

	Comparison	Trial design	Primary or secondary prevention	Run-in period	Study total N	Mean age	All AEs collected	SAEs (subset of AEs) collected	Discontinuation of study treatment reported and context
TRIAL ACRONYM									
Statin vs control									
AFCAPS/ TexCAPS	Lovastatin 20-40 mg vs placebo	DB RCT	Primary	Yes: AHA Step 1 diet and placebo	6605	58	Yes	Yes	Yes: AEs
ALERT	Fluvastatin 40mg (↑ to 80mg after ~2y)	DB RCT	Both: (kidney or combined kidney/pancreas transplant population)	None	2102	49 (fluva) 50 (placebo)	Yes	Yes	Yes: AEs
ALLHAT-LLT	Pravastatin 40mg vs usual care	Open label RCT	Both (people with prior MI not excluded)	No conventional run-in period: enrolment in the LLT arm took place an average of 88 days after randomization into ALLHAT	10,355	66	No	U	U
ALLIANCE	Atorvastatin up to 80mg daily vs usual care	Open label RCT	Secondary	No	2442	61	U	Yes	U

ASCOT-LLA	Atorvastatin 10 mg vs placebo	2x2 factorial design; antihypertensive arm = PROBE design; statin arm; DB RCT	Primary	Yes (but does not appear to be tablet run-in; rather screening visit then randomization visit)	10,305	63	Yes	Yes	Yes: CRF recorded reasons for discontinuing
ASPEN	Atorvastatin 10mg vs placebo	DB RCT	Both (population = NIDDM)	Yes: placebo run-in	2411 randomized but one patient in placebo arm did not receive any study medication	61	Yes	Yes	U
AURORA	Rosuvastatin 10mg vs placebo	DB RCT	Both (population = CKD: on maintenance haemodialysis)	Yes (but does not appear to be tablet run-in; rather screening visit then randomization visit)	2776 randomized; 3 excluded due to randomization issues so 2773 in ITT	64	Yes	Yes	Yes
CARDS	Atorvastatin 10mg vs placebo	DB RCT	Primary (population = type 2 DM)	Yes: placebo run-in	2841 initially randomized but 3 incorrectly randomized and no drug taken so analyses of 2838 people	61	Yes	Yes	U
CARE	Pravastatin 40mg vs placebo	DB RCT	Secondary	Yes: placebo run-in	4159	59	Yes	Yes	Yes
CORONA	Rosuvastatin 10mg vs placebo	DB RCT	Secondary (population = systolic heart failure of ischaemic aetiology)	Yes: placebo run-in	5011	73	Yes	Yes	Yes
DDDD (4D)	Atorvastatin 20mg vs placebo	DB RCT	Both (population = CKD: on maintenance haemodialysis)	Yes: placebo run-in	1255	66	Yes	Yes	U

GISSI-HF	Rosuvastatin 10mg vs placebo	2x2 factorial design: n3- PUFA and statin arms; DB RCT	Secondary (population = symptomatic heart failure)	No	4631	68	U	Yes	Probable
GISSI-P	Pravastatin 20mg vs no treatment	2x2 factorial design: n3- PUFA/vitamin E and statin arms; open controlled study	Secondary	No	4271	60	U	Yes	U
HPS	Simvastatin 40mg vs placebo	2x2 factorial design: vitamin and statin arms; DB RCT	Both (population = those at high risk of CHD)	Yes: placebo and then active statin run-in	20,536	46% > 65 at baseline	No	Yes	Yes
JUPITER	Rosuvastatin 20mg vs placebo	DB RCT	Primary (population = apparently healthy people with LDL-C levels of < 3.4 mmol/L and hsCRP levels of ≥2.0 mg/L)	Yes: 4 weeks placebo run-in	17,802	66	Yes	Yes	U
LIPID	Pravastatin 40mg vs placebo	DB RCT	Secondary	Yes: placebo run-in	9014	62	Yes	Yes	U
LIPS	Fluvastatin 80mg vs placebo	DB RCT	Secondary	U	1677	60	Yes	Yes	U
MEGA	Pravastatin 10-20mg vs diet	PROBE design	Primary	No	8214 randomized; 382 excluded from final analysis	58	Yes	Yes	U
Post-CABG	Aggressive-treatment group initially lovastatin 40 mg/day ; moderate treatment group 2.5 mg/day. Doses could be doubled by study staff i.e. up to 80mg and 5 mg based on lipid levels.	2x2 factorial design: lipid arm = aggressive or moderate statin regimen; anti-coagulant arm = warfarin or placebo	Secondary (population = CABG 1-11 years prior to study entry)	No	1351	61	U	U	U

