the original study population.
Bradford RH, Shear CI et al. Expanded clinical evaluation of lovastatin (EXCEL) study: design and patient characteristics of a double-blind, placebo-controlled study in patients with moderate hypercholesterolemia. <i>Am J Cardiol</i> . 1990 Sep 18; 66(8):44B-55B	Exclude- EXCEL study - design features
Branchi A RASD. Differential effects of simvastatin and bezafibrate on apolipoprotein-defined high-density lipoprotein subfractions in patients with hypercholesterolemia. <i>Curr Ther Res Clin Exp</i> 1996; 57:26-32.	Exclude - Not double blind
Branchi A, Rovellini A, Fiorenza AM, Sommariva D. Effects of bezafibrate and of 2 HMG-CoA reductase inhibitors on lipoprotein (a) level in hypercholesterolemic patients. <i>International Journal of Clinical Pharmacology & Therapeutics</i> 1995; 33:345-50.	Exclude - Not double blind
Bredie SJ, de Bruin TW, Demacker PN, Kastelein JJ, Stalenhoef AF. Comparison of gemfibrozil versus simvastatin in familial combined hyperlipidemia and effects on apolipoprotein-B-containing lipoproteins, low-density lipoprotein subfraction profile, and low-density lipoprotein oxidizability. <i>Am J Cardiol</i> 1995; 75:348-53.	Exclude - Familial hypercholesterolaemia
Bredie SJ, Westerveld HT, Knipscheer HC, de Bruin TW, Kastelein JJ, Stalenhoef AF. Effects of gemfibrozil or simvastatin on apolipoprotein-B-containing lipoproteins, apolipoprotein-CIII and lipoprotein(a) in familial combined hyperlipidaemia. <i>Neth J Med</i> 1996; 49:59-67.	Exclude - Familial hypercholesterolaemia
Broijersens A, Eriksson M, Leijd B, Angelin B, Hjerdahl P. No influence of simvastatin treatment on platelet function in vivo in patients with hypercholesterolemia. <i>Arteriosclerosis, Thrombosis & Vascular Biology</i> 1997; 17:273-8.	Exclude - fewer than 20 patients per group; cross-over trial; 10-12 wks duration

Excluded study	Reason for exclusion
Brorholt-Petersen J, Jensen H, Raungaard B, Gregersen N, Faergeman O. LDL-receptor gene mutations and the hypocholesterolemic response to statin therapy. <i>Clin Genet</i> 2001; 59(6):397-405.	Exclude - Familial hypercholesterolaemia
Brown AS, Bakker-Arkema RG, Yellen L et al. Treating patients with documented atherosclerosis to National Cholesterol Education Program-recommended low-density-lipoprotein cholesterol goals with atorvastatin, fluvastatin, lovastatin and simvastatin. <i>J Am Coll Cardiol</i> 1998; 32:665-72.	Exclude - open label
Broyles FE, Walden CE, Hunninghake DB, Hill-Williams D, Knopp RH. Effect of fluvastatin on intermediate density lipoprotein (remnants) and other lipoprotein levels in hypercholesterolemia. <i>Am J Cardiol</i> 1995; 76:129A-35A.	Exclude - duration less than 12 wks
Bruckert E, De Gennes JL, Malbecq W, Baigts F. Comparison of the efficacy of simvastatin and standard fibrate therapy in the treatment of primary hypercholesterolemia and combined hyperlipidemia. <i>Clin Cardiol</i> 1995;	Exclude - Details of five trials. 4 published as Farnier, Fricker, Lecerf & Douste-Blazy. One unpublished with no baseline data for individual treatment groups
Capurso A, Resta F, Bertolini S et al. Lipid control with low-dosage simvastatin in patients with moderate hypercholesterolaemia. An Italian multicentre double-blind placebo-controlled study. <i>Eur Heart J</i> 1992; 13 Suppl B:11-6.	Exclude - duration less than 12 wks
Carmena R et al. Pravastatin, cholestyramine, and bezafibrate in patients with heterozygous familial hypercholesterolemia: The Spanish Multicenter Pravastatin Study. <i>Cardiovascular Risk Factors</i> . 1996; 6:55-61.	Exclude - Familial hypercholesterolaemia
Carr-Lopez S, Exstrum T, Morse T, Shepherd M, Bush AC. Efficacy of three statins at lower maintenance doses. <i>Clin Ther</i> 1999; 21(2):331-9.	Exclude - not double blind (single blind)
Catalan M et al. Clinical trial of lovastatin versus gemfibrozil. <i>Rev Med Univ Navarra</i> 1992; 37(3): 127-33.	Exclude - Unable to obtain from British Library. No UK location
Cheung MC, Austin MA, Moulin P, Wolf AC, Cryer D, Knopp RH. Effects of pravastatin on apolipoprotein-specific high density lipoprotein subpopulations and low density lipoprotein subclass phenotypes in patients with primary hypercholesterolemia. <i>Atherosclerosis</i> 1993; 102:107-19.	Exclude - fewer than 20 patients per group
Cheung MC, Zhao XQ, Chait A, Albers JJ, Brown BG. Antioxidant supplements block the response of hdl to simvastatin-niacin therapy in patients with coronary artery disease and low hdl. <i>Arterioscler Thromb Vasc Biol</i> 2001; 21(8):1320-6.	Exclude - combination of simvastatin with niacin
Chisholm A, Mann J, Sutherland W, Williams S, Ball M. Dietary management of patients with familial hypercholesterolaemia treated with simvastatin [see comments]. <i>Q J Med</i> 1992; 85:825-31.	Exclude - Familial hypercholesterolaemia
Chong et al. Rosuvastatin for the treatment of patients with hyperchoelsterolemia. <i>Annals of Pharmacotherapy</i> 2002; 36: 93-101	Exclude - review
Cilla DD Jr, Whitfield LR, Gibson DM, Sedman AJ, Posvar EL. Multiple-dose pharmacokinetics, pharmacodynamics, and safety of atorvastatin, an inhibitor of HMG-CoA reductase, in healthy subjects. <i>Clinical Pharmacology & Therapeutics</i> 1996; 60:687-95.	Exclude - healthy volunteers

Excluded study	Reason for exclusion
Civeira F, Cenarro A, Ferrando J et al. Comparison of the hypolipidemic effect of gemfibrozil versus simvastatin in patients with type III hyperlipoproteinemia [see comments]. <i>Am Heart J</i> 1999; 138:156-62.	Exclude - fewer than 20 patients per group; type III hyperlipoproteinaemia
Cobbaert C, Jukema JW, Zwinderman AH, Withagen AJ, Lindemans J, Bruschke AV. Modulation of lipoprotein(a) atherogenicity by high density lipoprotein cholesterol levels in middle-aged men with symptomatic coronary artery disease and normal to moderately elevated serum cholesterol. Regression Growth Evaluation Statin Study (REGRESS) Study Group. <i>J Am Coll Cardiol</i> 1997; 30(6):1491-9.	Exclude - duplicated information REGRESS study; subset of trial population; data extracted from [Jukema et al, 1995]
Contacos C, Barter PJ, Sullivan DR. Effect of pravastatin and omega-3 fatty acids on plasma lipids and lipoproteins in patients with combined hyperlipidemia. <i>Arteriosclerosis & Thrombosis</i> 1993; 13:1755-62.	Exclude - duration less than 12 wks. Combination of pravastatin with fish oil
Contacos C, Barter PJ, Vrga L, Sullivan DR. Cholesteryl ester transfer in hypercholesterolaemia: fasting and postprandial studies with and without pravastatin. <i>Atherosclerosis</i> 1998; 141:87-98.	Exclude - duration less than 12 wks; fewer than 20 pts on treatment; cross-over study (each part 6 wks)
Contermans J, Smit JW, Bar PR, Erkelens DW. A comparison of the effects of simvastatin and pravastatin monotherapy on muscle histology and permeability in hypercholesterolaemic patients. <i>Br J Clin Pharmacol</i> 1995; 39:135-41.	Exclude - fewer than 20 patients per group.
Cortellaro M, Cofrancesco E, Boschetti C et al. Effects of fluvastatin and bezafibrate combination on plasma fibrinogen, t-plasminogen activator inhibitor and C reactive protein levels in coronary artery disease patients with mixed hyperlipidaemia (FACT study). Fluvastatin Alone and in Combination Treatment. <i>Thrombosis & Haemostasis</i> 2000; 83:549-53.	Exclude - no data to extract - baseline lipid levels not provided
Couture P, Brun LD, Szots F et al. Association of specific LDL receptor gene mutations with differential plasma lipoprotein response to simvastatin in young French Canadians with heterozygous familial hypercholesterolemia. <i>Arteriosclerosis, Thrombosis & Vascular Biology</i> 1998; 18:1007-12.	Exclude - Familial hypercholesterolaemia
Crouse JR 3rd, Byington RP, Bond MG et al. Pravastatin, Lipids, and Atherosclerosis in the Carotid Arteries (PLAC-II) [published erratum appears in <i>Am J Cardiol</i> 1995 Apr 15;75(12):862]. <i>Am J Cardiol</i> 1995; 75:455-9.	Exclude - PLAC II study. Design features only. Data extracted from [Byington et al, 1995]
Crouse JR 3rd, Frohlich J, Ose L, Mercuri M, Tobert JA. Effects of high doses of simvastatin and atorvastatin on high-density lipoprotein cholesterol and apolipoprotein A-I. <i>Am J Cardiol</i> 1999; 83:1476-7, A7.	Exclude - Did not provide baseline lipid levels by treatment group, only overall levels.
Crouse JR, Byington RP, Bond MG et al. Pravastatin, lipids, and atherosclerosis in the carotid arteries: design features of a clinical trial with carotid atherosclerosis outcome. <i>Control Clin Trials</i> 1992; 13:495-506.	Exclude - PLAC II study. Design features only. Data extracted from [Byington et al, 1995]
Cutler N, Sramek J, Veroff A, Block G, Stauffer L, Lines C. Effects of treatment with simvastatin and pravastatin on cognitive function in patients with hypercholesterolaemia. <i>Br J Clin Pharmacol</i> 1995; 39:333-6.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Daida H, Lee YJ, Yokoi H et al . Prevention of restenosis after percutaneous transluminal coronary angioplasty by reducing lipoprotein (a) levels with low-density lipoprotein apheresis. Low-Density Lipoprotein Apheresis Angioplasty Restenosis Trial (L-ART) Group. <i>Am J Cardiol</i> 1994; 73:1037-40.	Exclude - not statin trial; not double blind
Dallongeville J, Fruchart JC, Pfister P, Bard JM. Effect of fluvastatin on plasma apolipoprotein-B-containing particles, including lipoprotein(a). European Fluvastatin Study Group. <i>J Intern Med Suppl</i> 1994; 736:95-101.	Exclude - pooled analysis of several trials

Excluded study	Reason for exclusion
Dallongeville J, Fruchart JC, Pfister P, Bard JM. Fluvastatin reduces levels of plasma apo B-containing particles and increases those of LpA-I. European Fluvastatin Study Group. <i>Am J Med</i> 1994; 96:32S-6S.	Exclude - pooled analysis of data from 4 European trials; duration less than 12 wks
Dangas G, Badimon JJ, Smith DA et al. Pravastatin therapy in hyperlipidemia: effects on thrombus formation and the systemic hemostatic profile [see comments]. <i>J Am Coll Cardiol</i> 1999; 33:1294-304.	Exclude - Not double blind
Dangas G, Smith DA, Unger AH et al. Pravastatin: an antithrombotic effect independent of the cholesterol-lowering effect. <i>Thromb Haemost</i> 2000; 83(5):688-92.	Exclude - duplicate publication. Data from Dangas et al, 1999
Darling GM, Johns JA, McCloud PI, Davis SR. Estrogen and progestin compared with simvastatin for hypercholesterolemia in postmenopausal women [see comments]. <i>N Engl J Med</i> 1997; 337:595-601.	Exclude - not double blind
Davidson MH et al. Low-dose combination therapy with colesvelam hydrochloride and lovastatin effectively decreases low-density lipoprotein cholesterol in patients with primary hypercholesterolemia. <i>Clin Cardiol</i> 2001; 24:467-474	Exclude - duration less than 12 wks
Davidson MH, Ma P, Stein EA, Gotto AM et al. Comparison of effects on low-density lipoprotein cholesterol and high-density lipoprotein cholesterol with rosuvastatin versus atorvastatin in patients with Type IIa or IIb hypercholesterolemia. <i>Am J Cardiol</i> 2002; 89: 268-275.	Exclude - full journal publication of unpublished data provided by AstraZeneca Ltd, [Davidson et al, 2001]
Davidson MH, Macariola-Coad JR, McDonald AM, Maki KC, Hall HA. Separate and joint effects of marine oil and simvastatin in patients with combined hyperlipidemia. <i>Am J Cardiol</i> 1997; 80:797-8.	Exclude - No mention of blinding, fewer than 20 patients per treatment group
Davidson MH, Stein EA, Dujovne CA et al. The efficacy and six-week tolerability of simvastatin 80 and 160 mg/day [see comments]. <i>Am J Cardiol</i> 1997; 79:38-42.	Exclude - duration less than 12 wks; cross-over study with 3 x 6 wk phases)
Davidson MH, Testolin LM, Maki KC, von Duvillard S, Drennan KB. A comparison of estrogen replacement, pravastatin, and combined treatment for the management of hypercholesterolemia in postmenopausal women. <i>Arch Intern Med</i> 1997; 157:1186-92.	Exclude - fewer than 20 patients in placebo group
Davignon J et al. Clinical efficacy and safety of cerivastatin: Summary of pivotal phase lib/III studies. <i>Am J Cardiol</i> 1998; 82(4B): 33J-39J.	Exclude - Details of 4 trials. All excluded because duplicates of [Betteridge et al, 1999], [Leiter et al, 1999], one had duration <12 wks, and one had no baseline data for individual treatment groups & number of patient per group was unclear
Davignon J, Roederer G, Montigny M et al. Comparative efficacy and safety of pravastatin, nicotinic acid and the two combined in patients with hypercholesterolemia. <i>Am J Cardiol</i> 1994; 73:339-45.	Exclude - duration less than 12 wks; other lipid altering agents allowed in 88 wk active phase
Davis BR, Cutler JA, Gordon DJ et al. Rationale and design for the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). ALLHAT Research Group [see comments]. <i>Am J Hypertens</i> 1996; 9:342-60.	Exclude - open label
de Divitiis M, Rubba P, Di Somma S et al. Effects of short-term reduction in serum cholesterol with simvastatin in patients with stable angina pectoris and mild to moderate hypercholesterolemia. <i>Am J Cardiol</i> 1996; 78:763-8.	Exclude - fewer than 20 patients per treatment group

