

# Clinical trials of atorvastatin

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## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin high dose vs pravastatin</b>			
<a href="#">PROVE-IT , 2004</a> n=2099/2063 follow-up: 2 years	atorvastatin 80 mg daily versus Pravastatin 40 mg	acute myocardial infarction (with or without electrocardiographic evidence of ST-segment elevation) or highrisk unstable angina) in the preceding 10 days	Parallel groups double blind 8 countries

More details and results :

- cholesterol lowering intervention for acute myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q162>

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### PROVE-IT, 2004:

Cannon CP, Braunwald E, McCabe CH, Rader DJ, Rouleau JL, Belder R, Joyal SV, Hill KA, Pfeffer MA, Skene AM Intensive versus moderate lipid lowering with statins after acute coronary syndromes. N Engl J Med 2004;350:1495-504 [[15007110](#)]

Ray KK, Cannon CP, McCabe CH, Cairns R, Tonkin AM, Sacks FM, Jackson G, Braunwald E Early and late benefits of high-dose atorvastatin in patients with acute coronary syndromes: results from the PROVE IT-TIMI 22 trial. J Am Coll Cardiol 2005;46:1405-10 [[16226162](#)]

Rouleau J Improved outcome after acute coronary syndromes with an intensive versus standard lipid-lowering regimen: results from the Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction 22 (PROVE IT-TIMI 22) trial. Am J Med 2005;118 Suppl 12A:28-35 [[16356805](#)]

## 2 post stroke

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
<a href="#">SPARCL , 2006</a> [NCT00147602] n=2365/2366 follow-up: 4.9y (median)	atorvastatin 80mg daily versus placebo	patients who had had a stroke or TIA within one to six months before study entry, had low-density lipoprotein (LDL) cholesterol levels of 2.6 to 4.9 mmol per liter, and had no known coronary heart disease	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for post stroke in all type of patients at <http://www.trialresultscenter.org/go-Q153>

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### SPARCL, 2006:

Amarenco P, Bogousslavsky J, Callahan A 3rd, Goldstein LB, Hennerici M, Rudolph AE, Silleesen H, Simunovic L, Szarek M, Welch KM, Zivin JA High-dose atorvastatin after stroke or transient ischemic attack. N Engl J Med 2006 Aug 10;355:549-59 [16899775]

Amarenco P, Benavente O, Goldstein LB, Callahan A 3rd, Silleesen H, Hennerici MG, Gilbert S, Rudolph AE, Simunovic L, Zivin JA, Welch KM Results of the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) trial by stroke subtypes. Stroke 2009;40:1405-9 [19228842]

## 3 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin high dose vs atorvastatin</b>			
TNT , 2005 [NCT00327691] n=4995/5006 follow-up: 4.9 years	80 mg of atorvastatin daily versus 10 mg of atorvastatin daily	Chronic coronary artery disease LDL cholesterol <3.4 mmol/L	Parallel groups double blind 14 countries
<b>atorvastatin high dose vs lovastatin</b>			
Vascular basis , 2005 n=197/103 follow-up: 1 year	atorvastatin (80 mg) with or without vitamin C and E versus low dose lovastatin (5 mg)	Chronic coronary artery disease	Parallel groups double blind
<b>atorvastatin high dose vs pravastatin</b>			
REVERSAL , 2004 n=327/327 follow-up: 1.5 years	atorvastatin 80 mg daily versus Pravastatin(40 mg)	Chronic coronary artery disease	Parallel groups double blind
SAGE , 2007 n=446/445 follow-up: 1 years	atorvastatin 80 mg daily versus pravastatin(40 mg)	Chronic coronary artery disease	Parallel groups double blind
<b>atorvastatin high dose vs simvastatin</b>			
IDEAL , 2005 [NCT00159835] n=4439/4449 follow-up: 4.8 years	atorvastatin 80mg daily versus simvastatine 20mg/j	Men and women aged 80 years or younger with a history of a definite myocardial infarction and who qualified for statin therapy according to national guidelines	Parallel groups open Denmark, Finland, Iceland, Netherlands, Norway, Sweden

More details and results :

- cholesterol lowering intervention for post myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q45>

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Johnson C, Waters DD, DeMicco DA, Breazna A, Bittner V, Greten H, Grundy SM, LaRosa JC Comparison of effectiveness of atorvastatin 10 mg versus 80 mg in reducing major cardiovascular events and repeat revascularization in patients with previous percutaneous coronary intervention (post hoc analysis of the Treating to New Targets [TNT] Study). *Am J Cardiol* 2008;102:1312-7 [[18993147](#)]

