

# Clinical trials of antithrombotics for percutaneous coronary intervention in PCI with stent placement

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## 1 6 months DAPT

Trial	Treatments	Patients	Trials design and methods
<b>6-month dual antiplatelet therapy vs 12 months dual antiplatelet</b>			
<b>EXCELLENT , 2011</b> [NCT00698607] n=721/722 follow-up:	dual antiplatelet therapy for six months versus dual antiplatelet therapy for one year	patients with coronary artery disease	
<b>12 months dual antiplatelet vs 6 months dual antiplatelet</b>			
<b>ISAR-SAFE , 2009</b> [NCT00661206] n=NA follow-up: 12 months	additional 6 month period of clopidogrel versus placebo	Patients on clopidogrel therapy at least 6 months after DES implantation, who do not require a reintervention	Parallel groups double blind

## References

### EXCELLENT, 2011:

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Byrne RA, Schulz S, Mehilli J, Iijima R, Massberg S, Neumann FJ, ten Berg JM, Schmig A, Kastrati A Rationale and design of a randomized, double-blind, placebo-controlled trial of 6 versus 12 months clopidogrel therapy after implantation of a drug-eluting stent: The Intracoronary Stenting and Antithrombotic Regimen: Safety And Efficacy of 6 Months Dual Antiplatelet Therapy After Drug-Eluting Stenting (ISAR-SAFE) study. *Am Heart J* 2009 Apr;157:620-4.e2 [[19332187](#)] [10.1016/j.ahj.2008.12.019](#)

## 2 antiplatelet drugs

Trial	Treatments	Patients	Trials design and methods
<b>cilostazol vs aspirin</b>			
<b>Kunishima , 1997</b> n=30/40	Cilostazol 200 mg qD unspecified duration qD versus Aspirin 81 mg qD	-	

continued...

Trial	Treatments	Patients	Trials design and methods
<b>cilostazol + aspirin vs aspirin</b>			
Sekiya , 1998 n=63/63	Cilostazol 200 mg qD x6mos Aspirin 81 mg qD versus Coumadin unspecified regimen Aspirin 81 mg qD	-	
<b>ticlopidine + aspirin vs aspirin</b>			
STARS (vs aspirin) , 1998 n=546/557 follow-up:	Ticlopidine 250 mg BID 4 wks Aspirin 325 mg qD Dage/pj versus Aspirin 325 mg qD	-	
Hall , 1996 n=13/103	Ticlopidine 250 mg BID 1 mo Aspirin 325 mg qD 5 days versus Aspirin 325 mg qD	-	
<b>ticlopidine + aspirin vs coumadin + aspirin</b>			
STARS (vs coumadin+asp) , 1998 n=546/550 follow-up:	Ticlopidine 250 mg BID x4 wks Aspirin 325 mg qD versus Coumadin INR 22.5 x4 wks Aspirin 325 mg qDBID	-	
FANTASTIC , 1998 n=243/230	Ticlopidine 250 mg BID 6 wks Aspirin 100325 mg qD versus Coumadin INR 2.53.0 6 wks Aspirin 100325 mg qD/pj	-	
ISAR , 1996 n=257/260 follow-up:	Ticlopidine 250 mg BID 4 wks Aspirin 100 mg BIDage/pj versus Coumadin INR 3.54.5 4 wks Aspirin 100 mg BID	-	
MATTIS , 1998 n=177/173	Ticlopidine 250 mg BID 30 days Aspirin 250 mg qD versus Coumadin INR 2.53.0 x30 days Aspirin 250 mg qDg qD/pj	-	
Foussas , 2000 n=203/201	Ticlopidine 500mg qD 1 mo Aspirin 325 mg qD versus Coumadin INR 23 x4 wks Aspirin 325 mg qDg BID	-	
<b>cilostazol + aspirin vs ticlopidine + aspirin</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Kozuma , 2001 n=62/63	Cilostazol 200 mg qD x6 mos Aspirin 81mg mg qD versus Ticlopidine 200 mg qD x6 mos Aspirin 81mg mg qD	-	
Ochiai , 1999 n=25/25	Cilostazol 100 mg BID x6 mos Aspirin 81 mg TID versus Ticlopidine 100 mg BID x1 mo Aspirin 81 mg TID	-	
Park , 1999 n=247/243	Cilostazol 100 mg BID x6 mos Aspirin 200 mg qD versus Ticlopidine 250 mg BID x4 wks Aspirin 200 mg qD	-	
Yoon , 1999 n=147/149	Cilostazol 100 mg BID x30 days Aspirin 100 mg qD versus Ticlopidine 250 mg BID x30 days Aspirin 100 mg qD	-	
Kamishirado , 2002 n=65/65	Cilostazol 200 mg qD x6 mos Aspirin 81 mg qD versus Ticlopidine 200 mg qD x6 mos Aspirin 81 mg qD	-	
<b>clopidogrel + aspirin vs ticlopidine + aspirin</b>			
Mller , 2000 n=355/345	Clopidogrel 75 mg qD x4 wks Aspirin 100 mg qD versus Ticlopidine 250 mg BID x4 wks Aspirin 100 mg qD	-	
CLASSICS , 2000 n=345/340	Clopidogrel 300mg x1, 75 mg qD x4 wks Aspirin 325 mg qDyp versus Ticlopidine 250 mg BID x4 wks Aspirin 325 mg qD	-	
TOPPS , 2001 n=494/522	Clopidogrel 300 mg x1, unsp. Dose x2 wks Aspirin 325 mg qD versus Ticlopidine 500 mg x1, unsp. Dose x2 wks Aspirin 325 mg qD	-	
Piamsomboon , 2001 n=37/31	Clopidogrel 300 mg x1, 75 mg qD x4 wks Aspirin 300 mg BID x4 wks, 300 mg qD versus Ticlopidine 250 mg po BID x4 wks Aspirin 300 mg BID x4 wks, 300 mg qD	-	