Excluded study	Reason for exclusion
De Faire U et al. Secondary preventive potential of lipid-lowering drugs. The Bezafibrate Coronary Atherosclerosis Intervention trial (BECAIT. <i>Eur Heart J</i> 1996; 17:37-42.	Exclude - not a statin trial
De Groot E et al. B-mode ultrasound assessment of pravastatin treatment effect on carotid and femoral artery walls and its correlations with coronary arteriographic findings: A report of the regression growth evaluation statin study (REGRESS). <i>J Am Coll Cardiol</i> 1998; 31:1561-7.	Exclude - duplicated information REGRESS study; subset of study population; entire population data extracted from [Jukema et al, 1995]
Den Hartog FR et al. Pravastatin in acute ischaemic syndromes: results of a randomised placebo-controlled trial. <i>Int J Clin Pract</i> 2001; 55(5): 300-304.	Exclude - no data to extract. Baseline information not provided by treatment group
Deslypere JP. Clinical implications of the biopharmaceutical properties of fluvastatin. <i>Am J Cardiol</i> 1994; 73:12D-7D.	Exclude - review
Deslypere JP. Comparison between low-dose simvastatin and cholestyramine in moderately severe hypercholesterolemia. <i>Acta Cardiol</i> 1989; 44:379-88.	Exclude - duration less than 12 weeks
Di Mascio R, Marchioli R, Tognoni G. Cholesterol reduction and stroke occurrence: an overview of randomized clinical trials. <i>Cerebrovasc Dis</i> 2000; 10(2):85-92.	Exclude - review
Di Verolii C and Pastorelli R. Effectiveness and tolerability of simvastatin versus pravastatin. <i>Curr. Ther Res. Clin Exp</i> 1992; 52:1-6.	Exclude - randomisation and blinding not mentioned; duration less than 12 wks; fewer than 20 patients per treatment group
Dobs AS et al. Changes in serum lipoprotein(a) in hyperlipidemic subjects undergoing long-time treatment with lipid-lowering drugs. <i>Cardiovasc Drugs Ther</i> 1995; 9:677-84.	Exclude - subset of 32 patients from an unreferenced multicentre trial
Dobs AS, Prasad M, Goldberg A, Guccione M, Hoover DR. Changes in serum lipoprotein(a) in hyperlipidemic subjects undergoing long-term treatment with lipid-lowering drugs. <i>Cardiovascular Drugs & Therapy</i> 1995; 9:677-84.	Exclude - Fewer than 20 patients per treatment group
Dobs AS, Sarma PS, Schteingart D. Long-term endocrine function in hypercholesterolemic patients treated with pravastatin, a new 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor. <i>Metabolism: Clinical & Experimental</i> 1993; 42:1146-52.	Exclude - no data to extract - endocrine function only
Douste-Blazy P et al. Comparative study of the efficacy and tolerability of simvastatin and pravastatin in patients with primary hypercholesterolaemia. <i>DRUG INVEST.</i> 1993; 6:353-61.	Exclude - duration less than 12 wks
Downs JR et al. Primary prevention of acute coronary events with lovastatin in men and women with average cholesterol levels. <i>JAMA</i> 1998; 279: 1615-1622.	Exclude - no baseline data provided by treatment group.
Dujovne CA et al. Reduction of LDL cholesterol in patients with primary hypercholesterolemia by SCH 48461: results of a multicenter dose-ranging study. <i>J Clin Pharmacol</i> 2001; 41: 70-78.	Exclude - duration less than 12 wks

Excluded study	Reason for exclusion
Dujovne CA et al. Reduction of LDL cholesterol in patients with primary hypercholesterolemia by SCH 48461: results of a multicenter dose-ranging study. <i>J clin Pharmacol</i> 2001; 41(1): 70-8.	Exclude - duration less than 12 weeks
Dujovne CA, Davidson MH. Fluvastatin administration at bedtime versus with the evening meal: a multicenter comparison of bioavailability, safety, and efficacy. <i>Am J Med</i> 1994; 96:37S-40S.	Exclude - fewer than 20 patients per group
Dujovne CA, Chremos AN, Pool JL, Schnaper H; Bradford RH; Shear CL, Higgins J, Downton M, Franklin FA, Nash DT et al. Expanded Clinical Evaluation of Lovastatin (EXCEL) study results: IV. Additional perspectives on the tolerability of lovastatin. <i>Am J Med.</i> 1991 Jul 31; 91(1B):25S-30S; ISSN: 0002-9343.	Exclude - Excel study - safety data only
Dumont JM. Effect of cholesterol reduction by simvastatin on progression of coronary atherosclerosis: Design, baseline characteristics, and progress of the Multicenter Anti-Atheroma Study (MAAS). <i>Control Clin Trials</i> 1993; 14:209-28.	Exclude - MAAS study, duplicated information
Dupuis J, Tardif JC, Cernacek P, Theroux P. Cholesterol reduction rapidly improves endothelial function after acute coronary syndromes. The RECIFE (Reduction of Cholesterol in Ischemia and Function of the Endothelium) trial [see comments]. <i>Circulation</i> 1999; 99:3227-33.	Exclude - duration less than 12 wks on active treatment
Eagles CJ, Kendall MJ, Maxwell S. A comparison of the effects of fluvastatin and bezafibrate on exercise metabolism: a placebo-controlled study in healthy normolipidaemic subjects. <i>Br J Clin Pharmacol</i> 1996; 41:381-7.	Exclude - healthy volunteers
Eagles CJ, Kendall MJ. The effects of combined treatment with beta 1-selective receptor antagonists and lipid-lowering drugs on fat metabolism and measures of fatigue during moderate intensity exercise: a placebo-controlled study in healthy subjects. <i>Br J Clin Pharmacol</i> 1997; 43:291-300.	Exclude - healthy volunteers
Efficacy and tolerability of simvastatin and pravastatin in patients with primary hypercholesterolemia (multicountry comparative study). The European Study Group. <i>Am J Cardiol</i> 1992; 70(15):1281-6.	Exclude - open label
Eriksson M, Hadell K, Holme I, Walldius G, Kjellstrom T. Compliance with and efficacy of treatment with pravastatin and cholestyramine: a randomized study on lipid-lowering in primary care. <i>J Intern Med</i> 1998; 243:373-80.	Exclude - not double blind
Fagerberg B, Wikstrand J, Berglund G, Samuelsson O, Agewall S. Mortality rates in treated hypertensive men with additional risk factors are high but can be reduced: a randomized intervention study. <i>Am J Hypertens</i> 1998; 11:14-22.	Exclude - open label
Farish E et al J. A double-blind twelve-week placebo-controlled study to assess the efficacy of simvastatin in the treatment of hypercholesterolaemia in hypertensive patients. <i>J DRUG DEV SUPPL</i> 1990; 3:259-63.	Exclude - fewer than 20 patients in placebo group
Farmer JA, Washington LC, Jones PH, Shapiro DR, Gotto AM Jr, Mantell G. Comparative effects of simvastatin and lovastatin in patients with hypercholesterolemia. The Simvastatin and Lovastatin Multicenter Study Participants. <i>Clin Ther</i> 1992; 14:708-17.	Exclude - No data to extract, baseline lipid data
Farnier M et al. Effect of combined fluvastatin-fenofibrate therapy compared with fenofibrate monotherapy in severe primary hypercholesterolemia. <i>Am J cardiol</i> 2000; 85:53-57.	Exclude - combination of a statin with another drug

Excluded study	Reason for exclusion
Farnier M, Bonnefous F, Debbas N, Irvine A. Comparative efficacy and safety of micronized fenofibrate and simvastatin in patients with primary type IIa or IIb hyperlipidemia. Arch Intern Med 1994; 154:441-9.	Exclude - Cross-over study with no washout; fewer than 20 patients per group for analysis
Farnier M, Portal JJ, Maigret P. Efficacy of atorvastatin compared with simvastatin in patients with hypercholesterolemia. J Cardiovasc Pharmacol Ther 2000; 5(1):27-32.	Exclude - duration less than 12 wks
Feillet C, Farnier M, Monnier LH et al. Comparative effects of simvastatin and pravastatin on cholesterol synthesis in patients with primary hypercholesterolemia. Atherosclerosis 1995; 118:251-8.	Exclude - duration less than 12 wks
Feussner G, Eichinger M, Ziegler R. The influence of simvastatin alone or in combination with gemfibrozil on plasma lipids and lipoproteins in patients with type III hyperlipoproteinemia. Clin Investig 1992; 70:1027-35.	Exclude - fewer than 20 patients pre treatment group
Fey R, Pearson N. Statins and coronary heart disease. Lancet 1996; 347(9012):1389-90.	Exclude - Not randomised controlled trial
Fogari R et al. Effects of chronic treatment with pravastatin in patients with mild hypercholesterolemia and associated cardiovascular risk factors. CURR. THER. RES. CLIN. EXP. 1992; 51:896-905.	Exclude - fewer than 20 patients pre treatment group
Ford I et al. A Coronary Primary Prevention Study of Scottish men aged 45-64 years: Trial design. J CLIN EPIDEMIOL 1992; 45:849-60.	Exclude - duplicated patient information. WOSCOPS study
Forti N. [Reductions in lipid fraction plasma levels induced by simvastatin and bezafibrate. Brazilian multicenter study]. [Portuguese]. Arq Bras Cardiol 1993; 60:437-44.	Exclude - fewer than 20 patients per treatment group for analysis
Fricker et al. Efficacy & tolerability of simvastatin and fenofibrate in primary hypercholesterolaemia./ Presse Med 1990; 19: 1927-1930.	Exclude - duration less than 12 wks
Furberg CD et al. Effect of lovastatin on early carotid atherosclerosis and cardiovascular events. Circulation 1994; 90:1679-87.	Exclude - Add-on design (other lipid altering drugs were allowed)
Furberg CD, Byington RP, Crouse JR, Espeland MA. Pravastatin, lipids, and major coronary events. Am J Cardiol 1994; 73:1133-4.	Exclude - PLAC II study. Design features only. Data extracted from [Byington et al, 1995]
Garnett WR. A review of current clinical findings with fluvastatin. Am J Cardiol 1996; 78(6A):20-5.	Exclude - Review
Glasser SP et al. The efficacy and safety of pravastatin in patients aged 60 to 85 years with low-density lipoprotein cholesterol >160 mg/dL. Am J Cardiol 1996; 77: 83-85.	Exclude - duplicated data from [Jacobson et al, 1996] and [Meyers et al]