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### SAGE, 2007:

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## 4 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
<b>SALTIRE , 2005</b> n=77/78 follow-up: 25 mo (7-36)	atorvastatin 80mg daily versus placebo	patients with calcific aortic stenosis	Parallel groups double blind
<b>ASCOT (diabetics sub group) , 2003</b> n=1258/1274 follow-up:	10 mg atorvastatin versus placebo	hypertensive patients with no history of coronary heart disease (CHD) but at least three cardiovascular risk factors	
<b>Deutsche Diabetes Dialyse Studie (4D) , 2005</b> n=619/636 follow-up: 4 y (median)	atorvastatin 20mg daily versus matching placebo	patients with type 2 diabetes mellitus on maintenance hemodialysis	Parallel groups double blind
<b>SPARCL , 2006</b> [NCT00147602] n=2365/2366 follow-up: 4.9y (median)	atorvastatin 80mg daily versus placebo	patients who had had a stroke or TIA within one to six months before study entry, had low-density lipoprotein (LDL) cholesterol levels of 2.6 to 4.9 mmol per liter, and had no known coronary heart disease	Parallel groups double blind
<b>Strey , 2005</b> n=24/24 follow-up: 6 weeks	atorvastatin 40mg versus placebo	patients with stable, symptomatic heart failure (New York Heart Association Class II or III) and a left ventricular ejection fraction <40%	Cross over
<b>ASPEN , 2006</b> n=1211/1199 follow-up: 4y	atorvastatin 10mg daily versus placebo	patients s with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets	Parallel groups double blind
<b>ASCOT , 2003</b> n=5168/5137 follow-up: 3.3 years	atorvastatin 10mg/d versus placebo	hypertensive patients aged 40-79 years with at least three other cardiovascular risk factors	Parallel groups double blind UK et Scandinavie
<b>MIRACL , 2001</b> n=1538/1548 follow-up: 1 and 4 months	Atorvastatin, 80 mg (early initiation) versus Placebo	unstable angina or nonQ-wave acute MI	Parallel groups Double blind Europe, North America, South Africa, and Australasia
<b>ASPEN , 2006</b> n=1211/1199 follow-up: 4 year	atorvastatin 10mg versus placebo	subjects with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets	Parallel groups double blind 14 countries

