

# Clinical trials of fluvastatin

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## 1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
<b>fluvastatin vs placebo</b>			
<b>ALERT , 2003</b> n=1050/1052 follow-up: 5.1 years	fluvastatin versus placebo	renal transplant recipients with total cholesterol 4090 mmol/L.	Parallel groups double blind
<b>LIPS (sub group) , 2002</b> n=120/82 follow-up: 3.9y	fluvastatin versus placebo	patients (aged 18-80 years) with stable or unstable angina or silent ischemia following successful completion of their first PCI who had baseline total cholesterol levels between 135 and 270 mg/dL	Parallel groups double blind
<b>ALERT (sub group) , 2003</b> n=197/199 follow-up:	fluvastatin versus placebo	renal transplant recipients with total cholesterol 4090 mmol/L	Parallel groups double blind
<b>LIPS (sub groups) , 2002</b> n=417/407 follow-up: 1, 4, and 6 months	Fluvastatin, 80 mg versus Placebo	patients with unstable angina and successful first percutaneous coronary intervention	Parallel groups double blind Europe, Canada, and Brazil
<b>ALERT , 2003</b> n=1050/1052 follow-up: 5.1 years	fluvastatin 40 mg daily versus placebo	renal transplant recipients with total cholesterol 4.0-9.0 mmol/L	Parallel groups double-blind Belgium, Denmark, Finland, Germany, Norway,
<b>FLARE (subgroup) , 1999</b> n=179/187 follow-up: 0.8y	-	CAD requiring PCI, subgroup of age 65-80 y	parallel groups double blind
<b>FLORIDA , 2002</b> n=265/275 follow-up: 1, 4, and 6 months	Fluvastatin, 80 mg (early initiation) versus Placebo	patients with an AMI and total cholesterol of <6.5 mmol.l	Parallel groups double blind The Netherlands
<b>LIPS (subgroup) , 2002</b> n=324/299 follow-up: 3.9y	-	CAD requiring PCI, subgroup of age 65-80 y	parallel groups double blind

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>BCAPS , 2001</b> n=395/398 follow-up: 3.0 years	fluvastatin 40 mg once daily versus placebo	subjects who had carotid plaque but no symptoms of carotid artery disease	Factorial plan double-blind Sweden
<b>FLARE , 1999</b> n=409/425 follow-up: 40 weeks	fluvastatin 40 mg twice daily versus placebo	successful coronary balloon angioplasty	Parallel groups double blind
<b>HYRIM , 2005</b> n=283/285 follow-up: 4 year	fluvastatin 40 mg daily versus placebo	drug-treated hypertensive men aged 40-74 years with total cholesterol 4.5-8.0 mmol/L, triglycerides <4.5 mmol/L, body mass index 25-35 kg/m <sup>2</sup> , and a sedentary lifestyle	Factorial plan double blind Norway
<b>LCAS , 1997</b> n=164/157 follow-up: 2.5 years	fluvastatin 20 mg twice daily versus placebo	men and women aged 35 to 75 years with angiographic CHD and mean low-density lipoprotein (LDL) cholesterol of 115 to 190 mg/dl despite diet	Parallel groups double-blind
<b>LIPS , 2002</b> n=844/833 follow-up: 3.9 years	fluvastatin, 80 mg/d versus placebo	patients (aged 18-80 years) with stable or unstable angina or silent ischemia following successful completion of their first PCI who had baseline total cholesterol levels between 3.5-7.0 mmol/L and with fasting triglyceride levels of less than 4.5 mmol/L	Parallel groups double blind Europe, Canada, and Brazil
<b>Riegger et al. , 1999</b> n=187/178 follow-up: 1.0 years	fluvastatin 40 mg (o.a.d. or b.i.d.) versus placebo	hyperlipidaemic patients with symptomatic, clinically-diagnosed (exercise-ECG) coronary heart disease	Parallel groups double blind
<b>Czech trial ongoing</b> [NCT00171275] n=NA follow-up: 52 weeks	fluvastatin versus placebo	-	Parallel groups double blind

More details and results :

- cholesterol lowering intervention for cardiovascular prevention in patients with LDL elevation and without CHD at <http://www.trialresultscenter.org/go-Q5>
- 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 patients with prior MI or with CHD at <http://www.trialresultscenter.org/go-Q12>

- cholesterol lowering intervention for cardiovascular prevention in patients with other atherosclerotic localisation at <http://www.trialresultscenter.org/go-Q126>
- 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>
- statins for cardiovascular prevention in primary prevention at <http://www.trialresultscenter.org/go-Q688>
- statins for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q689>
- statins for cardiovascular prevention in hypertensive patients at <http://www.trialresultscenter.org/go-Q695>