Excluded study	Reason for exclusion
Glorioso N, Troffa C, Filigheddu F et al. Effect of the HMG-CoA reductase inhibitors on blood pressure in patients with essential hypertension and primary hypercholesterolemia. <i>Hypertension</i> 1999; 34(6):1281-6.	Exclude - provided a single baseline value for lipids, not separate baseline values for different treatment groups
Gomez-Perez FJ, Bustamante F, Vergara A, Villasenor J, Wong B, Rull JA. A controlled trial of pravastatin vs probucol in the treatment of primary hypercholesterolemia. <i>Rev Invest Clin</i> 1992; 44:53-61.	Exclude - fewer than 20 patients pre treatment group
Gould AI et al. Cholesterol reduction yields clinical benefit. A new look at old data. <i>Circulation</i> 1995; 91: 2274-2282.	Exclude- meta-analysis
Gould AL, Rossouw JE, Santanello NC, Heyse JF, Furberg CD. Cholesterol reduction yields clinical benefit: impact of statin trials. <i>Circulation</i> 1998; 97(10):946-52.	Exclude- meta-analysis
Granero R, Linfa-Homes G, Isaacura-Lopez C, Goyo A, Flores-Finizola A, Sira A. [Clinical trial with sodium fluvastatin in patients with hypercholesterolemia associated with mild and moderate essential arterial hypertension]. [Spanish]. <i>Invest Clin</i> 1997; 38:63-72.	Exclude - duration less than 12 wks
Green L. Selections from current literature: the fight over fat: is pharmacological lipid lowering useful for coronary primary prevention? <i>Fam Prac</i> 1997; 14 (5): 411-415.	Exclude - review
Gylling H, Radhakrishnan R, Miettinen TA. Reduction of serum cholesterol in postmenopausal women with previous myocardial infarction and cholesterol malabsorption induced by dietary sitostanol ester margarine: women and dietary sitostanol. <i>Circulation</i> 1997; 96(12):4226-31.	Exclude - not double blind; no baseline lipid measurements; multiple cross-over with different durations
Haasis R BJ. Fluvastatin vs. lovastatin in primary hypercholesterolemia. <i>Herz Kreislauf</i> . 1995; 27:375-80.	Exclude - duration less than 12 wks
Haffner SM et al. Reduced coronary events in simvastatin treated patients with coronary heart disease and diabetes or impaired fasting glucose levels. <i>Arch Intern Med</i> 1999; 159: 2661-2667	Exclude - Duplicated information - subgroup of 4S study. Patients with CHD and diabetes
Hanefeld M, Deslypere JP, Ose L, Durrington PN, Farnier M, Schmage N. Efficacy and safety of 300 micrograms and 400 micrograms cerivastatin once daily in patients with primary hypercholesterolaemia: a multicentre, randomized, double-blind, placebo-controlled study. <i>J Int Med Res</i> 1999; 27(3):115-29.	Exclude - duration less than 12 wks
Harrison RW, Ashton CH. Do cholesterol-lowering agents affect brain activity? A comparison of simvastatin, pravastatin, and placebo in healthy volunteers. <i>Br J Clin Pharmacol</i> 1994; 37:231-6.	Exclude - healthy volunteers
Hayashi et al. REGRESS (The Regression Growth Evaluation Statin Study). <i>Nippon Rinsho</i> 2001; 59: 3: 422-6.	Exclude - duplicated patient information. REGRESS study
Hayashi K. [REGRESS [The Regression Growth Evaluation Statin Study]]. <i>Nippon Rinsho</i> 2001; 59 Suppl 3:422-6.	Exclude - duplicated information REGRESS study

Excluded study	Reason for exclusion
Hayden MR & Jospelson R. Development of a program for identification of patients with familial hypercholesterolemia in British Columbia: A model for prevention of coronary disease. <i>Am J Cardiol</i> 1993;72:25D-29D.	Exclude - commentary on familial hypercholesterolaemia
Heikkinen AM, Niskanen L, Ryyananen M et al. Is the response of serum lipids and lipoproteins to postmenopausal hormone replacement therapy modified by ApoE genotype? <i>Arterioscler Thromb Vasc Biol</i> 1999; 19(2):402-7.	Exclude - not a statin trial
Heinonen TM, Stein E, Weiss SR et al. The lipid-lowering effects of atorvastatin, a new HMG-CoA reductase inhibitor: results of a randomized, double-masked study. <i>Clin Ther</i> 1996; 18:853-63.	Exclude - number of patients per treatment group not >20 for all relevant groups.
Helve E, Tikkanen MJ. Comparison of lovastatin and probucol in treatment of familial and non-familial hypercholesterolemia: different effects on lipoprotein profiles. <i>Atherosclerosis</i> 1988; 72(2-3):189-97.	Exclude - fewer than 20 patients per group (data split by type of hypercholesterolaemia)
Herd JA, Ballantyne CM, Farmer JA et al. Effects of fluvastatin on coronary atherosclerosis in patients with mild to moderate cholesterol elevations (Lipoprotein and Coronary Atherosclerosis Study [LCAS]). <i>Am J Cardiol</i> 1997; 80:278-86.	Exclude - Add-on design (patients were given open label cholestyramine (max 12 g/day) as adjunctive therapy from week 12)
Herd JA, West MS, Ballantyne C, Farmer J, Gotto AM Jr. Baseline characteristics of subjects in the Lipoprotein and Coronary Atherosclerosis Study (LCAS) with fluvastatin. <i>Am J Cardiol</i> 1994; 73:42D-9D.	Exclude - LCAS study. Data extracted from [Herd et al, 1997]
Herd JA. The lipoprotein and coronary atherosclerosis study (LCAS): lipid and metabolic factors related to atheroma and clinical events. <i>Am J Med</i> 1998; 104:42S-9S.	Exclude - LCAS study. Data extracted from [Herd et al, 1997]
Hodis et al. Triglyceride- and cholesterol-rich lipoproteins have a different effect on mild/moderate and severe lesion progression as assessed by quantitative angiography in a controlled trial of lovastatin. <i>Circulation</i> 1994; 90: 42-49.	Exclude - single baseline value for mean total cholesterol, instead of separate means for different treatment groups
Holme I. Cholesterol reduction and its impact on coronary artery disease and total mortality. <i>Am J Cardiol</i> 1995; 76(9):10C-7C.	Exclude - pooled analysis of data from several trials
Hoogerbrugge N et al. The additional effects of acipimox to simvastatin in the treatment of combined hyperlipidaemia. <i>J-Intern-Med</i> 1997; 241:151-5.	Exclude - all patients took simvastatin & additionally given placebo or acipimox; fewer than 20 patients pre treatment group
Hoogerbrugge N, Mol MJ, Van Dormaal JJ et al. The efficacy and safety of pravastatin, compared to and in combination with bile acid binding resins, in familial hypercholesterolaemia [see comments]. <i>J Intern Med</i> 1990; 228:261-6.	Exclude - Familial hypercholesterolaemia
Huhle G, Abletshauer C, Mayer N, Weidinger G, Harenberg J, Heene DL. Reduction of platelet activity markers in type II hypercholesterolemic patients by a HMG-CoA-reductase inhibitor. <i>Thromb Res</i> 1999; 95:229-34.	Exclude - not double blind, duration less than 12 wks, fewer than 20 patients per treatment group.
Hunninghake D, Bakker-Arkema RG, Wigand JP et al. Treating to meet NCEP-recommended LDL cholesterol concentrations with atorvastatin, fluvastatin, lovastatin, or simvastatin in patients with risk factors for coronary heart disease. <i>J Fam Pract</i> 1998; 47:349-56.	Exclude - open label

Excluded study	Reason for exclusion
Hunninghake D, Insull W, Knopp R et al. Comparison of the efficacy of atorvastatin versus cerivastatin in primary hypercholesterolemia. <i>Am J Cardiol</i> 2001; 88(6):635-9.	Exclude - duration less than 12 weeks
Hunninghake DB et al. Effects of one year of treatment with pravastatin, an HMG-CoA reductase inhibitor, on lipoprotein a. <i>J Clin Pharmacol</i> 1993; 33:574-80.	Exclude - Duplicated data from [Hunninghake et al, 1990 b]. Retrospective subset of 125 patients from the study population of 306
Hunninghake DB, Knopp RH, Schonfeld G et al. Efficacy and safety of pravastatin in patients with primary hypercholesterolemia. II. Once-daily versus twice-daily dosing. <i>Atherosclerosis</i> 1990; 85:219-227.	Exclude - duration less than 12 wks
Hunninghake DB, Stein EA, Dujovne CA et al. The efficacy of intensive dietary therapy alone or combined with lovastatin in outpatients with hypercholesterolemia. <i>N Engl J Med</i> 1993; 328(17):1213-9.	Exclude - duration less than 12 wks for each of the 4 comparisons.
Hunninghake DB. Clinical efficacy of cerivastatin: phase IIa dose-ranging and dose-scheduling studies. <i>Am J Cardiol</i> 1998; 82:26J-31J.	Exclude - describes two trials with duration less than 12 wks
Hunninghake DB. Clinical efficacy of cerivastatin: phase IIa dose-ranging and dose-scheduling studies. <i>Am J Cardiol</i> 1998; 82:26J-31J.	Exclude - duration less than 12 wks
Hunninghake DB. Therapeutic efficacy of the lipid-lowering armamentarium: the clinical benefits of aggressive lipid-lowering therapy. <i>Am J Med</i> 1998; 104(2A):9S-13S.	Exclude - review
Illingworth DR et al. A comparison of simvastatin and atorvastatin up to maximal recommended doses in a large multicenter randomized clinical trial. <i>Curr Med Res Opinion</i> 2001; 17(1): 43-50.	Exclude - duplicated data from [Kastelein et al, 2000]
Illingworth DR et al. A randomized multicenter trial comparing and efficacy of simvastatin and fluvastatin. <i>J Cardiovasc Pharmacol Ther</i> 1996; 1(1): 23-30.	Exclude - Triple cross-over with no washout between treatments. Each treatment given for 5 weeks only
Imai Y, Suzuki H, Saito T, Tsuji I, Abe K, Saruta T. The effect of pravastatin on renal function and lipid metabolism in patients with renal dysfunction with hypertension and hyperlipidemia. Pravastatin and Renal Function Research Group. <i>Clinical & Experimental Hypertension (New York)</i> 1999; 21:1345-55.	Exclude - patients with renal dysfunction
Insull W Jr, Black D, Dujovne C et al. Efficacy and safety of once-daily vs twice-daily dosing with fluvastatin, a synthetic reductase inhibitor, in primary hypercholesterolemia. <i>Arch Intern Med</i> 1994; 154:2449-55.	Exclude - duration less than 12 weeks
Isaacsohn JL, Bakker-Arkema, Fayyad R et al. Atorvastatin, a new HMG-CoA reductase inhibitor, does not affect glucocorticoid hormones in patients with hypercholesterolemia. <i>J cardiovasc Pharmacol Theraput</i> 1997; 2(4):243-250	Exclude - open label
Ismail F, Corder CN, Epstein S, Barbi G, Thomas S. Effects of pravastatin and cholestyramine on circulating levels of parathyroid hormone and vitamin D metabolites. <i>Clin Ther</i> 1990; 12:427-30.	Exclude - Fewer than 20 patients per treatment group

Excluded study	Reason for exclusion
Jacobs H, Van de Werf F, Lesaffre E, De Geest H, Collen D. A randomized placebo controlled trial on the effects of simvastatin, a HMG-CoA reductase inhibitor, on blood lipids and fibrinolytic parameters. <i>Acta Clin Belg</i> 1992; 47:82-9.	Exclude - Fewer than 20 patients per treatment group
Jacobson TA, Amorosa LF. Combination therapy with fluvastatin and niacin in hypercholesterolemia: a preliminary report on safety. <i>Am J Cardiol</i> 1994; 73:25D-9D.	Exclude - duplicate of Jacobson et al, 1994b
Jacobson TA, Chin MM, Fromell GJ, Jokubaitis LA, Amorosa LF. Fluvastatin with and without niacin for hypercholesterolemia. <i>Am J Cardiol</i> 1994; 74:149-54.	Exclude - Add-on design (niacin added for all patients after 6 wks on statin or placebo)
Jacobson TA, Jokubaitis LA, Amorosa LF. Fluvastatin and niacin in hypercholesterolemia: a preliminary report on gender differences in efficacy. <i>Am J Med</i> 1994; 96:64S-8S.	Exclude - Duration less than 12 wks on double blind treatment; add-on design - niacin was added for all patients after 6 wks then open label; fewer than 20 patients in placebo group
Jacotot B et al. Efficacy of a low dose-range of fluvastatin (XU 62-320) in the treatment of primary hypercholesterolaemia. A dose-response study in 431 patients. <i>BR J CLIN PHARMACOL</i> 1994; 38:257-63.	Exclude - duration less than 12 wks
Jacotot B, Banga JD, Pfister P, Mehra M. Efficacy of a low dose-range of fluvastatin (XU 62-320) in the treatment of primary hypercholesterolaemia. A dose-response study in 431 patients. The French-Dutch Fluvastatin Study Group. <i>Br J Clin Pharmacol</i> 1994; 38:257-63.	Exclude - duplicate of [Jacotot et al, 1994]
Jialal I, Stein D, Balis D, Grundy SM, Adams-Huet B, Devaraj S. Effect of hydroxymethyl glutaryl coenzyme a reductase inhibitor therapy on high sensitive C-reactive protein levels. <i>Circulation</i> 2001; 103(15):1933-5.	Exclude - duration less than 12 wks
John S, Schlaich M, Langenfeld M et al. Increased bioavailability of nitric oxide after lipid-lowering therapy in hypercholesterolemic patients: a randomized, placebo-controlled, double-blind study. <i>Circulation</i> 1998; 98:211-6.	Exclude - Fewer than 20 patients per treatment group
Jones P et al. Comparison dose efficacy study of atorvastatin versus simvastatin, pravastatin, lovastatin, and fluvastatin in patients with hypercholesterolaemia (The CURVES Study). <i>Am J Cardiol</i> 1998; 81: 582-587.	Exclude - open label
Jones PH, Farmer JA, Cressman MD et al. Once-daily pravastatin in patients with primary hypercholesterolemia: a dose-response study. <i>Clin Cardiol</i> 1991; 14:146-51.	Exclude - duration less than 12 wks
Kaikkonen J, Nyyssonen K, Tomasi A et al. Antioxidative efficacy of parallel and combined supplementation with coenzyme Q10 and d-alpha-tocopherol in mildly hypercholesterolemic subjects: a randomized placebo-controlled clinical study. <i>Free Radic Res</i> 2000; 33(3):329-40.	Exclude - not a statin trial
Kallien G, Lange K, Stange EF, Scheibner J. The pravastatin-induced decrease of biliary cholesterol secretion is not directly related to an inhibition of cholesterol synthesis in humans. <i>Hepatology</i> 1999; 30:14-20.	Exclude - healthy volunteers
Kastelein JJ, Isaacsohn JL, Ose L et al. Comparison of effects of simvastatin versus atorvastatin on high-density lipoprotein cholesterol and apolipoprotein A-I levels. <i>Am J Cardiol</i> 2000; 86:221-3.	Exclude - no data to extract; baseline lipid data