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
ASPEN (primary prevention sub group) , 2006 n=959/947 follow-up: 4 year	atorvastatin 10mg versus placebo	subjects with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets; primary prevention subgroup	Parallel groups double blind 14 countries
macin , 2005 n=NA follow-up: 30 days	atorvastatin 40 mg daily for 30 days versus placebo	patients admitted within 48 hours of onset of ACS with CRP levels $\geq$ 1.4 mg/dL	Parallel groups double-blind
Mohler III , 2003 n=240/114 follow-up: 1 an	Atorvastatine: 10 mg/ jour ou 80 mg/ jour pendant 12 mois (groupes 1 et 2). versus placebo	Stade de la maladie : II , stable pendant au moins 6 mois.	Parallel groups Double aveugle
CARDS , 2004 [NCT00327418] n=1429/1412 follow-up: 3.9 years	atorvastatin 10mg/d versus placebo	patients with type 2 diabetes without high concentrations of LDL-cholesterol and at least one of the following: retinopathy, albuminuria, current smoking, or hypertension.	Parallel groups double blind UK, Irelande
Mohler , 2003 n=NA follow-up: 12 months	atorvastatin (10 mg per day) versus placebo	patients with intermittent claudication	double blind
ASCOT (women subgroup) , 2003 n=979/963 follow-up: 3.3 y	Atorvastatin 10 mg daily versus placebo	hypertensive patients (aged 40-79 years with at least three other cardiovascular risk factors) - subgroup of women	Parallel groups double-blind Europe
<b>atorvastatin vs usual care</b>			
Colivicchi , 2002 n=40/41 follow-up: 1, 3, and 6 months	Atorvastatin, 80 mg daily early initiation versus Usual care	unstable angina pectoris or non-Q-wave myocardial infarction	Parallel groups open Italy
ESTABLISH , 2004 n=35/35 follow-up: 1, 4, and 6 months	Atorvastatin, 20 mg early initiation versus Usual care	patients with ACS undergoing emergency coronary angiography and percutaneous coronary intervention	Parallel groups open Japan
GREACE , 2002 n=800/800 follow-up: 3 years mean	atorvastatin 10-80 mg/d versus usual care	patients with established coronary heart disease	Parallel groups open
<b>atorvastatin high dose vs angioplasty</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>AVERT , 1999</b> n=164/177 follow-up: 1.5 years	atorvastatin 80 mg/d versus recommended percutaneous revascularization procedure(angioplasty) followed by usual care, which could include lipid-lowering treatment	patients referred for percutaneous revascularization, with stable coronary artery disease, relatively normal left ventricular function, asymptomatic or mild-to-moderate angina, and a serum level of low-density lipoprotein (LDL) cholesterol of at least 115 mg per deciliter (3.0 mmol per liter)	Parallel groups open US, Europe
<b>atorvastatin high dose vs atorvastatin</b>			
<b>TNT (diabetic sub group) , 2006</b> n=748/753 follow-up: 4.9 y	atorvastatin 80 mg daily versus atorvastatin 10 mg daily	patients with stable coronary heart disease	double blind
<b>TNT , 2005</b> [NCT00327691] n=4995/5006 follow-up: 4.9 years	80 mg of atorvastatin daily versus 10 mg of atorvastatin daily	Chronic coronary artery disease LDL cholesterol <3.4 mmol/L	Parallel groups double blind 14 countries
<b>atorvastatin high dose vs lovastatin</b>			
<b>Vascular basis , 2005</b> n=197/103 follow-up: 1 year	atorvastatin (80 mg) with or without vitamin C and E versus low dose lovastatin (5 mg)	Chronic coronary artery disease	Parallel groups double blind
<b>atorvastatin vs pravastatin</b>			
<b>PROVE IT - TIMI 22 , 2004</b> n=2099/2063 follow-up: 24 mo (18-36 mo)	80 mg of atorvastatin daily (intensive therapy). versus 40 mg of pravastatin daily (standard therapy)	patients who had been hospitalized for an acute coronary syndrome within the preceding 10 days	Parallel groups double blind UK, US, AUstralia, Italy, France, Germany, Spain, Canada
<b>atorvastatin high dose vs pravastatin</b>			
<b>PROVE-IT , 2004</b> n=2099/2063 follow-up: 2 years	atorvastatin 80 mg daily versus Pravastatin 40 mg	acute myocardial infarction (with or without electrocardiographic evidence of ST-segment elevation) or highrisk unstable angina) in the preceding 10 days	Parallel groups double blind 8 countries
<b>REVERSAL , 2004</b> n=327/327 follow-up: 1.5 years	atorvastatin 80 mg daily versus Pravastatin(40 mg)	Chronic coronary artery disease	Parallel groups double blind
<b>SAGE , 2007</b> n=446/445 follow-up: 1 years	atorvastatin 80 mg daily versus pravastatin(40 mg)	Chronic coronary artery disease	Parallel groups double blind

continued...

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin high dose vs simvastatin</b>			
IDEAL , 2005 [NCT00159835] n=4439/4449 follow-up: 4.8 years	atorvastatin 80mg daily versus simvastatine 20mg/j	Men and women aged 80 years or younger with a history of a definite myocardial infarction and who qualified for statin therapy according to national guidelines	Parallel groups open Denmark, Finland, Iceland, Netherlands, Norway, Sweden

More details and results :

- cholesterol lowering intervention for cardiovascular prevention in diabetic patients at <http://www.trialresultscenter.org/go-Q6>
- cholesterol lowering intervention for cardiovascular prevention in high risk patients with or without LDL cholesterol elevation at <http://www.trialresultscenter.org/go-Q11>
- cholesterol lowering intervention for cardiovascular prevention in patients with prior MI or with CHD at <http://www.trialresultscenter.org/go-Q12>
- cholesterol lowering intervention for cardiovascular prevention in patient with related disease at <http://www.trialresultscenter.org/go-Q137>
- cholesterol lowering intervention for cardiovascular prevention in all chronical situations at <http://www.trialresultscenter.org/go-Q154>
- cholesterol lowering intervention for cardiovascular prevention in post stroke (or TIA) at <http://www.trialresultscenter.org/go-Q155>
- cholesterol lowering intervention for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q241>
- cholesterol lowering intervention for cardiovascular prevention in patients with renal insufficiency (on hemodialysis or transplant) at <http://www.trialresultscenter.org/go-Q284>
- cholesterol lowering intervention for cardiovascular prevention in women at <http://www.trialresultscenter.org/go-Q435>
- statins for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q689>
- statins for cardiovascular prevention in diabetic patients at <http://www.trialresultscenter.org/go-Q694>
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Amarenco P, Benavente O, Goldstein LB, Callahan A 3rd, Silleesen H, Hennerici MG, Gilbert S, Rudolph AE, Simunovic L, Zivin JA, Welch KM Results of the Stroke Prevention by Aggressive Reduction in Cholesterol Levels (SPARCL) trial by stroke subtypes. *Stroke* 2009;40:1405-9 [[19228842](#)]

