

# Clinical trials of rosuvastatin

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## 1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
<b>rosuvastatin vs placebo</b>			
<b>AURORA , 2009</b> n=1391/1385 follow-up: 3.2 y mean (max 5.6y)	rosuvastatin 10 mg daily versus placebo	in patients with end-stage renal disease on hemodialysis	Parallel groups double blind
<b>JUPITER (elderly sub group) , 2009</b> n=5695 follow-up: double-blind	rosuvastatin 20mg daily versus placebo	healthy individuals aged $\geq 70$ years with normal LDL cholesterols but with CRP levels $\geq 2.0$ mg/dL	Parallel groups double blind
<b>ASTRONOMER , 2010</b> [ISRCTN 32424163] n=134/135 follow-up: 3.5 y	rosuvastatin 40 mg daily versus placebo	asymptomatic patients with mild to moderate aortic stenosis and no clinical indications for cholesterol lowering	Parallel groups double blind
<b>HOPE 3 , 2016</b> [NCT00468923] n=6361/6344 follow-up: 5.6 years	rosuvastatin 10 mg per day versus placebo	subjects who did not have cardiovascular disease and were at intermediate risk	Factorial plan double-blind 21 countries
<b>CORONA , 2007</b> [NCT00206310] n=2514/2497 follow-up: 32.9 months median	rosuvastatin 10mg/d versus placebo	patients at least 60 years of age with NYHA class II, III, or IV ischemic, systolic heart failure	Parallel groups double blind
<b>Krum , 2007</b> n=40/46 follow-up: 6 months	rosuvastatine 40mg/d versus placebo	patients with systolic (LVEF<40% ) CHF of ischemic or nonischemic etiology	Parallel groups double blind Australia
<b>GISSI-HF rosuvastatine , 2008</b> [NCT00336336] n=2314/2317 follow-up: 3.9y median (IQR 3-4.4)	low-dose rosuvastatin 10 mg daily versus placebo	Patients with NYHA classes II to IV heart failure, whatever the cause and the LVEF and already receiving optimized recommended therapy with no clear indication or contraindication to cholesterol-lowering therapy	Parallel groups double blind Italy

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
JUPITER , 2008 [NCT00239681] n=8901/8901 follow-up: median 1.9 year	rosuvastatin 20 mg daily versus placebo	apparently healthy individuals with low LDL-cholesterol levels of less than 130 mg per deciliter but elevated C-reactive-protein (high-sensitivity C-reactive protein levels of 2.0 mg per liter or higher)	Parallel groups double blind 26 countries
METEOR , 2007 [NCT00225589] n=702/282 follow-up:	rosuvastatin 40mg daily versus placebo	individuals, with either age (mean, 57 years) as the only coronary heart disease risk factor or a 10-year Framingham risk score of less than 10% , modest CIMT thickening (1.2-<3.5 mm), and elevated LDL cholesterol	Parallel groups double-blind USA, Europe
JUPITER (women subgroup) , 2008 n=3426/3375 follow-up: 1.9 y	Rosuvastatin 20 mg daily versus placebo	apparently healthy men and women with low-density lipoprotein cholesterol levels of less than 130 mg/dL and high-sensitivity C-reactive protein levels of 2.0 mg/L or higher - subgroup of women	Parallel groups double-blind 26 countries
<b>Rosuvastatin vs control</b>			
ASTEROID ongoing n=NA follow-up:	-	-	

More details and results :

- 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 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 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 primary prevention at <http://www.trialresultscenter.org/go-Q688>
- statins for cardiovascular prevention in diabetic patients at <http://www.trialresultscenter.org/go-Q694>

## References

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### **JUPITER (elderly sub group), 2009:**

Glynn RJ, Koenig W, Nordestgaard BG, Shepherd J, Ridker PM Rosuvastatin for primary prevention in older persons with elevated C-reactive protein and low to average low-density lipoprotein cholesterol levels: exploratory analysis of a randomized trial. Ann Intern Med 2010;152:488-96, W174 [20404379] 10.1059/0003-4819-152-8-201004200-00005