Excluded study	Reason for exclusion
Katznelson S & Kobashigawa JA. Dual roles of HMG-CoA reductase inhibitors in solid organ transplantation: Lipid lowering and immunosuppression.	Exclude - commentary
Kayikcioglu M, Ozerkan F, Soydan I. Effectiveness and safety of alternate-day simvastatin and fenofibrate on mixed hyperlipidemia. <i>Am J Cardiol</i> 1999; 83:1135-7, A9.	Exclude - combination of simvastatin with fenofibrate randomised to 2 different dosing regimes; no other comparator
Kehely A, MacMahon M, Barbir M et al. Combined bezafibrate and simvastatin treatment for mixed hyperlipidaemia [published erratum appears in <i>Q J Med</i> 1995 Oct;88(10):749]. <i>QJM</i> 1995; 88:421-7.	Exclude - single baseline value for mean total cholesterol not for different treatment groups
Kesteloot H, Claeys G, Blanckaert N, Lesaffre E. Time course of serum lipids and apolipoproteins after acute myocardial infarction: modification by pravastatin. <i>Acta Cardiol</i> 1997; 52:107-16.	Exclude - in patients after acute MI
Kjekshus J, Pedersen TR. Reducing the risk of coronary events: evidence from the Scandinavian Simvastatin Survival Study (4S). <i>Am J Cardiol</i> 1995; 76:64C-8C.	Exclude - 4S study. Data extracted from other reports
Knipscheer HC, Boelen CC, Kastelein JJ et al. Short-term efficacy and safety of pravastatin in 72 children with familial hypercholesterolemia [published erratum appears in <i>Pediatr Res</i> 1996 Dec;40(6):866]. <i>Pediatr Res</i> 1996; 39:867-71.	Exclude - Familial hypercholesterolaemia
Knopp RH et al. Comparative efficacy and safety of pravastatin and cholestyramine alone and combined in patients with hypercholesterolemia. <i>ARCH. INTERN. MED.</i> 1993; 153:1321-9.	Exclude - duration less than 12 wks for placebo comparison. Active treatments continued up to 24wks. Blinding was broken & placebo patients were reassigned to active treatment
Knopp RH et al. Effect of pravastatin in the treatment of patients with type III hyperlipoproteinemia. <i>Am J Ther</i> 1996; 3:755-62.	Exclude - duration less than 12 wks on active treatment; type III hyperlipoproteinaemia
Koh KK, Cardillo C, Bui MN et al. Vascular effects of estrogen and cholesterol-lowering therapies in hypercholesterolemic postmenopausal women. <i>Circulation</i> 1999; 99(3):354-60.	Exclude - duration less than 12 wks
Kontopoulos AG, Athyros VG, Papageorgiou AA, Hatzikonstandinou HA, Mayroudi MC, Boudoulas H. Effects of simvastatin and ciprofibrate alone and in combination on lipid profile, plasma fibrinogen and low density lipoprotein particle structure and distribution in patients with familial combined hyperlipidaemia and coronary artery disease. <i>Coron Artery Dis</i> 1996; 7:843-50.	Exclude - familial hypercholesterolaemia
Kool M, Lustermaans F, Kragten H et al. Does lowering of cholesterol levels influence functional properties of large arteries?. <i>Eur J Clin Pharmacol</i> 1995; 48:217-23.	Exclude - fewer than 20 patients per treatment group
Kostis JB, Rosen RC, Wilson AC. Central nervous system effects of HMG CoA reductase inhibitors: lovastatin and pravastatin on sleep and cognitive performance in patients with hypercholesterolemia. <i>J Clin Pharmacol</i> 1994; 34:989-96.	Exclude - duration less than 12 wks
Kou W, Lu Z, Guo J. [Effect of xuezhikang on the treatment of primary hyperlipidemia]. [Chinese]. <i>Chung-Hua Nei Ko Tsa Chih Chinese Journal of Internal Medicine</i> 1997; 36:529-31.	Exclude - duration less than 12 weeks

Excluded study	Reason for exclusion
Kou W, Lu Z, Guo J. [Effect of xuezhikang on the treatment of primary hyperlipidemia]. [Chinese]. <i>Chung-Hua Nei Ko Tsa Chih Chinese Journal of Internal Medicine</i> 1997; 36:529-31.	Exclude - duration less than 12 wks
Kuhn P et al. Dose-dependent lipid-lowering effects of simvastatin (MK-733) in the elderly. <i>CURR THER RES, CLIN EXP</i> 1989; 46:381-9.	Exclude - duration less than 12 wks
Lagrost L, Athias A, Lemort N et al. Plasma lipoprotein distribution and lipid transfer activities in patients with type IIb hyperlipidemia treated with simvastatin. <i>Atherosclerosis</i> 1999; 143:415-25.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Lambrech LJ, Malini PL. Efficacy and tolerability of simvastatin 20 mg vs pravastatin 20 mg in patients with primary hypercholesterolemia. European Study Group. <i>Acta Cardiol</i> 1993; 48:541-54.	Exclude - duration less than 12 wks
Lansberg PJ et al. Long-term efficacy and tolerability of simvastatin in a large cohort of elderly hypercholesterolemic patients. <i>Atherosclerosis</i> 1995; 116: 153-62.	Exclude - duplicated short-term efficacy data presented in [Walker et al, 1990]. Open label extension data
Lanzarotto F, Panarotto B, Sorbara R et al. Effect of long term simvastatin administration as an adjunct to ursodeoxycholic acid: evidence for a synergistic effect on biliary bile acid composition but not on serum lipids in humans. <i>Gut</i> 1999; 44:552-6.	Exclude - fewer than 20 patients per treatment group
Larsen ML. [The Scandinavian Simvastatin Survival Study: the clinical consequences]. <i>Rev-Esp-Cardiol</i> 1995; 48 Suppl 5:39-42.	Exclude - Duplicated information - Spanish description of 4S study
Larsen ML. [The Scandinavian Simvastatin Survival Study: the clinical consequences]. <i>Rev-Esp-Cardiol</i> 1995; 48 Suppl 5:39-42.	Exclude - Duplicated information. Spanish report of the 4S study. No additional data
Laszlo M. Stroke es cardiovascularis hatasok a statinokkal vegzett klinikai vegpontu, randomizalt, kontrollos vizsgalatokban. <i>Orvosi Hetilap</i> 2000; 141 (27): 1501-1505.	Exclude - review
Laties, A. M.; Shear, C. L.; Lippa, E. A.; Gould, A. L.; Taylor, H. R.; Hurley, D. P.; Stephenson, W. P.; Keates, E. U.; Tupy-Visich, M. A., and Chremos, A. N. Expanded Clinical Evaluation of Lovastatin (EXCEL) study results. II. Assessment of the human lens after 48 weeks of treatment with lovastatin. <i>Am J Cardiol.</i> 1991 Mar 1; 67(6):447-453; ISSN: 0002-9149.	Exclude - EXCEL study - assessment of the human lens
Le NA, Innis-Whitehouse W, Li X, Bakker-Arkema R, Black D, Brown WV. Lipid and apolipoprotein levels and distribution in patients with hypertriglyceridemia: effect of triglyceride reductions with atorvastatin. <i>Metabolism: Clinical & Experimental</i> 2000; 49:167-77.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Leitersdorf E, Eisenberg S, Eliav O et al. Efficacy and safety of high dose fluvastatin in patients with familial hypercholesterolaemia. <i>Eur J Clin Pharmacol</i> 1993; 45:513-8.	Exclude - Familial hypercholesterolaemia (heterozygous)
Leonhardt W, Kurktschiev T, Meissner D et al. Effects of fluvastatin therapy on lipids, antioxidants, oxidation of low density lipoproteins and trace metals.	Exclude - duration less than 12 wks

Excluded study	Reason for exclusion
Lepre F et al. Low-dose simvastatin in the treatment of mild to moderate hypercholesterolaemia. <i>Clinical Drug Investigation</i> 1997; 13:237-41.	Exclude - no extractable data at 12 wks for all simvastatin or placebo patients
Levin LA et al. A comparison of clinical and pharmacoeconomic properties of fluvastatin and simvastatin in the management of primary hypercholesterolaemia. <i>British Journal of Medical Economics</i> 1997; 11:23-35.	Exclude - duplicated data from [Schulte et al, 1996]
Lewis S et al. Effect of pravastatin on cardiovascular events in women after myocardial infarction: the Cholesterol and Recurrent Events (CARE) trial. <i>J Am Coll Cardiol</i> 1998; 32:140-6.	Exclude - CARE study. No lipid data to extract.
Lewis SJ, Moye LA, Sacks FM. Effect of pravastatin on cardiovascular events in older patients with myocardial infarction and cholesterol levels in the average range. Results of the Cholesterol and Recurrent Events (CARE) Trial. <i>Ann Intern Med</i> 1998; 129:681-9.	Exclude - CARE study. Subset analysis
Lijnen P, Celis H, Desager JP, Fagard R. Changes in plasma lipids, lipoproteins and apolipoproteins in hypercholesterolaemic patients treated with pravastatin. <i>J Hum Hypertens</i> 1995; 9:557-64.	Exclude - duplicated data as in [Lijnen et al, 1996]
Lindholm LH, Ekblom T, Dash C, Isacson A, Schersten B. Changes in cardiovascular risk factors by combined pharmacological and nonpharmacological strategies: the main results of the CELL Study. <i>J Intern Med</i> 1996; 240:13-22.	Exclude - no dietary advice or intervention before randomisation then randomised to usual or intensive advice & either active or placebo for 18 mths.
Lintott CJ SR. Low-dose simvastatin or pravastatin in the treatment of moderate hypercholesterolemia: A comparison with bezafibrate. <i>Cardiovascular Risk Factors</i> . 1995; 5:311-6.	Exclude - Not double blind (single blind)
Lintott CJ, Scott RS, Bremer JM, Shand BI. Fluvastatin for dyslipoproteinemia, with or without concomitant chronic renal insufficiency. <i>Am J Cardiol</i> 1995; 76:97A-101A.	Exclude - includes patients with chronic renal insufficiency
Lintott CJ, Scott RS, Nye ER, Robertson MC, Sutherland WH. Simvastatin (MK 733): an effective treatment for hypercholesterolemia. <i>Australian & New Zealand Journal of Medicine</i> 1989; 19:317-20.	Exclude - duration less than 12 weeks
Lu ZL. [Clinical evaluation of simvastatin in the treatment of hyperlipidemia]. [Chinese]. <i>Chung-Hua Hsin Hsueh Kuan Ping Tsa Chih [Chinese Journal of Cardiology]</i> 1993; 21:216-8, 253.	Exclude - unable to translate
Lu-YH. Comparison of HMG-CoA and duoxikan in the treatment of hyperlipidemia. <i>Chinese Journal of Medical Writings</i> 2000; 7:497-8.	Exclude - Unable to obtain from British Library. Incorrect citation
Magnani G, Carinci V, Magelli C, Potena L, Reggiani LB, Branzi A. Role of statins in the management of dyslipidemia after cardiac transplant: randomized controlled trial comparing the efficacy and the safety of atorvastatin with pravastatin. <i>Journal of Heart & Lung Transplantation</i> 2000 Jul;19(7):710-5 2000; 19:710-5.	Exclude - not double blind
Malacco E et al. Pravastatin vs gemfibrozil in the treatment of primary hypercholesterolaemia. <i>DRUG INVEST</i> 1994; 7:331-9.	Exclude - not double blind

