

Clinical trials of dual antiplatelet therapy for stent in all type of patients

TrialResults-center www.trialresultscenter.org

1 6 months DAPT

Trial	Treatments	Patients	Trials design and methods
6-month dual antiplatelet therapy vs 12 months dual antiplatelet			
EXCELLENT , 2011 [NCT00698607] n=721/722 follow-up:	dual antiplatelet therapy for six months versus dual antiplatelet therapy for one year	patients with coronary artery disease	
6 months DAPT vs 24 months DAPT			
ITALIC ongoing [NCT01476020] n=NA	-	-	
12 months dual antiplatelet vs 6 months dual antiplatelet			
ISAR-SAFE , 2009 [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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ITALIC, :

Gilard M, Barragan P, Noryani AA, Noor HA, Majwal T, Hovasse T, Castellant P, Schneeberger M, Maillard L, Bressolette E E, Wojcik J, Delarche N, Blanchard D, Jouve B, Ormezzano O, Paganelli F, Levy G, Sainsous J, Carrie D, Furber A, Berland J, Darremont O Six-month versus 24-month dual antiplatelet therapy after implantation of drug eluting stents in patients non-resistant to aspirin: ITALIC, a randomized multicenter trial. *J Am Coll Cardiol* 2014 Nov 16;: [[25461690](#)] [10.1016/j.jacc.2014.11.008](#)

ISAR-SAFE, 2009:

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 dual antiplatelet therapy

Trial	Treatments	Patients	Trials design and methods
clopidogrel+aspirin vs aspirin			
REAL-LATE, ZEST-LATE , 2010 [NCT00484926] n=1357/1344 follow-up: 19.2 months	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
Endeavor stent and three months of DAPT vs standard 12-month DAPT and other DES			
RESET [NCT01145079] n=NA follow-up:	-	-	-
Monitoring Adjusted Antiplatelet Treatment vs Common Antiplatelet Treatment			
ARTIC adjusted <i>ongoing</i> n=NA	-	-	-
high-dose clopidogrel vs normal-dose clopidogrel			
GRAVITAS , 2011 [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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References

REAL-LATE, ZEST-LATE, 2010:

Park SJ, Park DW, Kim YH, Kang SJ, Lee SW, Lee CW, Han KH, Park SW, Yun SC, Lee SG, Rha SW, Seong IW, Jeong MH, Hur SH, Lee NH, Yoon J, Yang JY, Lee BK, Choi YJ, Chung WS, Lim DS, Cheong SS, Kim KS, Chae JK, Nah DY, Jeon DS, Seung KB, Jang JS, Park HS, Le Duration of dual antiplatelet therapy after implantation of drug-eluting stents. *N Engl J Med* 2010;362:1374-82 [20231231] [10.1056/NEJMoa1001266](https://doi.org/10.1056/NEJMoa1001266)

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GRAVITAS, 2011:

Price MJ, Berger PB, Teirstein PS, Tanguay JF, Angiolillo DJ, Spriggs D, Puri S, Robbins M, Garratt KN, Bertrand OF, Stillablower ME, Aragon JR, Kandzari DE, Stinis CT, Lee MS, Manoukian SV, Cannon CP, Schork NJ, Topol EJ Standard- vs high-dose clopidogrel based on platelet function testing after percutaneous coronary intervention: the GRAVITAS randomized trial. *JAMA* 2011 Mar 16;305:1097-105 [21406646] [10.1001/jama.2011.290](https://doi.org/10.1001/jama.2011.290)

3 prolonged dual antiplatelet therapy

Trial	Treatments	Patients	Trials design and methods
24 months of dual antiplatelet treatment vs 6 months dual antiplatelet			
PRODIGY , 2011 [NCT00611286] n=NA follow-up: 2 years	24 months of dual antiplatelet treatment (clopidogrel plus aspirin) versus 6 months of dual antiplatelet treatment (clopidogrel plus aspirin)	patients (74 with acute coronary syndromes and 26 with stable angina) who underwent stenting	Parallel groups open
18 months dual antiplatelet vs 12 months dual antiplatelet			
ARTIC (extended dual antiplatelet) <i>ongoing</i> [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	-	
prolonged dual antiplatelet therapy vs 12 months dual antiplatelet			
DES-LATE , 2010 [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
OPTIMIZED <i>ongoing</i> n=NA	-	-	
DAPT <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

PRODIGY, 2011:

Valgimigli M, Campo G, Monti M, Vranckx P, Percoco G, Tumscitz C, Castriota F, Colombo F, Tebaldi M, Fuc G, Kubbajeh M, Cangiano E, Minarelli M, Scalone A, Cavazza C, Frangione A, Borghesi M, Marchesini J, Parrinello G, Ferrari R Short- versus long-term duration of dual-antiplatelet therapy after coronary stenting: a randomized multicenter trial. *Circulation* 2012;125:2015-26 [22438530] [10.1161/CIRCULATIONAHA.111.071589](https://doi.org/10.1161/CIRCULATIONAHA.111.071589)

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OPTIMIZED, :

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Trial	Treatments	Patients	Trials design and methods
prolonged dual antiplatelet therapy vs 12 months dual antiplatelet			
DES-LATE , 2010 [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
OPTIMIZED <i>ongoing</i> n=NA	-	-	
DAPT <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	

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DES-LATE, 2010:

Park SJ, Park DW, Kim YH, Kang SJ, Lee SW, Lee CW, Han KH, Park SW, Yun SC, Lee SG, Rha SW, Seong IW, Jeong MH, Hur SH, Lee NH, Yoon J, Yang JY, Lee BK, Choi YJ, Chung WS, Lim DS, Cheong SS, Kim KS, Chae JK, Nah DY, Jeon DS, Seung KB, Jang JS, Park HS, Le Duration of Dual Antiplatelet Therapy after Implantation of Drug-Eluting Stents. *N Engl J Med* 2010 Mar 15;: [20231231] [10.1056/NEJMoa1001266](https://doi.org/10.1056/NEJMoa1001266)

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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 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.

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