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## REVERSAL, 2004:

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## IDEAL, 2005:

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Pedersen TR, Cater NB, Faergeman O, Kastelein JJ, Olsson AG, Tikkanen MJ, Holme I, Larsen ML, Lindahl C, Szarek M Comparison of atorvastatin 80 mg/day versus simvastatin 20 to 40 mg/day on frequency of cardiovascular events late (five years) after acute myocardial infarction (from the Incremental Decrease in End Points through Aggressive Lipid Lowering [IDEAL] trial). Am J Cardiol 2010;106:354-9 [20643245] 10.1016/j.amjcard.2010.03.033

## 5 hypertension

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Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
ASCOT, 2003 n=5168/5137 follow-up: 3.3 years	atorvastatin 10mg/d versus placebo	hypertensive patients aged 40-79 years with at least three other cardiovascular risk factors	Parallel groups double blind UK et Scandinavie

More details and results :

- cholesterol lowering intervention for hypertension in all type of patients at <http://www.trialresultscenter.org/go-Q458>

## References

### ASCOT, 2003:

Sever PS, Dahlof B, Poulter NR, Wedel H, Beevers G, Caulfield M, Collins R, Kjeldsen SE, Kristinsson A, McInnes GT, Mehlsen J, Nieminen M, O'Brien E, Ostergren J, Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial-Lipid Lowering Arm (ASCOT-LLA): a multicentre randomised controlled trial. Lancet 2003; 361:1149-58 [12686036]

## 6 heart failure

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs control</b>			
Wojnicz , 2006 n=36/38 follow-up: 6 months	atorvastatin 40 mg/day versus conventional treatment for heart failure	patients with inflammatory dilated cardiomyopathy (DC) (positive immunohistochemistry results on endomyocardial biopsy)	Parallel groups open
Yamada , 2007 n=19/19 follow-up: mean 2.58y	atorvastatin 10 mg/d versus standard treatment	outpatients with mild to moderate CHF and radionuclide left ventricular ejection fraction (LVEF) <40%	Parallel groups
<b>atorvastatin vs placebo</b>			
Strey , 2005 n=24/24 follow-up: 6 weeks	atorvastatin 40mg versus placebo	patients with stable, symptomatic heart failure (New York Heart Association Class II or III) and a left ventricular ejection fraction <40%	Cross over
Sola , 2006 n=54/54 follow-up: 1y	atorvastatin 20 mg/day versus placebo	patients with nonischemic HF and a left ventricular ejection fraction (LVEF) <=35%	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q176>
- statins for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q696>

## References

### Wojnicz, 2006:

Wojnicz R, Wilczek K, Nowalany-Kozielska E, Szygula-Jurkiewicz B, Nowak J, Polonski L, Dyrbus K, Badzinski A, Mercik G, Zembala M, Wodniecki J, Rozek MM Usefulness of atorvastatin in patients with heart failure due to inflammatory dilated cardiomyopathy and elevated cholesterol levels. *Am J Cardiol* 2006;97:899-904 [16516598]

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Yamada T, Node K, Mine T, Morita T, Kioka H, Tsukamoto Y, Tamaki S, Masuda M, Okuda K, Fukunami M Long-term effect of atorvastatin on neurohumoral activation and cardiac function in patients with chronic heart failure: a prospective randomized controlled study. *Am Heart J* 2007;153:1055.e1-8 [17540209]

### Strey, 2005:

Strey CH, Young JM, Molyneux SL, George PM, Florkowski CM, Scott RS, Frampton CM Endothelium-ameliorating effects of statin therapy and coenzyme Q10 reductions in chronic heart failure. *Atherosclerosis* 2005;179:201-6 [15721028]

### Sola, 2006:

Sola S, Mir MQ, Lerakis S, Tandon N, Khan BV Atorvastatin improves left ventricular systolic function and serum markers of inflammation in nonischemic heart failure. *J Am Coll Cardiol* 2006;47:332-7 [16412856]