Excluded study	Reason for exclusion
Mancini JGB. Pravastatin limitation of atherosclerosis in the coronary arteries (PLAC 1. Rev Esp Cardiol 1995; 48:11-3.	Exclude - duplication of PLAC I study. Spanish language
Mansur AP, Serrano CV Jr, Nicolau JC, Cesar LA, Ramires JA. Effect of cholesterol lowering treatment on positive exercise tests in patients with hypercholesterolaemia and normal coronary angiograms. Heart 1999; 82(6):689-93.	Exclude - not double blind
Marian AJ, Safavi F, Ferlic L, Dunn JK, Gotto AM, Ballantyne CM. Interactions between angiotensin-I converting enzyme insertion/deletion polymorphism and response of plasma lipids and coronary atherosclerosis to treatment with fluvastatin: the lipoprotein and coronary atherosclerosis study. J Am Coll Cardiol 2000; 35:89-95.	Exclude - Not double blind.
Markwood TT, Kent SM, Coyle LC, Flaherty PJ, O'Malley PG, Taylor AJ. Design and rationale of the ARBITER trial (Arterial Biology for the Investigation of the Treatment Effects of Reducing Cholesterol)--a randomized trial comparing the effects of atorvastatin and pravastatin on carotid artery intima-media thickness. Am Heart J 2001; 141(3):342-7.	Exclude - open label
Marz W, Wollschlager H, Klein G, Neiss A, Wehling M. Safety of low-density lipoprotein cholesterol reduction with atorvastatin versus simvastatin in a coronary heart disease population (the TARGET TANGIBLE trial). Am J Cardiol 1999; 84:7-13.	Exclude - open label
McCormick LS et al. Rationale, design, and baseline characteristics of a trial comparing aggressive lipid-lowering with atorvastatin versus revascularisation treatments (AVERT). Am J cardiol 1997; 80: 1130-1133.	Exclude - open label
McDowell IF, Brennan GM, McEneny J et al. The effect of probucol and vitamin E treatment on the oxidation of low-density lipoprotein and forearm vascular responses in humans. Eur J Clin Invest 1994; 24:759-65.	Exclude - not a statin trial ; additive effect of probucol or vitamin E
McKenney JM, Barnett MD, Wright JT Jr, Proctor JP. Comparison of gemfibrozil and lovastatin in patients with high low-density lipoprotein and low high-density lipoprotein cholesterol levels. Arch Intern Med 1992; 152(9):1781-7.	Exclude - duration less than 12 weeks
McPherson R, Bedard J, Connelly P et al. Comparison of the short-term efficacy and tolerability of lovastatin and pravastatin in the management of primary hypercholesterolemia. Clin Ther 1992; 14:276-91.	Exclude - duration less than 12 wks
McPherson R. Comparative effects of simvastatin and cholestyramine on plasma lipoproteins and CETP in humans. Can J Clin Pharmacol 1999; 6:85-90.	Exclude - not double blind. No mention of blinding or matching of treatments for appearance
Meyers DG et al. Short-term efficacy and safety of pravastatin in hypercholesterolemic women. Journal of Women's Health. 1995; 4:357-65.	Duplicated data. Part of [Jacobson T et al 1995]
Miettinen TA et al. Baseline serum cholestanol as predictor of recurrent coronary events in subgroup of Scandinavian simvastatin survival study. Br Med J 1998; 316:1127-30.	Exclude - 4S study. Data extracted from other reports
Miettinen TA, Pyorala K, Olsson AG et al. Cholesterol-lowering therapy in women and elderly patients with myocardial infarction or angina pectoris: findings from the Scandinavian Simvastatin Survival Study (4S) [see comments]. Circulation 1997; 96:4211-8.	Exclude - 4S study. Data extracted from other reports

Excluded study	Reason for exclusion
Milani M, Cimminiello C, Merlo B, Lorena M, Arpaia G, Bonfardeci G. Effects of fluvastatin and pravastatin on lipid profiles and thromboxane production in type IIa hypercholesterolemia. <i>Am J Cardiol</i> 1995; 76:51A-3A.	Exclude - duration less than 12 wks
Miserez AR, Rossi FA, Keller U. Prediction of the therapeutic response to simvastatin by pretreatment lipid concentrations in 2082 subjects. <i>Eur J Clin Pharmacol</i> 1994; 46(2):107-14.	Exclude - not a randomised controlled trial; no comparator group
Mitropoulos KA, Armitage JM, Collins R et al. Randomized placebo-controlled study of the effects of simvastatin on haemostatic variables, lipoproteins and free fatty acids. The Oxford Cholesterol Study Group. <i>Eur Heart J</i> 1997; 18:235-41.	Exclude - duplicated information, sub-study from the Oxford Cholesterol Study
Molgaard J, von Schenck H, Olsson AG. Comparative effects of simvastatin and cholestyramine in treatment of patients with hypercholesterolaemia. <i>Eur J Clin Pharmacol</i> 1989; 36:455-60.	Exclude - duration less than 12 wks
Morgan TO et al. Effect of pravastatin, cholestyramine or their combination in the treatment of hypercholesterolaemia in elderly hypertensive patients. <i>Clinical Drug Investigation</i> . 1995; 9:314-23.	Exclude - Cross-over with no washout between treatments; cholestyramine was not double blind
Mortensen SA, Leth A, Agner E, Rohde M. Dose-related decrease of serum coenzyme Q10 during treatment with HMG-CoA reductase inhibitors. <i>Mol Aspects Med</i> 1997; 18 Suppl:S137-44.	Exclude - Fewer than 20 patients analysed for pravastatin.
Mostaza JM, Gomez MV, Gallardo F et al. Cholesterol reduction improves myocardial perfusion abnormalities in patients with coronary artery disease and average cholesterol levels. <i>J Am Coll Cardiol</i> 2000; 35:76-82.	Exclude - Not double blind (single blind), cross-over with no washout between treatments
Muggeo M et al. Long term treatment with pravastatin, simvastatin and gemfibrozil in patients with primary hypercholesterolaemia: A controlled study. <i>DRUG INVEST</i> 1992; 4:376-85.	Exclude - duplicated patient information for pravastatin & gemfibrozil. Subset of patients from [Crepaldi et al, 1991] which were followed up for longer. Simvastatin group - two few patients to include.
Muratti EN, Peters TK, Leitersdorf E. Fluvastatin in familial hypercholesterolemia: a cohort analysis of the response to combination treatment. <i>Am J Cardiol</i> 1994; 73:30D-8D.	Exclude - Familial hypercholesterolaemia
Nakamura for the Japanese cholesterol Lowering Atorvastain Study Group. Efficacy of atorvastatin in primary hypercholesterolemia. <i>Am J Cardiol</i> 1997; 79:1249-1252.	Exclude - duration less than 12 wks
Nakamura Y, Yamaoka O, Uchida K et al. Pravastatin reduces restenosis after coronary angioplasty of high grade stenotic lesions: results of SHIPS (SHIga Pravastatin Study). <i>Cardiovascular Drugs & Therapy</i> 1996; 10:475-83.	Exclude - patients were randomised to study treatment and then underwent coronary angioplasty
Nakandakare E, Garcia RC, Rocha JC, Sperotto G, Oliveira HC, Quintao EC. Effects of simvastatin, bezafibrate and gemfibrozil on the quantity and composition of plasma lipoproteins. <i>Atherosclerosis</i> 1990; 85(2-3):211-7.	Exclude - not a randomised controlled trial
Nakaya N et al. The effect of CS-514 on serum lipids and apolipoproteins in hypercholesterolemic subjects. <i>JAMA</i> 1987; 257 (22): 3088-93.	Exclude - duration less than 12 weeks; fewer than 20 patients per treatment group

Excluded study	Reason for exclusion
Nakaya N. Phase I study of an antihyperlipidemic BAY w 6228 (cerivastatin sodium): A placebo controlled, double blind, comparative study in hyperlipidemic volunteers. Japanese Pharmacology and Therapeutics 1996; 24:75-86.	Exclude - unable to translate. No English abstract. Double blind, placebo controlled trial of cerivastatin in hyperlipidaemic subjects. Duration?
Nawrocki JW, Weiss SR, Davidson MH et al. Reduction of LDL cholesterol by 25% to 60% in patients with primary hypercholesterolemia by atorvastatin, a new HMG-CoA reductase inhibitor. Arteriosclerosis, Thrombosis & Vascular Biology 1995; 15:678-82.	Exclude - duration less than 12 wks; fewer than 20 patients per group; no baseline data for different treatment groups
Neil HA, Meijer GW, Roe LS. Randomised controlled trial of use by hypercholesterolaemic patients of a vegetable oil sterol-enriched fat spread. Atherosclerosis 2001; 156(2):329-37.	Exclude - not a statin trial
Nestel P et al. A comparative study of the efficacy of simvastatin and gemfibrozil in combined hyperlipoproteinemia: Prediction of response by baseline lipids, apo E genotype, lipoprotein(a) and insulin. Atherosclerosis 1997; 129:231-9.	Exclude - open label
Neuman MP, Neuman HR, Neuman J. Significant increase of high-density lipoprotein-2- cholesterol under prolonged simvastatin treatment. Atherosclerosis 1991; 91 Suppl:S11-treatment group 9.	Exclude - Fewer than 20 patients per
Nordoy A, Bonna KH, Nilsen H, Berge RK, Hansen JB, Ingebretsen OC. Effects of Simvastatin and omega-3 fatty acids on plasma lipoproteins and lipid peroxidation in patients with combined hyperlipidaemia. J Intern Med 1998; 243:163-70.	Exclude - Duration less than 12 wks (several randomisation sequences within the trial, each with approx 5 wks on treatment)
Nordoy A, Bonna KH, Sandset PM, Hansen JB, Nilsen H. Effect of omega-3 fatty acids and simvastatin on hemostatic risk factors and postprandial hyperlipemia in patients with combined hyperlipemia. Arteriosclerosis, Thrombosis & Vascular Biology 2000; 20:259-65.	Exclude - Duration less than 12 wks (several randomisation sequences within the trial, each with approx 5 wks on treatment)
Nordoy A, Hansen JB, Brox J, Svensson B. Effects of atorvastatin and omega-3 fatty acids on LDL subfractions and postprandial hyperlipemia in patients with combined hyperlipemia. Nutr Metab Cardiovasc Dis 2001; 11(1):7-16.	Exclude - not a statin trial; designed to assess omega-3 fatty acids & corn oil
Notarbartolo A, Davi G, Averna M et al. Inhibition of thromboxane biosynthesis and platelet function by simvastatin in type IIa hypercholesterolemia. Arteriosclerosis, Thrombosis & Vascular Biology 1995; 15:247-51.	Exclude - Fewer than 20 patients per treatment group
O'Brien RC, Simons LA, Clifton P et al. Comparison of simvastatin and cholestyramine in the treatment of primary hypercholesterolaemia [published erratum appears in Med J Aust 1991 Feb 18;154(4):296]. Med J Aust 1990; 152:480-3.	Exclude - not double blind - no mention of blinding or matching of tablets for appearance
O'Callaghan CJ, Krum H, Conway EL et al. Efficacy of pravastatin in combination with captopril in hypertensive patients. Med J Aust 1995; 162:206-8.	Exclude - fewer than 20 patients per treatment group
O'Callaghan CJ, Krum H, Conway EL et al. Short term effects of pravastatin on blood pressure in hypercholesterolaemic hypertensive patients. Blood Press 1994; 3:404-6.	Exclude - Fewer than 20 patients per treatment group
O'Connor P et al. Effects of HMG Co-A reductase inhibitors on lipids and lipoprotein(a) in hypercholesterolaemia. DRUG INVEST 1992; 4:227-31.	Exclude - not double blind

Excluded study	Reason for exclusion
Ohmichi M et al, 2001. Effects of bezfibrate and simvastatin on plasma lipoproteins in hypercholesterolemia resistant to hormone replacement therapy. <i>Maturitas</i> 2001; 38: 279-286.	Exclude - not double blind, fewer than 20 patients per treatment group
Ohta H, Komukai S, Sugimoto I et al. Effect of a HMG-CoA reductase inhibitor combined with hormone replacement therapy on lipid metabolism in Japanese women with hypoestrogenic lipidemia: a multicenter double-blind controlled prospective study. <i>Maturitas</i> 1998; 29:163-71.	Exclude - no data to extract; numerically uninterpretable
Okamoto S et al. Effects of pravastatin and ursodeoxycholic acid on cholesterol and bile acid metabolism in patients with cholesterol gallstones. <i>J GASTROENTEROL</i> 1994; 29:47-55.	Exclude - patients underwent cholecystectomy for biliary disease & gall stones
O'Keefe JH Jr, Harris WS, Nelson J, Windsor SL. Effects of pravastatin with niacin or magnesium on lipid levels and postprandial lipemia. <i>Am J Cardiol</i> 1995; 76:480-4.	Exclude - not double blind for all treatments
Olsson AG, Pears J, McKellar J, Mizan J, Raza A. Effect of rosuvastatin on low-density lipoprotein cholesterol in patients with hypercholesterolemia. <i>Am J Cardiol</i> 2001; 88(5):504-8.	Exclude - duration less than 12 wks; describes dose-ranging 2 trials & combined lipid outcome data in analysis
Onaka H, Hirota Y, Kita Y et al. The effect of pravastatin on prevention of restenosis after successful percutaneous transluminal coronary angioplasty. <i>Jpn Circ J</i> 1994; 58:100-6.	Exclude - Not double blind (2 groups statin or no treatment)
Ordovas JM, Lopez-Miranda J, Perez-Jimenez F et al. Effect of apolipoprotein E and A-IV phenotypes on the low density lipoprotein response to HMG CoA reductase inhibitor therapy. <i>Atherosclerosis</i> 1995; 113:157-66.	Exclude - PLAC I study. Subgroup of trial population
Ortensi G et al. A comparative study of policosanol versus simvastatin in elderly patients with hypercholesterolemia. <i>Curr Ther Res Clin Exp</i> 1997; 58:390-401.	Exclude - duration less than 12 wks
Os I, Hofstad AE, Brekke M et al. The EWA (Estrogen in Women with Atherosclerosis) Study: a randomized study of the use of hormone replacement therapy in women with angiographically verified coronary artery disease. Characteristics of the study population. Effects on lipids and lipoproteins. <i>J Intern Med</i> 2000; 247(4):433-41.	Exclude - not a statin trial
Ose L et al. Double-blind comparison of the efficacy and tolerability of simvastatin and fluvastatin in patients with primary hypercholesterolaemia. <i>Clinical Drug Investigation</i> . 1995; 10:127-38.	Exclude - duration less than 12 wks
Otterstad JE, Hexeberg E, Holme I, Hjermann I. [Cholesterol lowering therapy after myocardial infarction. Consequences of the CARE study]. <i>Tidsskr Nor Laegeforen</i> 1997; 117(16):2341-4.	Exclude - duplicated data; CARE study. Data extracted from [Sacks et al, 1996] & [Plehn et al, 1999]
Packard CJ et al. Influence of pravastatin and plasma lipids on clinical events in the West of Scotland Coronary Prevention Study (WOSCOPS). <i>Circulation</i> 1998; 97:1440-5.	Exclude - WOSCOPS study. Duplicates data in [Shepherd et al, 1995]
Palomaki A, Malminiemi K, Solakivi T, Malminiemi O. Ubiquinone supplementation during lovastatin treatment: effect on LDL oxidation ex vivo. <i>J Lipid Res</i> 1998; 39:1430-7.	Exclude - duration less than 12 wks; cross-over at six wks