### **ASTRONOMER, 2010:**

Chan KL, Teo K, Dumesnil JG, Ni A, Tam J Effect of Lipid Lowering With Rosuvastatin on Progression of Aortic Stenosis. Results of the Aortic Stenosis Progression Observation: Measuring Effects of Rosuvastatin (ASTRONOMER) Trial. Circulation 2010 Jan 4;: [20048204]

### **HOPE 3, 2016:**

Yusuf S, Bosch J, Dagenais G, Zhu J, Xavier D, Liu L, Pais P, Lopez-Jaramillo P, Leiter LA, Dans A, Avezum A, Piegas LS, Parkhomenko A, Keltai K, Keltai M, Sliwa K, Peters RJ, Held C, Chazova I, Yusuf K, Lewis BS, Jansky P, Khunti K, Toff WD, Reid CM, Va Cholesterol Lowering in Intermediate-Risk Persons without Cardiovascular Disease. N Engl J Med 2016 Apr 2;: [27040132] 10.1056/NEJMoa1600176

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Kjekshus J, Apetrei E, Barrios V, Bhm M, Cleland JG, Cornel JH, Dunselman P, Fonseca C, Goudev A, Grande P, Gullestad L, Hjalmarsen A, Hradec J, Jnosi A, Kamensk G, Komajda M, Korewicki J, Kuusi T, Mach F, Mareev V, McMurray JJ, Ranjith N, Schaufelberg Rosuvastatin in older patients with systolic heart failure. N Engl J Med 2007;357:2248-61 [17984166]

### **Krum, 2007:**

Krum H, Ashton E, Reid C, Kalff V, Rogers J, Amarena J, Singh B, Tonkin A Double-blind, randomized, placebo-controlled study of high-dose HMG CoA reductase inhibitor therapy on ventricular remodeling, pro-inflammatory cytokines and neurohormonal parameters in patients with chronic systolic heart failure. J Card Fail 2007;13:1-7 [17338996]

### **GISSI-HF rosuvastatine, 2008:**

Tavazzi L, Tognoni G, Franzosi MG, Latini R, Maggioni AP, Marchioli R, Nicolosi GL, Porcu M Rationale and design of the GISSI heart failure trial: a large trial to assess the effects of n-3 polyunsaturated fatty acids and rosuvastatin in symptomatic congestive heart failure. Eur J Heart Fail 2004 Aug;6:635-41 [15302013]

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Crouse JR 3rd, Raichlen JS, Riley WA, Evans GW, Palmer MK, O'Leary DH, Grobbee DE, Bots ML Effect of rosuvastatin on progression of carotid intima-media thickness in low-risk individuals with subclinical atherosclerosis: the METEOR Trial. JAMA 2007 Mar 28;297:1344-53 [17384434]

#### **JUPITER (women subgroup) , 2008:**

Ridker PM, Danielson E, Fonseca FA, Genest J, Gotto AM Jr, Kastelein JJ, Koenig W, Libby P, Lorenzatti AJ, MacFadyen JG, Nordestgaard BG, Shepherd J, Willerson JT, Glynn RJ Rosuvastatin to prevent vascular events in men and women with elevated C-reactive protein. N Engl J Med 2008;359:2195-207 [18997196]  
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#### **ASTEROID, 0:**

ongoing trial

## 2 heart failure

Trial	Treatments	Patients	Trials design and methods
<b>rosuvastatin vs placebo</b>			
<b>CORONA , 2007</b> [NCT00206310] n=2514/2497 follow-up: 32.9 months median	rosuvastatin 10mg/d versus placebo	patients at least 60 years of age with NYHA class II, III, or IV ischemic, systolic heart failure	Parallel groups double blind
<b>Krum , 2007</b> n=40/46 follow-up: 6 months	rosuvastatine 40mg/d versus placebo	patients with systolic (LVEF<40% ) CHF of ischemic or nonischemic etiology	Parallel groups double blind Australia
<b>GISSI-HF rosuvastatine , 2008</b> [NCT00336336] n=2314/2317 follow-up: 3.9y median (IQR 3-4.4)	low-dose rosuvastatin 10 mg daily versus placebo	Patients with NYHA classes II to IV heart failure, whatever the cause and the LVEF and already receiving optimized recommended therapy with no clear indication or contraindication to cholesterollowering therapy	Parallel groups double blind Italy