## 7 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs control</b>			
<b>Ozaydin , 2006</b> n=24/24 follow-up: 3 months	atorvastatin 10 mg versus standard therapy	Persistent AF and scheduled EC	open
<b>atorvastatin vs placebo</b>			
<b>MIRACL (AF ancillary study) , 2001</b> n=1421/1440 follow-up: 16 weeks	atorvastatin 80mg daily versus placebo	Acute coronary syndrome; subgroup without history of AF	Parallel groups double-blind
<b>Chello , 2006</b> n=20/20 follow-up: 3 weeks	atorvastatin 20mg daily versus placebo	patients with scheduled coronary bypass surgery	Parallel groups double-blind
<b>ARMYDA-3 (AF ancillary study) , 2006</b> n=101/99 follow-up: 30 days	atorvastatin 40mg daily versus placebo	patients with scheduled cardiac surgery without history of AF	
<b>Almroth , 2009</b> n=118/116 follow-up:	atorvastatin 80 mg daily versus placebo	patients with persistent atrial fibrillation undergoing electrical cardioversion	Parallel groups double blind Sweden
<b>MIRACL (sub-group) (Schwartz) , 2004</b> n=118/108 follow-up: 16 weeks	atorvastatin 80 mg versus placebo	Acute coronary syndrome	double blind
<b>Dernellis , 2006</b> n=40/40 follow-up: 46 months	atorvastatin 2040 mg versus placebo	Paroxysmal AF with CRP between 0.8 and 13 mg/L	NA
<b>STOP-AF ongoing</b> [NCT00252967] n=NA follow-up:	atorvastatin 80mg daily versus placebo	-	double blind

More details and results :

- prevention for atrial fibrillation in patient with history of atrial fibrillation at <http://www.trialresultscenter.org/go-Q328>
- prevention for atrial fibrillation in patients without history of AF (primary prevention) at <http://www.trialresultscenter.org/go-Q331>

## References

### Ozaydin, 2006:

Ozaydin M, Varol E, Aslan SM, Kucuktepe Z, Dogan A, Ozturk M, Altinbas A Effect of atorvastatin on the recurrence rates of atrial fibrillation after electrical cardioversion. *Am J Cardiol* 2006;97:1490-3 [[16679090](#)] [10.1016/j.amjcard.2005.11.082](#)

### MIRACL (AF ancillary study), 2001:

Schwartz GG, Olsson AG, Chaitman B, Goldberger J, Szarek M, *Circulation* 2004;110 Suppl:S740

Schwartz GG, Olsson AG, Ezekowitz MD, Ganz P, Oliver MF, Waters D, Zeiher A, Chaitman BR, Leslie S, Stern T Effects of atorvastatin on early recurrent ischemic events in acute coronary syndromes: the MIRACL study: a randomized controlled trial. *JAMA* 2001;285:1711-8 [[11277825](#)]

### Chello, 2006:

Chello M, Patti G, Candura D, Mastrobuoni S, Di Sciascio G, Agr F, Carassiti M, Covino E Effects of atorvastatin on systemic inflammatory response after coronary bypass surgery. *Crit Care Med* 2006;34:660-7 [[16505650](#)] [10.1097/01.CCM.0000201407.89977.EA](#)

### ARMYDA-3 (AF ancillary study), 2006:

Patti G, Chello M, Candura D, Pasceri V, D'Ambrosio A, Covino E, Di Sciascio G Randomized trial of atorvastatin for reduction of postoperative atrial fibrillation in patients undergoing cardiac surgery: results of the ARMYDA-3 (Atorvastatin for Reduction of MYocardial Dysrhythmia After cardiac surgery) study. *Circulation* 2006;114:1455-61 [[17000910](#)] [10.1161/CIRCULATIONAHA.106.621763](#)

### Almroth, 2009:

Almroth H, Hglund N, Boman K, Englund A, Jensen S, Kjellman B, Tornvall P, Rosenqvist M Atorvastatin and persistent atrial fibrillation following cardioversion: a randomized placebo-controlled multicentre study. *Eur Heart J* 2009;30:827-33 [[19202157](#)]

### MIRACL (sub-group) (Schwartz), 2004:

Schwartz GG, Olsson AG, Chaitman B, Goldberger J, Szarek M *Circulation* 2004;110 Suppl:S740

### Dernellis, 2006:

Dernellis J, Panaretou M Effect of C-reactive protein reduction on paroxysmal atrial fibrillation. *Am Heart J* 2005;150:1064 [[16290998](#)] [10.1016/j.ahj.2005.06.032](#)

