

# Clinical trials of statin for percutaneous coronary intervention in all type of patients

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 pretreatment with statin

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>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
<b>various statins vs placebo</b>			
<b>Briguori , 2004</b> n=226/225 follow-up: <24h	physician preference 331 d before PCI versus placebo	-	

## 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, :**

**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, Gaspardone 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]

**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]

**Briguori, 2004:**

Briguori C, Colombo A, Airoidi F, Violante A, Focaccio A, Balestrieri P, Paolo Elia P, Golia B, Lepore S, Riviezzo G, Scarpato P, Librera M, Bonizzoni E, Ricciardelli B Statin administration before percutaneous coronary intervention: impact on periprocedural myocardial infarction. Eur Heart J 2004;25:1822-8 [15474697]

## 2 statins

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
<b>pravastatin vs placebo</b>			
<b>PREDICT , 1997</b> n=347/348 follow-up: 6 mo	Pravastatin 40 mg/d 1 d after PCI versus placebo	patient undergoing PCI	double blind
<b>atorvastatin vs usual care</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>GAIN , 2001</b> n=65/66 follow-up: 12 mo	Atorvastatin 2040 mg/d 1 d after PCI versus usual care	-	open

## 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](#)]

### PREDICT, 1997:

Bertrand ME, McFadden EP, Fruchart JC, Van Belle E, Commeau P, Grollier G, Bassand JP, Machecourt J, Cassagnes J, Mossard JM, Vacheron A, Castaigne A, Danchin N, Lablanche JM Effect of pravastatin on angiographic restenosis after coronary balloon angioplasty. The PREDICT Trial Investigators. Prevention of Restenosis by Elisor after Transluminal Coronary Angioplasty. *J Am Coll Cardiol* 1997;30:863-9 [[9316510](#)]

### GAIN, 2001:

Schartl M, Bocksch W, Koschik 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](#)]

## 3 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.