More details and results :

- cholesterol lowering intervention for heart failure in elderly at <http://www.trialresultscenter.org/go-Q77>
- 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

### CORONA, 2007:

Kjekshus J, Apetrei E, Barrios V, Bhm M, Cleland JG, Cornel JH, Dunselman P, Fonseca C, Goudev A, Grande P, Gullestad L, Hjalmarson A, Hradec J, Jnosi A, Kamensk G, Komajda M, Korewicki J, Kuusi T, Mach F, Mareev V, McMurray JJ, Ranjith N, Schaufelberg Rosuvastatin in older patients with systolic heart failure. N Engl J Med 2007;357:2248-61 [17984166]

### Krum, 2007:

Krum H, Ashton E, Reid C, Kalff V, Rogers J, Amarena J, Singh B, Tonkin A Double-blind, randomized, placebo-controlled study of high-dose HMG CoA reductase inhibitor therapy on ventricular remodeling, pro-inflammatory cytokines and neurohormonal parameters in patients with chronic systolic heart failure. J Card Fail 2007;13:1-7 [17338996]

### GISSI-HF rosuvastatine, 2008:

Tavazzi L, Tognoni G, Franzosi MG, Latini R, Maggioni AP, Marchioli R, Nicolosi GL, Porcu M Rationale and design of the GISSI heart failure trial: a large trial to assess the effects of n-3 polyunsaturated fatty acids and rosuvastatin in symptomatic congestive heart failure. Eur J Heart Fail 2004 Aug;6:635-41 [15302013]

Tavazzi L, Maggioni AP, Marchioli R, Barlera S, Franzosi MG, Latini R, Lucci D, Nicolosi GL, Porcu M, Tognoni G Effect of rosuvastatin in patients with chronic heart failure (the GISSI-HF trial): a randomised, double-blind, placebo-controlled trial. Lancet 2008;372:1231-9 [18757089]

## 3 atrial fibrillation

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Trial	Treatments	Patients	Trials design and methods
<b>rosuvastatin vs placebo</b>			
GISSI HF (subgroup and ancillary study) , 2009 [NCT00336336] n=1855/1835 follow-up: 3.7y (median)	rosuvastatin 10mg daily versus placebo	patients with chronic heart failure who were not in AF at study entry	Factorial plan double-blind Italy

More details and results :

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

## References

### GISSI HF (subgroup and ancillary study), 2009:

Maggioni AP, Fabbri G, Lucci D, Marchioli R, Franzosi MG, Latini R, Nicolosi GL, Porcu M, Cosmi F, Stefanelli S, Tognoni G, Tavazzi L Effects of rosuvastatin on atrial fibrillation occurrence: ancillary results of the GISSI-HF trial. Eur Heart J 2009 Oct;30:2327-36 [19717850]

## 4 aortic stenosis

Trial	Treatments	Patients	Trials design and methods
<b>rosuvastatin vs placebo</b>			
<b>ASTRONOMER , 2010</b> [ISRCTN 32424163] n=134/135 follow-up: 3.5 y	rosuvastatin 40 mg daily versus placebo	asymptomatic patients with mild to moderate aortic stenosis and no clinical indications for cholesterol lowering	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

#### **ASTRONOMER, 2010:**

Chan KL, Teo K, Dumesnil JG, Ni A, Tam J Effect of Lipid Lowering With Rosuvastatin on Progression of Aortic Stenosis. Results of the Aortic Stenosis Progression Observation: Measuring Effects of Rosuvastatin (ASTRONOMER) Trial. Circulation 2010 Jan 4;: [20048204]

Entry terms: Crestor