

Clinical trials of fluvastatin

TrialResults-center www.trialresultscenter.org

1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
fluvastatin vs placebo			
ALERT , 2003 n=1050/1052 follow-up: 5.1 years	fluvastatin versus placebo	renal transplant recipients with total cholesterol 4090 mmol/L.	Parallel groups double blind
LIPS (diabetic 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 (diabetic sub group) , 2003 n=197/199 follow-up:	fluvastatin versus placebo	renal transplant recipients with total cholesterol 4090 mmol/L	Parallel groups double blind
LIPS (sub groups) , 2002 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
ALERT , 2003 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,
FLARE (elderly subgroup) , 1999 n=179/187 follow-up: 0.8y	-	CAD requiring PCI, subgroup of age 65-80 y	parallel groups double blind
FLORIDA , 2002 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

continued...

Trial	Treatments	Patients	Trials design and methods
LIPS (elderly subgroup) , 2002 n=324/299 follow-up: 3.9y	-	CAD requiring PCI, subgroup of age 65-80 y	parallel groups double blind
BCAPS , 2001 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
FLARE , 1999 n=409/425 follow-up: 40 weeks	fluvastatin 40 mg twice daily versus placebo	successful coronary balloon angioplasty	Parallel groups double blind
HYRIM , 2005 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 ² , and a sedentary lifestyle	Factorial plan double blind Norway
LCAS , 1997 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
LIPS , 2002 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
Riegger et al. , 1999 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
Czech trial ongoing [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 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 chronic 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>

3

References

ALERT, 2003:

Holdaas H, Fellstrom B, Jardine AG, Holme I, Nyberg G, Fauchald P, Gronhagen-Riska C, Madsen S, Neumayer HH, Cole E, Maes B, Ambuhl 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 Jun 14;361:2024-31 [12814712]

LIPS (diabetic sub group), 2002:

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 (diabetic 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, Ambuhl 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]

LIPS (sub groups), 2002:

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]

ALERT, 2003:

Holdaas H, Fellström B, Jardine AG, Holme I, Nyberg G, Fauchald P, Grnhagen-Riska C, Madsen S, Neumayer HH, Cole E, Maes B, Ambhl 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](#)]

FLARE (elderly subgroup), 1999:

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](#)]

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](#)]

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](#)]

LIPS (elderly subgroup), 2002:

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;287:3215-22 [[12076217](#)]

BCAPS, 2001:

Hedblad B, Wikstrand J, Janzon L, Wedel H, Berglund G Low-dose metoprolol CR/XL and fluvastatin slow progression of carotid intima-media thickness: Main results from the Beta-Blocker Cholesterol-Lowering Asymptomatic Plaque Study (BCAPS). *Circulation* 2001;103:1721-6 [[11282901](#)]

FLARE, 1999:

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](#)]

HYRIM, 2005:

Anderssen SA, Hjelstuen AK, Hjermmann I, Bjerkan K, Holme I *Atherosclerosis* 2005 Feb;178:387-97 [[15694949](#)]

LCAS, 1997:

Herd JA, Ballantyne CM, Farmer JA, Ferguson JJ 3rd, Jones PH, West MS, Gould KL, Gotto AM Jr Effects of fluvastatin on coronary atherosclerosis in patients with mild to moderate cholesterol elevations (Lipoprotein and Coronary Atherosclerosis Study [LCAS]). *Am J Cardiol* 1997;80:278-86 [[9264419](#)]

LIPS, 2002:

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; 287:3215-22 [[12076217](#)]

Riegger et al., 1999:

Riegger G, Abletshauser C, Ludwig M, Schwandt P, Widimsky J, Weidinger G, Welzel D The effect of fluvastatin on cardiac events in patients with symptomatic coronary artery disease during one year of treatment. *Atherosclerosis* 1999;144:263-70 [[10381299](#)]

Czech trial, :

ongoing trial NCT00171275

2 hypertension

Trial	Treatments	Patients	Trials design and methods
fluvastatin vs placebo			
HYRIM , 2005 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 ² , 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

HYRIM, 2005:

Anderssen SA, Hjelstuen AK, Hjermann I, Bjerkan K, Holme I Atherosclerosis 2005 Feb;178:387-97 [[15694949](#)]

CT

3 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
fluvastatin vs placebo			
LIPS (sub groups) , 2002 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
FLORIDA , 2002 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
Czech trial ongoing [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>

References

LIPS (sub groups), 2002:

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
fluvastatin vs placebo			
LIPS (diabetic 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 (diabetic 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>
- cholesterol lowering intervention for diabetes type 2 in secondary prevention at <http://www.trialresultscenter.org/go-Q721>

References

LIPS (diabetic sub group), 2002:

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 (diabetic 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, Ambhl 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
fluvastatin vs placebo			
FLARE , 1999 n=409/425 follow-up: 10 mo	Fluvastatin 40 mg twice daily 1530 d before PCI versus placebo	patients undergoing PTCA	double blind
LIPS , 2002 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

FLARE, 1999:

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]

LIPS, 2002:

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;287:3215-22 [12076217]

Entry terms: fluvastatin, fluindostatin, Lescol, XU 62-320, XU-62320, XU 62320, fluvastatin sodium, fluvastatin sodium salt,