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### 3 dual antiplatelet therapy

Trial	Treatments	Patients	Trials design and methods
<b>Monitoring Adjusted Antiplatelet Treatment vs Common Antiplatelet Treatment</b>			
<b>ARTIC adjusted</b> <i>ongoing</i> n=NA	-	-	
<b>high-dose clopidogrel vs normal-dose clopidogrel</b>			
<b>GRAVITAS, 2011</b> [NCT00645918] n=1109/1105 follow-up: 6 months	High-dose clopidogrel (600-mg initial dose, 150 mg daily thereafter) versus regular clopidogrel dose	patients receiving drug-eluting stents with high residual platelet activity (PRU $\geq$ 230) on the regular clopidogrel dose (platelet-function tests with the VerifyNow assay 12 to 24 hours after PCI)	Parallel groups open North America

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## 4 prolonged dual antiplatelet therapy

Trial	Treatments	Patients	Trials design and methods
<b>18 months dual antiplatelet vs 12 months dual antiplatelet</b>			
<b>ARTIC (extended dual antiplatelet) ongoing</b> [NCT00827411] n=NA follow-up:	Pursuit of a dual oral antiplatelet therapy (aspirin and clopidogrel) beyond one year versus Interruption of clopidogrel therapy after one year	-	
<b>prolonged dual antiplatelet therapy vs 12 months dual antiplatelet</b>			
<b>DES-LATE , 2010</b> [NCT00484926] n=1357/1344 follow-up: 19.2 mo	dual antiplatelet therapy (clopidogrel plus aspirin) versus aspirin alone	patients who had received drug eluting stents and had been free of major adverse cardiac or cerebrovascular events and major bleeding for a period of at least 12 months	Parallel groups open South Korea
<b>OPTIMIZED ongoing</b> n=NA	-	-	
<b>DAPT ongoing</b> [NCT00977938] n=20645 follow-up:	additional 18 months of thienopyridine treatment versus placebo	Subjects Undergoing Percutaneous Coronary Intervention With Either Drug-eluting Stent or Bare Metal Stent Placement for the Treatment of Coronary Artery Lesions	

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## References

**ARTIC (extended dual antiplatelet), 0:**

**DES-LATE, 2010:**

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**OPTIMIZED, :**

**DAPT, :**

Mauri L, Kereiakes DJ, Yeh RW, Driscoll-Shempp P, Cutlip DE, Steg PG, Normand SL, Braunwald E, Wiviott SD, Cohen DJ, Holmes DR Jr, Krucoff MW, Hermiller J, Dauerman HL, Simon DI, Kandzari DE, Garratt KN, Lee DP, Pow TK, Lee PV, Rinaldi MJ, Massaro JM Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents. N Engl J Med 2014 Nov 16;: [25399658] [10.1056/NEJMoa1409312](https://doi.org/10.1056/NEJMoa1409312)

## 5 prolonged dual antiplatelet therapy antiplatelet th

Trial	Treatments	Patients	Trials design and methods
<b>prolonged dual antiplatelet therapy vs 12 months dual antiplatelet</b>			

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Trial	Treatments	Patients	Trials design and methods
<b>DES-LATE , 2010</b> [NCT00484926] n=1357/1344 follow-up: 19.2 mo	dual antiplatelet therapy (clopidogrel plus aspirin) versus aspirin alone	patients who had received drug eluting stents and had been free of major adverse cardiac or cerebrovascular events and major bleeding for a period of at least 12 months	Parallel groups open South Korea
<b>OPTIMIZED</b> <i>ongoing</i> n=NA	-	-	
<b>DAPT</b> <i>ongoing</i> [NCT00977938] n=20645 follow-up:	additional 18 months of thienopyridine treatment versus placebo	Subjects Undergoing Percutaneous Coronary Intervention With Either Drug-eluting Stent or Bare Metal Stent Placement for the Treatment of Coronary Artery Lesions	

## References

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### DAPT, :

Mauri L, Kereiakes DJ, Yeh RW, Driscoll-Shempp P, Cutlip DE, Steg PG, Normand SL, Braunwald E, Wiviott SD, Cohen DJ, Holmes DR Jr, Krucoff MW, Hermiller J, Dauerman HL, Simon DI, Kandzari DE, Garratt KN, Lee DP, Pow TK, Lee PV, Rinaldi MJ, Massaro JM Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents. *N Engl J Med* 2014 Nov 16;: [25399658] [10.1056/NEJMoa1409312](#)

## 6 triple antiplatelet

Trial	Treatments	Patients	Trials design and methods
<b>triple antiplatelet vs dual antiplatelet therapy</b>			
<b>CILON-T , 2010</b> n=457/458 follow-up: 6 mo	triple antiplatelet therapy with aspirin, clopidogrel, and cilostazol for 6 month versus dual antiplatelet therapy	real-world patients undergoing PCI	Parallel groups

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## 7 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.