

Clinical trials of simvastatin

TrialResults-center www.trialresultscenter.org

1 post stroke

Trial	Treatments	Patients	Trials design and methods
simvastatin vs placebo			
HPS (post stroke sub group), 2004 n=920/900 follow-up:	simvastatin 40mg daily versus placebo	adults with cerebrovascular disease, total cholesterol ≥ 35 mmol/L and without coronaro disease (n=1820)	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>

References

HPS (post stroke sub group), 2004:

Collins R, Armitage J, Parish S, Sleight P, Peto R Effects of cholesterol-lowering with simvastatin on stroke and other major vascular events in 20536 people with cerebrovascular disease or other high-risk conditions. Lancet 2004;363:757-67 [[15016485](#)]

2 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
simvastatin vs placebo			
4S, 1994 n=2221/2223 follow-up: 5.4 years	simvastatin 20 or 40 mg/d, target CT between 3 et 5.2 mmol/l versus placebo	patients with angina pectoris or previous myocardial infarction and serum cholesterol 5.5-8.0 mmol/L on a lipid-lowering diet	Parallel groups double blind Scandinavia

More details and results :

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

References

4S, 1994:

, Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S) Lancet 1994; 344:1383-9 [7968073]

3 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
simvastatin vs control			
Hong , 2005 n=106/96 follow-up: 1 year	simvastatin versus no treatment	patients with ischemic heart failure who underwent percutaneous coronary intervention (PCI) for acute myocardial infarction (left ventricular [LV] ejection fraction <40%)	Parallel groups open
ezetimibe+simvastatin vs placebo			
SHARP , 2010 [NCT00125593] n=4193/4191 follow-up: 4.9 years	Simvastatin 20mg/Ezetimibe 10mg versus placebo	patients with established chronic kidney disease (dialysis or pre-dialysis)	Parallel groups double-blind 20 countries
SEAS , 2008 [NCT00092677] n=944/929 follow-up: 52.2 mo	simvastatin 40mg plus ezetimibe 10 mg daily versus placebo	patients with mild-to-moderate, asymptomatic aortic stenosis	Parallel groups double blind Europe
simvastatin vs placebo			
4S , 1994 n=2221/2223 follow-up: 5.4 years	simvastatin 20 or 40 mg/d, target CT between 3 et 5.2 mmol/l versus placebo	patients with angina pectoris or previous myocardial infarction and serum cholesterol 5.5-8.0 mmol/L on a lipid-lowering diet	Parallel groups double blind Scandinavia
Mondillo , 2003 n=43/43 follow-up: 6 mois	simvastatine: 40 mg/ jour pendant 6 mois. versus placebo	Stade de la maladie: II.	Parallel groups Double aveugle
Aronow , 2003 n=34/35 follow-up: 1 an	simvastatine 40 mg/j versus placebo	Stade II	Parallel groups Non dterminable

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Trial	Treatments	Patients	Trials design and methods
HPS (diabetic sub group) , 2002 n=2978/2985 follow-up:	simvastatin 40mg daily versus placebo	Men and women diabetes aged about 40-80 years with non-fasting blood total cholesterol concentrations of at least 35 mmol/L (135 mg/dL)	Parallel groups double blind
4S (diabetic sub group) , 1999 n=251/232 follow-up: 5.4y	simvastatin versus placebo	diabetic men and women aged 35 to 70 years with previous MI or active, stable angina pectoris and with serum total cholesterol level between 5.5 to 8.0 mmol/L and serum triglyceride level <=2.5 mmol/L	Parallel groups double blind Denmark, Finland, Iceland, Norway, and Sweden
Node , 2003 n=24/27 follow-up:	simvastatin 10mg/d versus placebo	patients with symptomatic, nonischemic, dilated cardiomyopathy	
4S (elderly subgroup) , 1997 n=518/503 follow-up: 5.4y	-	MI 6 months or stable angina, subgroup of age 65-70 y	parallel groups double blind
HPS (elderly subgroup) , 2002 n=5366/5331 follow-up: 5.0y	-	Vascular disease or diabetes, subgroup of age 65-80 y	parallel groups double blind
HPS (post stroke sub group) , 2004 n=920/900 follow-up:	simvastatin 40mg daily versus placebo	adults with cerebrovascular disease, total cholesterol >=35 mmol/L and without coronaro disease (n=1820)	Parallel groups double blind
A to Z , 2004 n=2265/2232 follow-up: 4 months	Simvastatin, 40-80 mg early initiation versus Placebo	patient with an acute coronary syndrome (ACS)	Parallel groups Double aveugle 41 countries
Ren , 2009 n=NA follow-up:	simvastatin (40 mg/d for 4 weeks) versus placebo	patients with unstable angina pectoris	Parallel groups double-blind
CIS , 1997 n=129/125 follow-up: 2.3 years	simvastatin 40 mg versus placebo	men with documented coronary artery disease and hypercholesterolaemia	Parallel groups double blind
HPS , 2002 n=10269/10267 follow-up: 5 years	simvastatin 40 mg/d versus placebo	adults (aged 40-80 years) with coronary disease, other occlusive arterial disease, or diabete	Factorial plan double blind UK