### STOP-AF, :

ongoing trial NCT00252967

## 8 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
<a href="#">MIRACL, 2001</a> n=1538/1548 follow-up: 1 and 4 months	Atorvastatin, 80 mg (early initiation) versus Placebo	unstable angina or nonQ-wave acute MI	Parallel groups Double blind Europe, North America, South Africa, and Australasia
<b>atorvastatin vs usual care</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>Colivicchi , 2002</b> n=40/41 follow-up: 1, 3, and 6 months	Atorvastatin, 80 mg daily early initiation versus Usual care	unstable angina pectoris or non-Q-wave myocardial infarction	Parallel groups open Italy
<b>ESTABLISH , 2004</b> n=35/35 follow-up: 1, 4, and 6 months	Atorvastatin, 20 mg early initiation versus Usual care	patients with ACS undergoing emergency coronary angiography and percutaneous coronary intervention	Parallel groups open Japan
<b>atorvastatin vs pravastatin</b>			
<b>PROVE IT - TIMI 22 , 2004</b> n=2099/2063 follow-up: 24 mo (18-36 mo)	80 mg of atorvastatin daily (intensive therapy). versus 40 mg of pravastatin daily (standard therapy)	patients who had been hospitalized for an acute coronary syndrome within the preceding 10 days	Parallel groups double blind UK, US, AUstralia, Italy, France, Germany, Spain, Canada

More details and results :

- cholesterol lowering intervention for acute coronary syndrome in early initiation at <http://www.trialresultscenter.org/go-Q21>

## References

### MIRACL, 2001:

Schwartz GG, Olsson AG, Ezekowitz MD, Ganz P, Oliver MF, Waters D, Zeiher A, Chaitman BR, Leslie S, Stern T Effects of atorvastatin on early recurrent ischemic events in acute coronary syndromes: the MIRACL study: a randomized controlled trial. *JAMA* 2001 Apr 4;285:1711-8 [[11277825](#)]

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Colivicchi F, Guido V, Tubaro M, Ammirati F, Montefoschi N, Varveri A, Santini M Effects of atorvastatin 80 mg daily early after onset of unstable angina pectoris or non-Q-wave myocardial infarction. *Am J Cardiol* 2002;90:872-4 [[12372577](#)]

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Okazaki S, Yokoyama T, Miyauchi K, Shimada K, Kurata T, Sato H, Daida H Early statin treatment in patients with acute coronary syndrome: demonstration of the beneficial effect on atherosclerotic lesions by serial volumetric intravascular ultrasound analysis during half a year after coronary event: the ESTABLISH Study. *Circulation* 2004;110:1061-8 [[15326073](#)]

### PROVE IT - TIMI 22, 2004:

Cannon CP, Braunwald E, McCabe CH, Rader DJ, Rouleau JL, Belder R, Joyal SV, Hill KA, Pfeffer MA, Skene AM Intensive versus moderate lipid lowering with statins after acute coronary syndromes. *N Engl J Med* 2004 Apr 8;350:1495-504 [[15007110](#)]

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Murphy SA, Cannon CP, Wiviott SD, de Lemos JA, Blazing MA, McCabe CH, Califf RM, Braunwald E Effect of intensive lipid-lowering therapy on mortality after acute coronary syndrome (a patient-level analysis of the Aggrastat to Zocor and Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction 22 trials). *Am J Cardiol* 2007 Oct 1;100:1047-51 [[17884359](#)]

Ray KK, Cannon CP, McCabe CH, Cairns R, Tonkin AM, Sacks FM, Jackson G, Braunwald E Early and late benefits of high-dose atorvastatin in patients with acute coronary syndromes: results from the PROVE IT-TIMI 22 trial. J Am Coll Cardiol 2005 Oct 18;46:1405-10 [16226162]

Giraldez RR, Giugliano RP, Mohanavelu S, Murphy SA, McCabe CH, Cannon CP, Braunwald E Baseline low-density lipoprotein cholesterol is an important predictor of the benefit of intensive lipid-lowering therapy: a PROVE IT-TIMI 22 (Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis In Myocardial Infarction 22) analysis. J Am Coll Cardiol 2008 Sep 9;52:914-20 [18772061]

## 9 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
ASCOT (diabetics sub group) , 2003 n=1258/1274 follow-up:	10 mg atorvastatin versus placebo	hypertensive patients with no history of coronary heart disease (CHD) but at least three cardiovascular risk factors	
ASPEN , 2006 n=1211/1199 follow-up: 4y	atorvastatin 10mg daily versus placebo	patients s with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets	Parallel groups double blind
ASPEN (primary prevention sub group) , 2006 n=959/947 follow-up: 4 year	atorvastatin 10mg versus placebo	subjects with type 2 diabetes and LDL cholesterol levels below contemporary guideline targets; primary prevention subgroup	Parallel groups double blind 14 countries
CARDS , 2004 [NCT00327418] n=1429/1412 follow-up: 3.9 years	atorvastatin 10mg/d versus placebo	patients with type 2 diabetes without high concentrations of LDL-cholesterol and at least one of the following: retinopathy, albuminuria, current smoking, or hypertension.	Parallel groups double blind UK, Irelande
<b>atorvastatin high dose vs atorvastatin</b>			
TNT (diabetic sub group) , 2006 n=748/753 follow-up: 4.9 y	atorvastatin 80 mg daily versus atorvastatin 10 mg daily	patients with stable coronary heart disease	double blind