PROSPER	Pravastatin 40mg vs placebo	DB RCT	Secondary (population = elderly: 70-82 years old)	Yes: placebo run-in	5804	75	Yes	Yes	Y
SPARCL	Atorvastatin 80mg vs placebo	DB RCT	Secondary (population = previous stroke or TIA but no known CHD)	Yes (but does not appear to be tablet run-in; rather screening visit then randomization visit)	4731	63	Yes	Yes	U
SSSS (4S)	Simvastatin 20-40mg vs placebo	DB RCT	Secondary	Yes: placebo run-in	4444	59	Yes	Yes	U
WOSCOPS	Pravastatin 40mg vs placebo	DB RCT	Primary (population all male)	Yes: 3 visits prior to randomization during which dietary advice given but does not appear to have been a placebo run-in	6595	55	Yes	Yes	U

More vs less

A to Z	40 mg simvastatin for 1 month followed by 80mg thereafter vs placebo for 4 months followed by 20 mg of simvastatin	2x2 factorial design: statin arm = A phase = enoxaparin vs unfractionated heparin in combination with tirofiban and aspirin as initial therapy for high-risk patients with nSTE-ACS; Z phase = 40 mg/d simvastatin for 1 month followed by 80mg/d thereafter compared to placebo for 4 months followed by 20 mg/d of simvastatin; Z phase = DB RCT	Secondary (population = ACS patients)	4497	61	Yes	Yes	U	
IDEAL	followed by 20 mg/d of simvastatin	PROBE design	Secondary (population = definite history of previous MI)	No run-in medication (although there was a screening visit prior to randomization)	8888	62	U	U	U
PROVE-IT/TIMI-22	Atorvastatin 80mg vs pravastatin 40mg	2x2 factorial design: statin arm atorvastatin 80mg vs pravastatin 40mg; antibiotic arm gatifloxacin vs placebo; DB RCT	Secondary (population = patients hospitalized for acute coronary syndrome within previous 10 days)	No	4162	58	U	U	U
SEARCH	Simvastatin 80mg vs 20mg	2x2 factorial design: high vs low dose statin (80 vs 20mg simvastatin) and homocysteine lowering with folic acid 2 mg plus vitamin B12 1 mg daily vs matching placebo; DB RCT	Secondary (population = MI survivors)	Yes: simvastatin 20 mg daily and placebo vitamin tablets for approximately 2 months	12,064	64	No	Yes	Yes

TNT	Atorvastatin 80 mg vs atorvastatin 10mg	DB RCT	Secondary (population = clinical evidence of CHD)	Yes: 8-week run-in period of open-label treatment with 10 mg atorvastatin per day	10,001	61	Yes	Yes	U
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Others

GREACE	Atorvastatin 10-80mg to achieve NCEP target LDL of 2.6mmol/L vs usual care	Open label RCT	Secondary (population = patients with CHD)	U	1600	58 for atorva group; 59 for usual care group	U	U	U
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SEAS	Simvastatin 40mg plus ezetimibe 10mg vs placebo	DB RCT	Primary (population = those with mild-to moderate, asymptomatic aortic stenosis with no diagnosis or symptoms of coronary artery disease or peripheral arterial disease)	Yes: 4-week run-in period of single blind placebo tablets and lipid-lowering diet according to the recommendations of the NCEP	1873	67	Yes	Yes	U
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SHARP	Simvastatin 20mg plus ezetimibe 10mg vs placebo	DB RCT	Both (population = those with CKD, both dialysis and pre-dialysis. Those with prior MI excluded but could have CHD)	Yes: placebo run-in	9438 (9270 from 1 year randomization)	62	No	Yes	Yes
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