Excluded study	Reason for exclusion
Pan HY, DeVault AR, Swites BJ et al. Pharmacokinetics and pharmacodynamics of pravastatin alone and with cholestyramine in hypercholesterolemia. <i>Clinical Pharmacology & Therapeutics</i> 1990; 48:201-7.	Exclude - fewer than 20 patients per treatment group
Parhofer KG, Barrett PH, Dunn J, Schonfeld G. Effect of pravastatin on metabolic parameters of apolipoprotein B in patients with mixed hyperlipoproteinemia. <i>Clin Investig</i> 1993; 71:939-46.	Exclude - duration less than 12 wks
Pearson TA. Primary and secondary prevention of coronary artery disease: trials of lipid lowering with statins. <i>Am J Cardiol</i> 1998; 82(10A):28S-30S.	Exclude - review
Pedersen TR et al. Baseline serum cholesterol and treatment effect in the Scandinavian Simvastatin Survival Study (4S). <i>Lancet</i> 1995; 345:1274-5.	Exclude - 4S study. Data extracted from other reports
Pedersen TR, Berg K, Cook TJ et al. Safety and tolerability of cholesterol lowering with simvastatin during 5 years in the Scandinavian Simvastatin Survival Study. <i>Arch Intern Med</i> 1996; 156:2085-92.	Exclude - 4S study. Data extracted from other reports
Pedersen TR, Wilhelmsen L, Faergeman O et al. Follow-up study of patients randomized in the Scandinavian Simvastatin Survival Study (4S) of cholesterol lowering. <i>Am J Cardiol</i> 2000; 86:257-62.	Exclude - 4S study. Data extracted from other reports
Pedersen TR. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: The Scandinavian Simvastatin Survival Study (4S). <i>Lancet</i> 1994; 344:1383-9.	Exclude - 4S study. Data extracted from other reports
Pfeffer MA, Sacks FM, Moye LA et al. Cholesterol and Recurrent Events: a secondary prevention trial for normolipidemic patients. CARE Investigators. <i>Am J Cardiol</i> 1995; 76:98C-106C.	Exclude - CARE study. No lipid data to extract.
Pfeffer MA, Sacks FM, Moye LA et al. Influence of baseline lipids on effectiveness of pravastatin in the CARE Trial. Cholesterol And Recurrent Events. <i>J Am Coll Cardiol</i> 1999; 33:125-30.	Exclude - duplicated patient information. CARE study
Pflugfelder PW, Huff M, Oskalns R, Rudas L, Kostuk WJ. Cholesterol-lowering therapy after heart transplantation: a 12-month randomized trial [see comments]. <i>Journal of Heart & Lung Transplantation</i> 1995; 14:613-22.	Exclude - patients had heart transplantation
Pietro DA, Alexander S, Mantell G, Stagers JE, Cook TJ. Effects of simvastatin and probucol in hypercholesterolemia (Simvastatin Multicenter Study Group II). <i>Am J Cardiol</i> 1989; 63:682-6.	Exclude - Mean baseline lipids given without dispersion for entire patient population rather than for each treatment group
Pitt B et al. Pravastatin limitation of atherosclerosis in the coronary arteries (PLAC-1): reduction in atherosclerosis progression and clinical events. <i>J Am Coll Cardiol</i> 1995; 26: 1133-9.	Exclude - PLAC I study, progression of atherosclerosis. No lipid data
Pitt B, Waters D, Brown WV et al. Aggressive lipid-lowering therapy compared with angioplasty in stable coronary artery disease. Atorvastatin versus Revascularization Treatment Investigators. <i>N Engl J Med</i> 1999; 341:70-6.	Exclude - open label

Excluded study	Reason for exclusion
Plehn JF, Davis BR, Sacks FM et al. Reduction of stroke incidence after myocardial infarction with pravastatin: the Cholesterol and Recurrent Events (CARE) study. The Care Investigators [see comments]. <i>Circulation</i> 1999; 99:216-23.	Exclude - CARE study. No lipid data to extract.
Poli A, Menotti A. [Use of statins in primary prevention: from the theoretical presuppositions to complex scenarios of the real world]. <i>G Ital Cardiol</i> 1999; 29(10):1123-30.	Exclude - review
Porsch-Ozcurumez M et al. Effects of fluvastatin on biliary lipids in subjects with an elevated cholesterol saturation index. <i>Eur J Clin Pharmacol</i> 2001; 56: 873-879.	Exclude - fewer than 20 patients per treatment group
Prat H, Roman O, Pino E. [Comparative effects of policosanol and two HMG-CoA reductase inhibitors on type II hypercholesterolemia]. [Spanish]. <i>Rev Med Chil</i> 1999; 127:286-94.	Exclude - duration less than 12 wks
Pravastatin bei patienten mit kardialen risikofaktoren. <i>Forschr Med</i> 1994; 112: 57-64	Exclude - duplicate of The Pravastatin Multinational Study Group for Cardiac Risk Patients. <i>Am J Cardiol</i> 1993; 72:1031-7.
Qian-WC H-JW-HW-XaC-D. Study on the therapeutic effect of domestic simvastatin in treatment of primary hypercholesterolemia. <i>Chinese New Drugs Journal</i> 2000; 9:407-10.	Exclude - Unable to obtain from British Library
Qian-WC H-JW-HW-XaC-D. Study on the therapeutic effect of domestic simvastatin in treatment of primary hypercholesterolemia. <i>Chinese New Drugs Journal</i> 2000; 9:407-10.	Exclude - Unable to obtain from British Library. No UK location
Raal FJ, Pilcher GJ, Illingworth DR et al. Expanded-dose simvastatin is effective in homozygous familial hypercholesterolaemia. <i>Atherosclerosis</i> 1997; 135:249-56.	Exclude - Familial hypercholesterolaemia
Rabini RA et al. Effect of hydroxymethylglutaryl-CoA reductase inhibitors on the functional properties of erythrocyte membranes. <i>EXP MOL PATHOL</i> 1993; 59:51-7.	Exclude - Familial hypercholesterolaemia
Raggi P et al. Aggressive versus moderate lipid-lowering therapy in postmenopausal women with hypercholesterolemia: Rationales and design of the Beyond Endorsed Lipid Lowering with EBT Scanning (BELLES) trial. <i>Am Heart J</i> 2001; 141(5): 722-6.	Exclude - ongoing trial. Design only described.
Resning et al. [Lipid intervention and coronary heart disease in men less than 56 years of age. The Coronary Intervention Study: CIS]. <i>Z Kardiol</i> 1999; 88:270-82.	Exclude - duplicate of Bestehorn in German
Resta F et al The effect of low-dose simvastatin on serum lipid, lipoprotein, and apolipoprotein concentrations in primary moderate hypercholesterolemia. <i>Cur Ther Res Clin Exp</i> 1993; 54:508-18.	Exclude - Duration less than 12 wks (double blind); fewer than 20 patients per treatment group
Ridker PM, Rifai N, Clearfield M et al. Measurement of C-reactive protein for the targeting of statin therapy in the primary prevention of acute coronary events. <i>N Engl J Med</i> 2001; 344(26):1959-65.	Exclude - no data to extract (measurement of acute coronary events)

Excluded study	Reason for exclusion
Ridker PM, Rifai N, Pfeffer MA, Sacks F, Braunwald E. Long-term effects of pravastatin on plasma concentration of C-reactive protein. The Cholesterol and Recurrent Events (CARE) Investigators. <i>Circulation</i> 1999; 100:230-5.	Exclude - CARE study. No lipid data to extract.
Romano M, Mezzetti A, Marulli C et al. Fluvastatin reduces soluble P-selectin and ICAM-1 levels in hypercholesterolemic patients: role of nitric oxide. <i>J Investig Med</i> 2000; 48:183-9.	Exclude - fewer than 20 patients per treatment group
Rosendorff C. Statins for prevention of stroke. <i>Lancet</i> 1998; 351(9108):1002-3.	Exclude - review
Rothe G, Herr AS, Stohr J, Abletshauser C, Weidinger G, Schmitz G. A more mature phenotype of blood mononuclear phagocytes is induced by fluvastatin treatment in hypercholesterolemic patients with coronary heart disease. <i>Atherosclerosis</i> 1999; 144:251-61.	Exclude - all patients received fluvastatin prior to randomisation with no washout
Sacks FM, Pfeffer MA, Moye' L et al. Rationale and design of a secondary prevention trial of lowering normal plasma cholesterol levels after acute myocardial infarction: the Cholesterol and Recurrent Events trial (CARE) [published erratum appears in <i>Am J Cardiol</i> 1992 Feb 15;69(5):574]. <i>Am J Cardiol</i> 1991; 68:1436-46.	Exclude - duplicated data, CARE study
Sahni et al. Prevention of restenosis by lovastatin after successful coronary angioplasty. <i>Am Heart J</i> 1991; 121 (6): 1600-8.	Exclude - all patients underwent PTCA
Saito Y, Goto Y, Nakaya N et al. Dose-dependent hypolipidemic effect of an inhibitor of HMG-CoA reductase, pravastatin (CS-514), in hypercholesterolemic subjects. A double blind test. <i>Atherosclerosis</i> 1988; 72:205-11.	Exclude - duration less than 12 wks
Salonen R, Nyyssonen K, Porkkala-Sarataho E, Salonen JT. The Kuopio Atherosclerosis Prevention Study (KAPS): effect of pravastatin treatment on lipids, oxidation resistance of lipoproteins, and atherosclerotic progression. <i>Am J Cardiol</i> 1995; 76:34C-39C.	Exclude - duplicated patient information [Salonen et al, 1995b]
Santos RD, Sposito AC, Ventura LI, Cesar LA, Ramires JA, Maranhao RC. Effect of pravastatin on plasma removal of a chylomicron-like emulsion in men with coronary artery disease. <i>Am J Cardiol</i> 2000; 85:1163-6.	Exclude - not double blind (single blind)
Sardo MA et al. Effects of simvastatin treatment on sICAm-1 and sE-selectin levels in hypercholesterolemic subjects. <i>Atherosclerosis</i> 2001; 155: 143-147.	Exclude - not double blind
Sasaki J, Arakawa K, Yamamoto K, Kobori S, Ageta M, Kono S. [A comparative long-term trial of sodium cerivastatin, a new HMG-CoA reductase inhibitor, in patients presenting with primary hypercholesterolemia]. [French]. <i>Rev Med Interne</i> 1999; 20 Suppl 3:393s-8s.	Exclude - duplicate of Sasaki et al, <i>Clin Ther</i> 1998; 20: 539-48
Sasaki J, Arakawa K, Yamamoto K, Kobori S, Ageta M, Kono S. [A comparative long-term trial of sodium cerivastatin, a new HMG-CoA reductase inhibitor, in patients presenting with primary hypercholesterolemia]. [French]. <i>Rev Med Interne</i> 1999; 20 Suppl 3:393s-8s.	Exclude - not double blind
Sasaki J, Arakawa K, Yamamoto K, Kobori S, Ageta M, Kono S. A long-term comparative trial of cerivastatin sodium, a new HMG-CoA reductase inhibitor, in patients with primary hypercholesterolemia. <i>Clin Ther</i> 1998; 20:539-48.	Exclude - not double blind