More details and results :

- cholesterol lowering intervention for diabetes type 2 in diabetic patients with or without hypercholesterolemia at <http://www.trialresultscenter.org/go-Q85>
- cholesterol lowering intervention for diabetes type 2 in primary prevention at <http://www.trialresultscenter.org/go-Q720>



- cholesterol lowering intervention for diabetes type 2 in secondary prevention at <http://www.trialresultscenter.org/go-Q721>

## References

### ASCOT (diabetics sub group), 2003:

Sever PS, Poulter NR, Dahlf B, Wedel H, Collins R, Beevers G, Caulfield M, Kjeldsen SE, Kristinsson A, McInnes GT, Mehlsen J, Nieminen M, O'Brien E, Ostergren J Reduction in cardiovascular events with atorvastatin in 2,532 patients with type 2 diabetes: Anglo-Scandinavian Cardiac Outcomes Trial–lipid-lowering arm (ASCOT-LLA). *Diabetes Care* 2005 May;28:1151-7 [[15855581](#)]

### ASPEN, 2006:

Knopp RH, d'Emden M, Smilde JG, Pocock SJ Efficacy and safety of atorvastatin in the prevention of cardiovascular end points in subjects with type 2 diabetes: the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in non-insulin-dependent diabetes mellitus (ASPEN). *Diabetes Care* 2006 Jul;29:1478-85 [[16801565](#)]

### ASPEN (primary prevention sub group), 2006:

Knopp RH, d'Emden M, Smilde JG, Pocock SJ Efficacy and safety of atorvastatin in the prevention of cardiovascular end points in subjects with type 2 diabetes: the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in non-insulin-dependent diabetes mellitus (ASPEN). *Diabetes Care* 2006;29:1478-85 [[16801565](#)] [10.2337/dc05-2415](#)

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Colhoun HM, Betteridge DJ, Durrington PN, Hitman GA, Neil HA, Livingstone SJ, Thomason MJ, Mackness MI, Charlton-Menys V, Fuller JH Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. *Lancet* 2004 Aug 21;364:685-96 [[15325833](#)]

### TNT (diabetic sub group), 2006:

Shepherd J, Barter P, Carmena R, Deedwania P, Fruchart JC, Haffner S, Hsia J, Breazna A, LaRosa J, Grundy S, Waters D *Diabetes Care* 2006;29:1220-6 [[16731999](#)] [10.2337/dc05-2465](#)

## 10 CABG surgery

Trial	Treatments	Patients	Trials design and methods
<b>preoperative atorvastatin vs placebo</b>			
<a href="#">Chello et al. , 2006</a> n=20/20 follow-up: 7 days	preoperative atorvastatin 20 mg/d, started 3 wks before surgery versus placebo	elective CABG	double blind
<a href="#">Patti et al. , 2006</a> n=101/99 follow-up: 30 days	preoperative atorvastatin 40 mg/d, starting 7 days before operation versus placebo	patients undergoing elective cardiac surgery with cardiopulmonary bypass, without previous statin treatment or history of AF	double blind

More details and results :

- cholesterol lowering intervention for CABG surgery in preoperative statins at <http://www.trialresultscenter.org/go-Q89>

## References

### Chello et al., 2006:

Chello M, Patti G, Candura D, Mastrobuoni S, Di Sciascio G, Agr F, Carassiti M, Covino E Effects of atorvastatin on systemic inflammatory response after coronary bypass surgery. Crit Care Med 2006;34:660-7 [16505650]

### Patti et al., 2006:

Patti G, Chello M, Candura D, Pasceri V, D'Ambrosio A, Covino E, Di Sciascio G Randomized trial of atorvastatin for reduction of postoperative atrial fibrillation in patients undergoing cardiac surgery: results of the ARMYDA-3 (Atorvastatin for Reduction of MYocardial Dysrhythmia After cardiac surgery) study. Circulation 2006;114:1455-61 [17000910]

## 11 peripheral vascular diseases

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
<b>Mohler III , 2003</b> n=240/114 follow-up: 1 an	Atorvastatine: 10 mg/ jour ou 80 mg/ jour pendant 12 mois (groupes 1 et 2). versus placebo	Stade de la maladie : II , stable pendant au moins 6 mois.	Parallel groups Double aveugle