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Trial	Treatments	Patients	Trials design and methods
HPS (diabetic primary prevention sub group) , 2003 n=1455/1457 follow-up: 5 years	simvastatin 40 mg/d versus placebo	adults (aged 40-80 years) with diabetes (primary prevention subgroup)	Parallel groups double blind UK
MAAS , 1994 n=193/188 follow-up: 4 y	simvastatin 20 mg daily versus placebo	patients with coronary heart disease	Parallel groups double blind
HPS (women subgroup) , 2002 n=914/902 follow-up: 5 y	Simvastatin 40 mg versus placebo	UK adults (aged 40-80 years) with coronary disease, other occlusive arterial disease, or diabetes - subgroup of women without CHD	Parallel groups double blind UK
simvastatin vs ezetimibe			
Landmesser , 2005 n=10/10 follow-up:	simvastatin 10mg/d versus ezetimibe 10mg/d	patients with chronic heart failure	
simvastatin high dose vs simvastatin			
SEARCH , 2010 [NCT00124072] n=6031/6033 follow-up: 6.7 years (mean)	simvastatin 80 mg daily versus simvastatin 20mg daily	MI survivors	Parallel groups

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 elderly at <http://www.trialresultscenter.org/go-Q7>
- 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 chronic 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>

References

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Hong YJ, Jeong MH, Hyun DW, Hur SH, Kim KB, Kim W, Lim SY, Lee SH, Hong SN, Kang DG, Yun KH, Kim KH, Lee YS, Park HW, Kim JH, Ahn YK, Cho JG, Park JC, Kang JC Prognostic significance of simvastatin therapy in patients with ischemic heart failure who underwent percutaneous coronary intervention for acute myocardial infarction. *Am J Cardiol* 2005;95:619-22 [[15721103](#)]

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Sharp Collaborative Group Study of Heart and Renal Protection (SHARP): Randomized trial to assess the effects of lowering low-density lipoprotein cholesterol among 9,438 patients with chronic kidney disease. *Am Heart J* 2010 Nov;160:785-794.e10 [[21095263](#)] [10.1016/j.ahj.2010.08.012](https://doi.org/10.1016/j.ahj.2010.08.012)

Baigent C, Landray MJ, Reith C, Emberson J, Wheeler DC, Tomson C, Wanner C, Krane V, Cass A, Craig J, Neal B, Jiang L, Hooi LS, Levin A, Agodoa L, Gaziano M, Kasiske B, Walker R, Massy ZA, Feldt-Rasmussen B, Krairitichai U, Ophascharoensuk V, Fellström B The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. *Lancet* 2011 Jun 25;377:2181-2192 [[21663949](#)] [10.1016/S0140-6736\(11\)60739-3](https://doi.org/10.1016/S0140-6736(11)60739-3)

SEAS, 2008:

Rosseb AB, Pedersen TR, Boman K, Brudi P, Chambers JB, Egstrup K, Gerds E, Gohlke-Brwolf C, Holme I, Kesniemi YA, Malbecq W, Nienaber CA, Ray S, Skjaerpe T, Wachtell K, Willenheimer R Intensive lipid lowering with simvastatin and ezetimibe in aortic stenosis. *N Engl J Med* 2008 Sep 25;359:1343-56 [[18765433](#)]

4S, 1994:

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Effects of simvastatin on walking performance and symptoms of intermittent claudication in hypercholesterolemic patients with peripheral vascular disease. *Mondillo S, Ballo P, Barbati R, Guerrini F, Ammataro T, Agricola E, Pastore M, Borrello F, Belcastro M, Picchi A, Nami R Am J Med* 2003 Apr 1;114:359-64 [[12714124](#)]