Excluded study	Reason for exclusion
Sasaki S, Sawada S, Nakata T et al. Crossover trial of simvastatin versus pravastatin in patients with primary hypercholesterolemia. <i>J Cardiovasc Pharmacol</i> 1997; 30:142-7.	Exclude - duration less than 12 weeks
Saunders E, Ferdinand K, Yellen LG, Tonkon MJ, Krug-Gourley S, Poland M. Efficacy and safety of cerivastatin and pravastatin in the treatment of primary hypercholesterolemia. <i>Journal of the National Medical Association</i> 2000 Jul;92(7):319-26 2000; 92:319-26.	Exclude - duration less than 12 wks
Saxenhofer H, Weidmann P, Riesen WF et al. Therapeutic efficacy of the HMG-CoA-reductase inhibitor pravastatin in hyperlipoproteinaemia type II. <i>Eur J Clin Pharmacol</i> 1990; 39:101-5.	Exclude - fewer than 20 patients per treatment group
Sbarouni E, Kyriakides ZS, Kremastinos DTh. The effect of hormone replacement therapy alone and in combination with simvastatin on plasma lipids of hypercholesterolemic postmenopausal women with coronary artery disease [see comments]. <i>J Am Coll Cardiol</i> 1998; 32:1244-50.	Exclude - duration less than 12 weeks for each cross-over
Scandinavian Simvastatin Survival Study Group. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). <i>Lancet</i> 1994; 344:1383-9.	Exclude - duplicated patient information. 4S study outline
Scheen Aj. [Clinical study of the month. The LIPID study: "long-term intervention with pravastatin in ischaemic disease"]. <i>Rev Med Liege</i> 1999; 54(1):2-3.	Exclude - duplicated patient information. LIPID study
Schrott HG et al. A multicentre, placebo-controlled, dose-ranging study of atorvastatin. <i>J Cardiovasc Pharmacol Therapeut</i> 1998;3(2):119-124.	Exclude - duration less than 12 wks
Schrott HG, Knapp H, Davila M, Shurzinske L, Black D. Effect of atorvastatin on blood lipid levels in the first 2 weeks of treatment: a randomized, placebo-controlled study. <i>Am Heart J</i> 2000; 140:249-52.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Schulte KL BS. Efficacy and tolerability of fluvastatin and simvastatin in hypercholesterolaemic patients: A double-blind, randomised, parallel- group comparison. <i>Clinical Drug Investigation</i> . 1996; 12:119-26.	Exclude - duration less than 12 wks
Schulzeck P et al. Comparishn between simvastatin and bezafibrate in effect on plasma lipoproteins and apolipoproteins in primary hyperchoelsterolaemia. <i>The Lancet</i> 1988;1(8586): 611-13	Exclude - fewer than 20 patients
Schuster H, Berger J, Luft FC. Randomised, double-blind, parallel-group trial of atorvastatin and fluvastatin on plasma lipid levels in patients with untreated hyperlipidaemia. <i>Br. J Card.</i> 1998; 5(Issue11):597-602.	Exclude - no extractable data. Information given for individual/groups of doses but not consistently reported at different time points
Schwartz G et al. Rationale and design of the Myocardial Ischemia Reduction with Aggressive Cholesterol Lowering (MIRACL) study that evaluates atorvastatin in unstable angina pectoris and in non-Q-wave acute myocardial infarction. <i>Am J Cardiol</i> 1998; 81:578-81.	Exclude - Patients in hospital with unstable angina pectoris or non-Q-wave acute MI; MIRACL study. Design and rationale
Schwartz GG, Olsson AG, Ezekowitz MD et al. Effects of atorvastatin on early recurrent ischemic events in acute coronary syndromes: the MIRACL study: a randomized controlled trial. <i>JAMA</i> 2001; 285(13):1711-8.	Exclude - Patients in hospital with unstable angina pectoris or non-Q-wave acute MI; MIRACL study, results

Excluded study	Reason for exclusion
Schwartzkopff W, Bimmermann A, Schleicher J. [Comparison of the effectiveness of the HMG-CoA-reductase inhibitors pravastatin versus cholestyramine in hypercholesteremia]. [German]. <i>Arzneimittelforschung</i> 1990; 40:1322-7.	Exclude - not double blind
Serruys PW, Foley DP, Jackson Gea. A randomised placebo-controlled trial of fluvastatin for prevention of restenosis after successful coronary balloon angioplasty. <i>Eur Heart J</i> 1999; 20:58-69.	Exclude - patients were randomised to study treatment and then underwent coronary angioplasty
Sever PS, Dahlof B, Poulter NR et al. Rationale, design, methods and baseline demography of participants of the Anglo-Scandinavian Cardiac Outcomes Trial. ASCOT investigators. <i>J Hypertens</i> 2001; 19(6):1139-47.	Exclude - trial in progress (ASCOT) - double blind subsample of PROBE study population
Shear CL, Franklin FA, Stinnett S et al. Expanded Clinical Evaluation of Lovastatin (EXCEL) study results. Effect of patient characteristics on lovastatin-induced changes in plasma concentrations of lipids and lipoproteins. <i>Circulation</i> . 1992 Apr; 85(4):1293-1303; ISSN: 0009-7322.	Exclude - EXCEL study - duplicated information
Shepherd J et al Baseline risk factors and their association with outcome in the West of Scotland Coronary Prevention Study. <i>Am J Cardiol</i> 1997; 79:756-62.	Exclude - WOSCOPS study. Duplicates data in [Shepherd et al, 1995]
Shepherd J et al. Screening experience and baseline characteristics in the West of Scotland Coronary Prevention Study. <i>Am J Cardiol</i> 1995; 76:485-91.	Exclude - WOSCOPS study. Screening & baseline data only
Shepherd J, Cobbe SM, Ford I et al. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. West of Scotland Coronary Prevention Study Group [see comments]. <i>N Engl J Med</i> 1995; 333:1301-7.	Exclude - WOSCOPS study. Duplicates data in [Shepherd et al, 1995]
Shepherd J. The West of Scotland Coronary Prevention Study: a trial of cholesterol reduction in Scottish men. <i>Am J Cardiol</i> 1995; 76:113C-7C.	Exclude - WOSCOPS study. Duplicates data in [Shepherd et al, 1995]
Shviiri I & Leitersdorff E. The patient at risk: who should we be treating. <i>Brit J Clin Pract</i> 1996; suppl 77A: 24-7.	Exclude - commentary
Sierra-Perez JC et al. Pravastatin vs. probucol in the treatment of hypercholesterolaemia. A double blind study. <i>Arch Inst Cardiol Mex</i> 1991; 61: 365-73.	Exclude - Fewer than 20 patients per treatment group
Simons LA, Simons J, Parfitt A. Successful management of primary hypercholesterolaemia with simvastatin and low-dose colestipol. <i>Med J Aust</i> 1992; 157:455-9.	Exclude - all patients received simvastatin & were randomised to either placebo or colestipol
Simoons ML et al. Effect of simvastatin on coronary atheroma: The Multicentre Anti-Atheroma Study (MAAS). <i>Lancet</i> 1994; 344:633-8.	Exclude - MAAS study, duplicated information
Sing K, Ballantyne CM, Ferlic L et al. Lipoprotein lipase gene mutations, plasma lipid levels, progression/regression of coronary atherosclerosis, response to therapy, and future clinical events. Lipoproteins and Coronary Atherosclerosis Study. <i>Atherosclerosis</i> 1999; 144:435-42.	Exclude - LCAS study. Data extracted from [Herd et al, 1997]

Excluded study	Reason for exclusion
Slunga L, Johnson O, Dahlen GH. Changes in Lp(a) lipoprotein levels during the treatment of hypercholesterolaemia with simvastatin. <i>Eur J Clin Pharmacol</i> 1992; 43:369-73.	Exclude - No data to extract. Cross-over trial with no washout between treatments & no data available for the first phase before cross-over
Smilde TJ, van Wissen S, Wollersheim H, Trip MD, Kastelein JJ, Stalenhoef AF. Effect of aggressive versus conventional lipid lowering on atherosclerosis progression in familial hypercholesterolaemia (ASAP): a prospective, randomised, double-blind trial. <i>Lancet</i> 2001; 357(9256):577-81.	Exclude - Familial hypercholesterolaemia
Smit JW, De Bruin TW, Eekhoff EM, Glatz J, Erkelens DW. Combined hyperlipidemia is associated with increased exercise-induced muscle protein release which is improved by triglyceride-lowering intervention. <i>Metabolism: Clinical & Experimental</i> 1999; 48:1518-23.	Exclude - subset of a trial population; aim to examine skeletal muscle pathology
Smit JW, Jansen GH, de Bruin TW, Erkelens DW. Treatment of combined hyperlipidemia with fluvastatin and gemfibrozil, alone or in combination, does not induce muscle damage. <i>Am J Cardiol</i> 1995; 76:126A-8A.	Exclude - aim to examine skeletal muscle pathology; duration shorter than 12 wks, fewer than 20 patients per treatment group
Smit JW, Wijnne HJ, Schobben F, Sitsen A, De Bruin TW, Erkelens DW. Effects of alcohol and fluvastatin on lipid metabolism and hepatic function. <i>Ann Intern Med</i> 1995; 122:678-80.	Exclude - Duration less than 12 weeks for each part of the cross-over; fewer than 20 patients per treatment group
Smith DG et al. <i>Clin drug Invest</i> 1999; 17: 185-193.	Exclude - open label study
Spieker LE, Noll G, Hannak M, Luscher TF. Efficacy and tolerability of fluvastatin and bezafibrate in patients with hyperlipidemia and persistently high triglyceride levels. <i>J Cardiovasc Pharmacol</i> 2000; 35(3):361-5.	Exclude - patients in different treatment groups were on treatment for different lengths of time
Sprecher DL, Abrams J, Allen JW et al. Low-dose combined therapy with fluvastatin and cholestyramine in hyperlipidemic patients [see comments]. <i>Ann Intern Med</i> 1994; 120:537-43.	Exclude - no data to extract (baseline data not provided)
Stalenhoef AF, Lansberg PJ, Kroon AA et al. Treatment of primary hypercholesterolaemia. Short-term efficacy and safety of increasing doses of simvastatin and pravastatin: a double-blind comparative study. <i>J Intern Med</i> 1993; 234:77-82.	Exclude - duplicated data. Data extracted from [Lintot et al, 1996]
Stein E, Isaacsohn J, Stoltz R et al. Pharmacodynamics, safety, tolerability, and pharmacokinetics of the 0.8-mg dose of cerivastatin in patients with primary hypercholesterolemia. <i>Am J Cardiol</i> 1999; 83:1433-6.	Exclude - duration less than 12 wks; no baseline data provided
Stein E, Plotkin D, Bays H et al. Effects of simvastatin (40 and 80 mg/day) in patients with mixed hyperlipidemia. <i>Am J Cardiol</i> 2000; 86:406-11.	Exclude - duration less than 12 wks; multiple cross-over with no washout between treatments
Stein E, Sprecher D, Allenby KS, Tosiello RL, Whalen E, Ripa SR. Cerivastatin, a New Potent Synthetic HMG Co-A Reductase Inhibitor: Effect of 0.2 mg Daily in Subjects With Primary Hypercholesterolemia. <i>J Cardiovasc Pharmacol Ther</i> 1997; 2(1):7-16.	Exclude - duration less than 12 wks
Stein E. Cerivastatin in primary hyperlipidemia: a multicenter analysis of efficacy and safety. <i>Am J Cardiol</i> 1998; 82 (4B):40J-46J.	Exclude - Pooled analysis from trials >8 wk duration

Excluded study	Reason for exclusion
Stein E. Cerivastatin in primary hyperlipidemia--a multicenter analysis of efficacy and safety. <i>Atherosclerosis</i> 1998; 139 Suppl 1:S15-22.	Exclude - Pooled analysis from trials of cerivastatin
Stein EA, Davidson MH, Dobs AS et al. Efficacy and safety of simvastatin 80 mg/day in hypercholesterolemic patients. The Expanded Dose Simvastatin U.S. Study Group [see al, 1996], [Bakker-Arekema et al, 1996], and [Ose et al, 2000]. <i>Am J Cardiol</i> 1998; 82:311-6.	Exclude - duplicated information from [Stein et al, 1996], [Bakker-Arekema et al, 1996], and [Ose et al, 2000]
Stein EA, Illingworth DR, Kwiterovich PO Jr et al. Efficacy and safety of lovastatin in adolescent males with heterozygous familial hypercholesterolemia: a randomized controlled trial. <i>JAMA</i> 1999; 281(2):137-44.	Exclude - familial hypercholesterolaemia
Stein EA, Lane M, Laskarzewski P. Comparison of statins in hypertriglyceridemia. <i>Am J Cardiol</i> 1998; 81(4A):66B-9B.	Exclude - duplicated data from [Stein et al, 1996] and [Bakker-Arkema,1996]
Stein et al. Efficacy and tolerability of low-dose simvastatin and niacin, alone and in combination, in patients with combined hyperlipidaemia: a prospective trial. <i>J Cardiovasc Pharmacol Therapeut</i> 1996; 1: 107-116.	Exclude - Duplicated information discussed in [Stein et al, 1998] (<i>Am J Cardiol</i>)
Stiffman MN. "Statin" drugs, mortality, and stroke prevention. <i>J Fam Pract</i> 1997;45(4):293-4.	Exclude - meta-analysis
Stohler R, Keller U, Riesen WF. Effects of simvastatin and fenofibrate on serum lipoproteins and apolipoproteins in primary hypercholesterolaemia [published erratum appears in <i>Eur J Clin Pharmacol</i> 1989;37(6):623]. <i>Eur J Clin Pharmacol</i> 1989; 37:199-203.	Exclude - duration less than 12 weeks; fewer than 20 patients per treatment group
Strauss WE, Lapsley D, Gaziano JM. Comparative efficacy and tolerability of low-dose pravastatin versus lovastatin in patients with hypercholesterolemia. <i>Am Heart J</i> 1999; 137:458-62.	Exclude - duration less than 12 wks
Straznicky NE, Howes LG, Lam W, Louis WJ. Effects of pravastatin on cardiovascular reactivity to norepinephrine and angiotensin II in patients with hypercholesterolemia and systemic hypertension. <i>Am J Cardiol</i> 1995; 75:582-6.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Szucs T et al. [Pharmacoeconomic evaluation of pravastatin in the secondary prevention of coronary heart disease in patients with average cholesterol levels. An analysis for Germany based on the CARE study]. <i>Herz</i> 1998; 23:319-29.	Exclude - Duplicated data, CARE study.
Tamura A, Mikuriya Y, Nasu M. Effect of pravastatin (10 mg/day) on progression of coronary atherosclerosis in patients with serum total cholesterol levels from 160 to 220 mg/dl and angiographically documented coronary artery disease. Coronary Artery Regression Study (CARS) Group. <i>Am J Cardiol</i> 1997; 79:893-6.	Exclude - not double blind
Tannous M, Cheung R, Vignini A, Mutus B. Atorvastatin increases eNOS levels in human platelets of hyperlipidemic subjects. <i>Thrombosis & Haemostasis</i> 1999; 82:1390-4.	Exclude - duration less than 12 wks; fewer than 20 patients per group
Tao P et al. Efficacy and safety of cerivastatin 0.1 mg, 0.2 mg and 0.3 mg in Chinese patients with primary hypercholesterolaemia: a multicentre, randomised, double-blind, placebo-controlled study. <i>Journal of Drug Assessment</i> 2000; 3 (Part 1):21-32.	Exclude - duration less than 12 wks