More details and results :

- cholesterol lowering intervention for peripheral vascular diseases in all type of patients at <http://www.trialresultscenter.org/go-Q52>

## References

### Mohler III, 2003:

Cholesterol reduction with atorvastatin improves walking distance in patients with peripheral arterial disease. Mohler ER 3rd, Hiatt WR, Creager MA Circulation 2003 Sep 23;108:1481-6 [12952839]

## 12 percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs control</b>			
<b>NAPLES II (Briguori) , 2009</b> n=338/330 follow-up: 24h	atorvastatin 80 mg loading dose administered within 24 hours prior to elective PCI versus no statin therapy	Patients with coronary artery disease scheduled for elective PCI and not on statin therapy	Parallel groups open
<b>ESTATE</b> <i>ongoing</i> [NCT00979940] n=NA follow-up:	-	-	
<b>atorvastatin vs placebo</b>			
<b>ARMYDA , 2004</b> n=76/77 follow-up: 1 mo	atorvastatin 40 mg/day seven days prior to the procedure versus placebo	Patients scheduled for elective PCI	double blind
<b>atorvastatin reload vs placebo</b>			
<b>ARMYDA-RECAPTURE , 2009</b> n=229/228 follow-up: 30 days	atorvastatin reload (80 mg 12 h before intervention, with a further 40-mg pre-procedural dose) versus placebo	patient with long-term atorvastatin treatment thereafter (40 mg/day) undergoing PCI (for stable angina or NSTEMI ACS)	Parallel groups double blind Italy
<b>atorvastatin vs usual care</b>			
<b>GAIN , 2001</b> n=65/66 follow-up: 12 mo	Atorvastatin 2040 mg/d 1 d after PCI versus usual care	-	open

More details and results :

- statins for percutaneous coronary intervention in all type of patients at <http://www.trialresultscenter.org/go-Q148>

## References

### **NAPLES II (Briguori), 2009:**

Briguori Novel Approaches for Preventing or Limiting Events (NAPLES) II Trial: Impact of Loading Dose of Atorvastatin on Periprocedural Myocardial Infarction ACC.09/i2, Orlando, FL, March 2009.

Briguori C, Visconti G, Focaccio A, Golia B, Chieffo A, Castelli A, Mussardo M, Montorfano M, Ricciardelli B, Colombo A Novel approaches for preventing or limiting events (Naples) II trial: impact of a single high loading dose of atorvastatin on periprocedural myocardial infarction. J Am Coll Cardiol 2009;54:2157-63 [19664895]

### **ESTATE, :**

ongoing trial NCT00979940

### ARMYDA, 2004:

Pasceri V, Patti G, Nusca A, Pristipino C, Richichi G, Di Sciascio G Randomized trial of atorvastatin for reduction of myocardial damage during coronary intervention: results from the ARMYDA (Atorvastatin for Reduction of MYocardial Damage during Angioplasty) study. *Circulation* 2004;110:674-8 [15277322]

### ARMYDA-RECAPTURE, 2009:

Di Sciascio G, Patti G, Pasceri V, Gasparone A, Colonna G, Montinaro A Efficacy of atorvastatin reload in patients on chronic statin therapy undergoing percutaneous coronary intervention: results of the ARMYDA-RECAPTURE (Atorvastatin for Reduction of Myocardial Damage During Angioplasty) Randomized Trial. *J Am Coll Cardiol* 2009;54:558-65 [19643320]

### GAIN, 2001:

Schartl M, Bocksch W, Koschyk DH, Voelker W, Karsch KR, Kreuzer J, Hausmann D, Beckmann S, Gross M Use of intravascular ultrasound to compare effects of different strategies of lipid-lowering therapy on plaque volume and composition in patients with coronary artery disease. *Circulation* 2001;104:387-92 [11468198]

## 13 aortic stenosis

Trial	Treatments	Patients	Trials design and methods
<b>atorvastatin vs placebo</b>			
SALTIRE , 2005 n=77/78 follow-up: 25 mo (7-36)	atorvastatin 80mg daily versus placebo	patients with calcific aortic stenosis	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for aortic stenosis in all type of patients at <http://www.trialresultscenter.org/go-Q385>

## References

### SALTIRE, 2005:

Cowell SJ, Newby DE, Prescott RJ, Bloomfield P, Reid J, Northridge DB, Boon NA A randomized trial of intensive lipid-lowering therapy in calcific aortic stenosis. *N Engl J Med* 2005 Jun 9;352:2389-97 [15944423] 10.1056/NEJMoa043876

Entry terms: Lipitor