Aronow , 2003:

Effect of simvastatin versus placebo on treadmill exercise time until the onset of intermittent claudication in older patients with peripheral arterial disease at six months and at one year after treatment. *Aronow WS, Nayak D, Woodworth S, Ahn C Am J Cardiol* 2003 Sep 15;92:711-2 [[12972114](#)]

HPS (diabetic sub group), 2002:

Collins R, Armitage J, Parish S, Sleight P, Peto R MRC/BHF Heart Protection Study of cholesterol-lowering with simvastatin in 5963 people with diabetes: a randomised placebo-controlled trial. *Lancet* 2003 Jun 14;361:2005-16 [[12814710](#)]

4S (diabetic sub group), 1999:

Haffner SM, Alexander CM, Cook TJ, Boccuzzi SJ, Musliner TA, Pedersen TR, Kjekshus J, Pyrl K Reduced coronary events in simvastatin-treated patients with coronary heart disease and diabetes or impaired fasting glucose levels: subgroup analyses in the Scandinavian Simvastatin Survival Study. Arch Intern Med 1999 Dec 13-27;159:2661-7 [[10597756](#)]

Node, 2003:

Node K, Fujita M, Kitakaze M, Hori M, Liao JK Short-term statin therapy improves cardiac function and symptoms in patients with idiopathic dilated cardiomyopathy. Circulation 2003;108:839-43 [[12885745](#)]

4S (elderly subgroup), 1997:

Miettinen TA, Pyrl K, Olsson AG, Musliner TA, Cook TJ, Faergeman O, Berg K, Pedersen T, Kjekshus J Cholesterol-lowering therapy in women and elderly patients with myocardial infarction or angina pectoris: findings from the Scandinavian Simvastatin Survival Study (4S) Circulation 1997;96:4211-8 [[9416884](#)]

HPS (elderly subgroup), 2002:

Champagne J, Geelen P, Philippon F, Brugada P Recurrent cardiac events in patients with idiopathic ventricular fibrillation, excluding patients with the Brugada syndrome. BMC Med 2005;3:1 [[15627402](#)]

HPS (post stroke sub group), 2004:

Collins R, Armitage J, Parish S, Sleight P, Peto R Effects of cholesterol-lowering with simvastatin on stroke and other major vascular events in 20536 people with cerebrovascular disease or other high-risk conditions. Lancet 2004;363:757-67 [[15016485](#)]

A to Z, 2004:

de Lemos JA, Blazing MA, Wiviott SD, Lewis EF, Fox KA, White HD, Rouleau JL, Pedersen TR, Gardner LH, Mukherjee R, Ramsey KE, Palmisano J, Bilheimer DW, Pfeffer MA, Califf RM, Braunwald E Early intensive vs a delayed conservative simvastatin strategy in patients with acute coronary syndromes: phase Z of the A to Z trial. JAMA 2004 Sep 15;292:1307-16 [[15337732](#)]

Ren, 2009:

Ren HZ, Ma LL, Wang LX Effect of simvastatin on plasma interleukin-6 in patients with unstable angina. Clin Invest Med 2009;32:E280-4 [[19640331](#)]

CIS, 1997:

Bestehorn HP, Rensing UF, Roskamm H, Betz P, Benesch L, Schemitat K, Blmchen G, Claus J, Mathes P, Kappenberger L, Wieland H, Neiss A The effect of simvastatin on progression of coronary artery disease. The Multicenter coronary Intervention Study (CIS). Eur Heart J 1997;18:226-34 [[9043838](#)]

HPS, 2002:

, MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002; 360:7-22 [[12114036](#)]

Armitage J, Collins R Need for large scale randomised evidence about lowering LDL cholesterol in people with diabetes mellitus: MRC/BHF heart protection study and other major trials. Heart 2000;84:357-60 [[10995396](#)]

MRC/BHF Heart Protection Study of cholesterol-lowering therapy and of antioxidant vitamin supplementation in a wide range of patients at increased risk of coronary heart disease death: early safety and efficacy experience. Eur Heart J 1999;20:725-41 [[10329064](#)]

HPS (diabetic primary prevention sub group), 2003:

Collins R, Armitage J, Parish S, Sleight P, Peto R MRC/BHF Heart Protection Study of cholesterol-lowering with simvastatin in 5963 people with diabetes: a randomised placebo-controlled trial. Lancet 2003;361:2005-16 [[12814710](#)]

MAAS, 1994:

Effect of simvastatin on coronary atheroma: the Multicentre Anti-Atheroma Study (MAAS) Lancet 1994;344:633-8 [7864934]

HPS (women subgroup) , 2002:

MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002;360:7-22 [12114036] 10.1016/S0140-6736(02)09327-3

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Study Of The Effectiveness Of Additional Reductions In Cholesterol And Homocysteine Search Collaborative Group Intensive lowering of LDL cholesterol with 80 mg versus 20 mg simvastatin daily in 12?064 survivors of myocardial infarction: a double-blind randomised trial. Lancet 2010 Nov 8;: [21067805] 10.1016/S0140-6736(10)60310-8

4 heart failure

Trial	Treatments	Patients	Trials design and methods
simvastatin vs control			
Hong , 2005 n=106/96 follow-up: 1 year	simvastatin versus no treatment	patients with ischemic heart failure who underwent percutaneous coronary intervention (PCI) for acute myocardial infarction (left ventricular [LV] ejection fraction <40%)	Parallel groups open
simvastatin vs placebo			
Node , 2003 n=24/27 follow-up:	simvastatin 10mg/d versus placebo	patients with symptomatic, nonischemic, dilated cardiomyopathy	
simvastatin vs ezetimibe			
Landmesser , 2005 n=10/10 follow-up:	simvastatin 10mg/d versus ezetimibe 10mg/d	patients with chronic heart failure	

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

Hong, 2005:

Hong YJ, Jeong MH, Hyun DW, Hur SH, Kim KB, Kim W, Lim SY, Lee SH, Hong SN, Kang DG, Yun KH, Kim KH, Lee YS, Park HW, Kim JH, Ahn YK, Cho JG, Park JC, Kang JC Prognostic significance of simvastatin therapy in patients with ischemic heart failure who underwent percutaneous coronary intervention for acute myocardial infarction. Am J Cardiol 2005;95:619-22 [15721103]

Node, 2003:

Node K, Fujita M, Kitakaze M, Hori M, Liao JK Short-term statin therapy improves cardiac function and symptoms in patients with idiopathic dilated cardiomyopathy. Circulation 2003;108:839-43 [12885745]

Landmesser, 2005:

Landmesser U, Bahlmann F, Mueller M, Spiekermann S, Kirchhoff N, Schulz S, Manes C, Fischer D, de Groot K, Fliser D, Fauler G, Mrz W, Drexler H Simvastatin versus ezetimibe: pleiotropic and lipid-lowering effects on endothelial function in humans. Circulation 2005;111:2356-63 [15867181]

5 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
simvastatin vs placebo			
A to Z , 2004 n=2265/2232 follow-up: 4 months	Simvastatin, 40-80 mg early initiation versus Placebo	patient with an acute coronary syndrome (ACS)	Parallel groups Double aveugle 41 countries

More details and results :

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

References

A to Z, 2004:

de Lemos JA, Blazing MA, Wiviott SD, Lewis EF, Fox KA, White HD, Rouleau JL, Pedersen TR, Gardner LH, Mukherjee R, Ramsey KE, Palmisano J, Bilheimer DW, Pfeffer MA, Califf RM, Braunwald E Early intensive vs a delayed conservative simvastatin strategy in patients with acute coronary syndromes: phase Z of the A to Z trial. JAMA 2004 Sep 15;292:1307-16 [15337732]

6 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
simvastatin vs placebo			
HPS (diabetic sub group) , 2002 n=2978/2985 follow-up:	simvastatin 40mg daily versus placebo	Men and women diabetes aged about 40-80 years with non-fasting blood total cholesterol concentrations of at least 35 mmol/L (135 mg/dL)	Parallel groups double blind
4S (diabetic sub group) , 1999 n=251/232 follow-up: 5.4y	simvastatin versus placebo	diabetic men and women aged 35 to 70 years with previous MI or active, stable angina pectoris and with serum total cholesterol level between 5.5 to 8.0 mmol/L and serum triglyceride level <=2.5 mmol/L	Parallel groups double blind Denmark, Finland, Iceland, Norway, and Sweden

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>

References

HPS (diabetic sub group), 2002:

Collins R, Armitage J, Parish S, Sleight P, Peto R MRC/BHF Heart Protection Study of cholesterol-lowering with simvastatin in 5963 people with diabetes: a randomised placebo-controlled trial. *Lancet* 2003 Jun 14;361:2005-16 [12814710]

4S (diabetic sub group), 1999:

Haffner SM, Alexander CM, Cook TJ, Bocuzzi SJ, Musliner TA, Pedersen TR, Kjekshus J, Pyrl K Reduced coronary events in simvastatin-treated patients with coronary heart disease and diabetes or impaired fasting glucose levels: subgroup analyses in the Scandinavian Simvastatin Survival Study. *Arch Intern Med* 1999 Dec 13-27;159:2661-7 [10597756]

7 CABG surgery

Trial	Treatments	Patients	Trials design and methods
preoperative simvastatin vs no treatment			
Christenson , 1999 n=40/37 follow-up: 7 days	preoperative simvastatin 20 mg/d, stated 4 weeks before surgery versus no statins	patients with hypercholesterolemia (total cholesterol >or =6.2 mmol/l) planned for CABG	

More details and results :

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

References

Christenson, 1999:

Christenson JT Preoperative lipid-control with simvastatin reduces the risk of postoperative thrombocytosis and thrombotic complications following CABG. Eur J Cardiothorac Surg 1999;15:394-9; discussion 399-400 [10371111]

8 peripheral vascular diseases

Trial	Treatments	Patients	Trials design and methods
simvastatin vs placebo			
Mondillo , 2003 n=43/43 follow-up: 6 mois	simvastatine: 40 mg/ jour pendant 6 mois. versus placebo	Stade de la maladie: II.	Parallel groups Double aveugle
Aronow , 2003 n=34/35 follow-up: 1 an	simvastatine 40 mg/j versus placebo	Stade II	Parallel groups Non dterminable
HPS (sub group) , 2002 n=10269/10267 follow-up: 5 ans	simvastatine 40 mg/ jour pendant 5 ans versus placebo	32.85% des patients prsentaient une arthropathie des membres infrieurs	Factorial plan 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

Mondillo, 2003:

Effects of simvastatin on walking performance and symptoms of intermittent claudication in hypercholesterolemic patients with peripheral vascular disease. Mondillo S, Ballo P, Barbati R, Guerrini F, Ammaturio T, Agricola E, Pastore M, Borrello F, Belcastro M, Picchi A, Nami R Am J Med 2003 Apr 1;114:359-64 [12714124]

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Effect of simvastatin versus placebo on treadmill exercise time until the onset of intermittent claudication in older patients with peripheral arterial disease at six months and at one year after treatment. Aronow WS, Nayak D, Woodworth S, Ahn C Am J Cardiol 2003 Sep 15;92:711-2 [12972114]

HPS (sub group), 2002:

Amann W, Berg P, Gerbasch P, Gamain J, Raphael JH, Ubbink DT. Spinal cord stimulation in the treatment of non reconstructable stable critical leg ischaemia: results of the European peripheral vascular disease outcomes study (SCS-EPOS) European journal of vascular and endovascular surgery 26, 280-286 (2003).

Aung PP, Maxwell HG, Jepson RG, Price JF, Leng GC Lipid-lowering for peripheral arterial disease of the lower limb. Cochrane Database Syst Rev 2007 Oct 17;:CD000123 [17943736]

9 aortic stenosis

Trial	Treatments	Patients	Trials design and methods
ezetimibe+simvastatin vs placebo			
SEAS , 2008 [NCT00092677] n=944/929 follow-up: 52.2 mo	simvastatin 40mg plus ezetimibe 10 mg daily versus placebo	patients with mild-to-moderate, asymptomatic aortic stenosis	Parallel groups double blind Europe

More details and results :

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

References

SEAS, 2008:

Rosseb AB, Pedersen TR, Boman K, Brudi P, Chambers JB, Egstrup K, Gerds E, Gohlke-Brwolf C, Holme I, Kesniemi YA, Malbecq W, Nienaber CA, Ray S, Skjaerpe T, Wachtell K, Willenheimer R Intensive lipid lowering with simvastatin and ezetimibe in aortic stenosis. N Engl J Med 2008 Sep 25;359:1343-56 [18765433]

Entry terms: ezetimibe, Zetia, Ezetrol, Zocor