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### **ALERT, 2003:**

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**Czech trial, :**

ongoing trial NCT00171275

## 2 hypertension

Trial	Treatments	Patients	Trials design and methods
<b>fluvastatin vs placebo</b>			
<b>HYRIM , 2005</b> n=283/285 follow-up: 4 year	fluvastatin 40 mg daily versus placebo	drug-treated hypertensive men aged 40-74 years with total cholesterol 4.5-8.0 mmol/L, triglycerides <4.5 mmol/L, body mass index 25-35 kg/m <sup>2</sup> , and a sedentary lifestyle	Factorial plan double blind Norway

More details and results :

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

## References

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## 3 acute coronary syndrome

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Trial	Treatments	Patients	Trials design and methods
<b>fluvastatin vs placebo</b>			
<b>LIPS (sub groups) , 2002</b> n=417/407 follow-up: 1, 4, and 6 months	Fluvastatin, 80 mg versus Placebo	patients with unstable angina and successful first percutaneous coronary intervention	Parallel groups double blind Europe, Canada, and Brazil
<b>FLORIDA , 2002</b> n=265/275 follow-up: 1, 4, and 6 months	Fluvastatin, 80 mg (early initiation) versus Placebo	patients with an AMI and total cholesterol of <6.5 mmol.l	Parallel groups double blind The Netherlands
<b>Czech trial ongoing</b> [NCT00171275] n=NA follow-up: 52 weeks	fluvastatin versus placebo	-	Parallel groups double blind

More details and results :

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

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Serruys PW, de Feyter P, Macaya C, Kokott N, Puel J, Vrolix M, Branzi A, Bertolami MC, Jackson G, Strauss B, Meier B Fluvastatin for prevention of cardiac events following successful first percutaneous coronary intervention: a randomized controlled trial. JAMA 2002 Jun 26;287:3215-22 [12076217]

### FLORIDA, 2002:

Liem AH, van Boven AJ, Veeger NJ, Withagen AJ, Robles de Medina RM, Tijssen JG, van Veldhuisen DJ Effect of fluvastatin on ischaemia following acute myocardial infarction: a randomized trial. Eur Heart J 2002;23:1931-7 [12473255]

### Czech trial, :

ongoing trial NCT00171275

## 4 diabetes type 2

Trial	Treatments	Patients	Trials design and methods
<b>fluvastatin vs placebo</b>			
LIPS (sub group) , 2002 n=120/82 follow-up: 3.9y	fluvastatin versus placebo	patients (aged 18-80 years) with stable or unstable angina or silent ischemia following successful completion of their first PCI who had baseline total cholesterol levels between 135 and 270 mg/dL	Parallel groups double blind
ALERT (sub group) , 2003 n=197/199 follow-up:	fluvastatin versus placebo	renal transplant recipients with total cholesterol 4090 mmol/L	Parallel groups 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>

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Serruys PW, de Feyter P, Macaya C, Kokott N, Puel J, Vrolix M, Branzi A, Bertolami MC, Jackson G, Strauss B, Meier B JAMA 2002;287:3215-22 [12076217]

### ALERT (sub group), 2003:

Holdaas H, Fellström B, Jardine AG, Holme I, Nyberg G, Fauchald P, Grnhagen-Riska C, Madsen S, Neumayer HH, Cole E, Maes B, Ambühl P, Olsson AG, Hartmann A, Solbu DO, Pedersen TR Effect of fluvastatin on cardiac outcomes in renal transplant recipients: a multicentre, randomised, placebo-controlled trial. Lancet 2003;361:2024-31 [12814712]

## 5 percutaneous coronary intervention

Trial	Treatments	Patients	Trials design and methods
<b>fluvastatin vs placebo</b>			
<b>FLARE , 1999</b> n=409/425 follow-up: 10 mo	Fluvastatin 40 mg twice daily 1530 d before PCI versus placebo	patients undergoing PTCA	double blind
<b>LIPS , 2002</b> n=844/833 follow-up: 45 mo (median)	Fluvastatin 40 mg twice daily 022 d after PCI versus placebo	patients with stable or unstable angina or silent ischemia and successful completion of their first PCI	double blind

More details and results :

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

### References

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Serruys PW, Foley DP, Jackson G, Bonnier H, Macaya C, Vrolix M, Branzi A, Shepherd J, Suryapranata H, de Feyter PJ, Melkert R, van Es GA, Pfister PJ A randomized placebo-controlled trial of fluvastatin for prevention of restenosis after successful coronary balloon angioplasty; final results of the fluvastatin angiographic restenosis (FLARE) trial. Eur Heart J 1999;20:58-69 [10075142]

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