Excluded study	Reason for exclusion
Teo KK, Burton JR, Buller C, Plante S, Yokoyama S, Montague TJ. Rationale and design features of a clinical trial examining the effects of cholesterol lowering and angiotensin-converting enzyme inhibition on coronary atherosclerosis: Simvastatin/Enalapril Coronary Atherosclerosis Trial (SCAT). SCAT Investigators. <i>Can J Cardiol</i> 1997; 13:591-9.	Exclude - Duplicated data; design and rationale for SCAT study. Data extracted from [Teo et al, 2000]
The effect of aggressive lowering of low-density lipoprotein cholesterol levels and low-dose anticoagulation on obstructive changes in saphenous-vein coronary-artery bypass grafts. The Post Coronary Artery Bypass Graft Trial Investigators. <i>N Engl J Med</i> 1997; 336(3):153-62.	Exclude - not double blind
Thuraisingham S, Tan KH, Chong KS, Yap SF, Pasamanikam K. A randomised comparison of simvastatin versus simvastatin and low cholesterol diet in the treatment of hypercholesterolaemia. <i>Int J Clin Pract</i> 2000; 54(2):78-84.	Exclude - not double blind
Tomei R, Rossi L, Carbonieri E et al. [Efficacy and tolerability of simvastatin and omega-3 fatty acid combination in patients with coronary disease, hypercholesterolemia and hypertriglyceridemia]. [Italian]. <i>Cardiologia</i> 1993; 38:773-8.	Exclude - Not double blind
Tomita N, Morishita R, Ogihara T. [Ongoing clinical trials by vascular statin, cerivastatin]. <i>Nippon Rinsho</i> 2001; 59 Suppl 3:477-82.	Exclude - details of ongoing trials [Japanese]
Tonstad S, Gorbitz C, Ose L, Malt UF. [A comparison between lovastatin and pravastatin - effects on lipids, sleep and quality of life in primary hyperlipidemia]. [Norwegian]. <i>Tidsskr Nor Laegeforen</i> 1994; 114:2262-4.	Exclude - duration less than 12 wks
Tonstad S, Sundt E, Ose L et al. The effect of growth hormone on low-density lipoprotein cholesterol and lipoprotein (a) levels in familial hypercholesterolemia. <i>Metabolism</i> 1996; 45(11):1415-21.	Exclude - not a statin trial (effect of growth hormone on lipid parameters)
Tuomilehto J, Guimaraes AC, Kettner H et al. Dose-response of simvastatin in primary hypercholesterolemia. <i>J Cardiovasc Pharmacol</i> 1994; 24:941-9.	Exclude - duration less than 12 wks
Vacek JL et al. Comparison of lovastatin (20 mg) and nicotinic acid (1.2 g) with either drug alone for Type II hyperlipoproteinemia. <i>Am J Cardiol</i> 1995; 76: 182-4.	Exclude - Not double blind; peculiar randomisation schedule
Valerio G et al. Low-dose simvastatin treatment in patients with moderate-grade familial hypercholesterolemia. <i>Curr Ther Res Clin Exp.</i> 1990; 48:701-6.	Exclude - Familial hypercholesterolaemia
Vanhanen H. Cholesterol malabsorption caused by sitostanol ester feeding and neomycin in pravastatin-treated hypercholesterolaemic patients. <i>EUR J CLIN PHARMACOL</i> 1994; 47:169-76.	Exclude - induced malabsorption of cholesterol
Vanhanen HT, Miettinen TA. Cholesterol absorption and synthesis during pravastatin, gemfibrozil and their combination. <i>Atherosclerosis</i> 1995; 115:135-46.	Exclude - Fewer than 20 patients per treatment group
Vega GL, Krauss RM, Grundy SM. Pravastatin therapy in primary moderate hypercholesterolaemia: changes in metabolism of apolipoprotein B-containing lipoproteins. <i>J Intern Med</i> 1990; 227:81-94.	Exclude - duration less than 2 wks; fewer than 20 patients per treatment group

Excluded study	Reason for exclusion
Vergani C SP. Efficacy and tolerability of gemfibrozil in hypercholesterolemic patients previously treated with simvastatin. <i>ADV THER</i> 1993; 10:189-96.	Exclude - not double blind (simvastatin given in open phase to all patients, then randomisation to gemfibrozil or placebo)
Vigna GB, Donega P, Passaro A et al. Post-prandial effects of gemfibrozil vs simvastatin in hypercholesterolemic subjects with borderline hypertriglyceridemia. <i>Nutrition Metabolism & Cardiovascular Diseases</i> 1999; 9:234-43.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Villecco AS et al. Comparison of the effects of simvastatin versus hormone replacement therapy in the treatment of postmenopausal women with primary hypercholesterolemia. <i>Curr Ther Res Clin Exp</i> 1995; 56:515-29.	Exclude - fewer than 20 patients per treatment group
Wakatsuki A, Ikenoue N, Izumiya C, Okatani Y, Sagara Y. Effect of estrogen and simvastatin on low-density lipoprotein subclasses in hypercholesterolemic postmenopausal women. <i>Obstetrics & Gynecology</i> 1998; 92:367-72.	Exclude - open label
Walker JF et al. Efficacy and tolerability of simvastatin (epistatin) in the elderly. <i>DRUG INVEST</i> 1990; 2:53-6.	Exclude - duration less than 12 wks
Walker JF, Shapiro DR. Hydroxymethylglutaryl coenzyme A reductase inhibitors as monotherapy in the treatment of hypercholesterolemia. <i>Am J Cardiol</i> 1990; 65:19F-22F.	Exclude - review
Wang W et al. Pravastatin vs inositol nicotinate in treating primary hypercholesterolemia. <i>Chinese New Drugs and Clinical Remedies</i> 1995; 14:71-4.	Exclude - unable to translate
Wang-SR and Li-FG. Simvastatin vs lovastatin in treating hyperlipidemia. <i>Chinese Journal of New Drugs and Remedies</i> 2000; 19:264-6.	Exclude - unable to translate
Wardle J, Armitage J, Collins R, Wallendszus K, Keech A, Lawson A. Randomised placebo controlled trial of effect on mood of lowering cholesterol concentration. Oxford Cholesterol Study Group. <i>BMJ</i> 1996; 313:75-8.	Exclude - duplicated information, Oxford Cholesterol Study
Waters DD. Medical therapy versus revascularization: the atorvastatin versus revascularization treatment AVERT trial. <i>Can J Cardiol</i> 2000; 16 Suppl A:11A-3A.	Exclude - open label
Weisweiler P. Simvastatin and bezafibrate: effects on serum lipoproteins and lecithin: cholesterol acyltransferase activity in familial hypercholesterolaemia. <i>Eur J Clin Pharmacol</i> 1988; 35:579-83.	Exclude - Familial hypercholesterolaemia
Wenke K et al. Long-term Simvastatin therapy for hypercholesterolemia in heart transplant recipients. <i>Z Kardiol</i> 1995; 84:130-6.	Exclude - Patients entered in the study had recent heart transplantation.
Wenke K, Meiser B, Thiery J et al. Simvastatin reduces graft vessel disease and mortality after heart transplantation: a four-year randomized trial [see comments]. <i>Circulation</i> 1997; 96:1398-402.	Exclude - Duplicate of [Wenke et al, <i>Helv Chir Acta</i> 1994] in German

Excluded study	Reason for exclusion
Wenke K, Thiery J, Arndtz N, Seidel D, Reichart B. [Can hyperlipidemia after heart transplantation be optimally and safely treated?]. [German]. <i>Helv Chir Acta</i> 1994; 60:1163-8.	Exclude - duplicated data from [Wenke et al, 1995]
Wenke K, Thiery J, Arndtz N, Seidel D, Reichart B. [Can hyperlipidemia after heart transplantation be optimally and safely treated?]. [German]. <i>Helv Chir Acta</i> 1994; 60:1163-8.	Exclude - Patients entered in the study had recent heart transplantation.
Wenke K, Thiery J, Meiser B, Arndtz N, Seidel D, Reichart B. [Therapy of hypercholesterolemia after heart transplantation with the HMG-CoA reductase inhibitor simvastatin in long-term follow-up]. [German]. <i>Z Kardiol</i> 1995; 84:130-6.	Exclude - Patients entered in the study had recent heart transplantation.
West M et al. The Lipoprotein and Coronary Atherosclerosis Study (LCAS): design, methods, and baseline data of a trial of fluvastatin in patients without severe hypercholesterolemia. <i>Control-Clin-Trials</i> 1996; 17:550-83.	Exclude - LCAS study. Data extracted from [Herd et al, 1997]
Wiklund O, Angelin B, Fager G et al. Treatment of familial hypercholesterolaemia: a controlled trial of the effects of pravastatin or cholestyramine therapy on lipoprotein and apolipoprotein levels [see comments]. <i>J Intern Med</i> 1990; 228:241-7.	Exclude - Familial hypercholesterolaemia
Wiklund O, Bondjers G, Wright I, Camejo G. Insoluble complex formation between LDL and arterial proteoglycans in relation to serum lipid levels and effects of lipid lowering drugs. <i>Atherosclerosis</i> 1996; 119:57-67.	Exclude - duplicated data from [Wiklund et al, 1993] - subset
Wilmink HW, Twickler MB, Banga JD et al. Effect of statin versus fibrate on postprandial endothelial dysfunction: role of remnant-like particles. <i>Cardiovasc Res</i> 2001; 50(3):577-82.	Exclude - not hypercholesterolaemia, healthy volunteers
Witchitz S, Provendier O, Arsenescu I. [Comparative effects of captopril and atenolol on lipid metabolism in hypertensive hypercholesterolemic patients treated with pravastatin. A multicenter controlled trial]. [French]. <i>Presse Med</i> 1996; 25:2013-6.	Exclude - not a statin trial (assess effect of atenolol & captopril on lipids)
Ytre-Arne K, Nordoy A. Simvastatin and cholestyramine in the long-term treatment of hypercholesterolaemia. <i>J Intern Med</i> 1989; 226:285-90.	Exclude - not double blind
Yuan JN, Tsai MY, Hegland J, Hunninghake DB. Effects of fluvastatin (XU 62-320), an HMG-CoA reductase inhibitor, on the distribution and composition of low density lipoprotein subspecies in humans. <i>Atherosclerosis</i> 1991; 87:147-57.	Exclude - duration less than 12 wks; fewer than 20 patients per treatment group
Zambon S et al. Pravastatin treatment in combined hyperlipidaemia. <i>Eur J Clin Pharmacol</i> 1994; 46:221-4.	Exclude - not double blind (single blind); fewer than 20 patients per treatment group
Zanchetti A, Crepaldi G, Bond MG et al. Systolic and pulse blood pressures (but not diastolic blood pressure and serum cholesterol) are associated with alterations in carotid intima-media thickness in the moderately hypercholesterolaemic hypertensive patients of the Plaque Hypertension Lipid Lowering Italian Study. PHYLLIS study group. <i>J Hypertens</i> 2001; 19(1):79-88.	Exclude - combination therapy; PHYLLIS study results
Zanchetti A. The hypertensive patient with multiple risk factors: Is treatment really so difficult? <i>Am J Hypertens</i> 1997; 10:223S-9S.	Exclude - review

Excluded study	Reason for exclusion
Zavoral JH et al. Efficacy of fluvastatin, a totally synthetic 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor. <i>Am J cardiol</i> 1995;76:37A-40A	Exclude - Interim results from the FLUENT trial
Ziegler O, Drouin P. Safety, tolerability, and efficacy of simvastatin and fenofibrate-- a multicenter study. Simvastatin-Fenofibrate Study Group. <i>Cardiology</i> 1990; 77 Suppl 4:50-7.	Exclude - duration less than 12 wks

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