

Clinical trials of Drug eluting stent for coronary artery disease in all type of patients

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1 abciximab-coated stent

Trial	Treatments	Patients	Trials design and methods
abciximab-coated stent vs bare-metal stent			
Kim , 2010 n=93 follow-up: 6 mo (2y)	abciximab-coated stent versus bare metal stents	patients undergoing PCI for de novo coronary lesions	Parallel groups open Korea

References

Kim, 2010:

Kim SS, Hong YJ, Jeong MH, Kim W, Kim HK, Ko JS, Lee MG, Sim DS, Park KH, Yoon NS, Yoon HJ, Kim KH, Park HW, Kim JH, Ahn Y, Cho JG, Park JC, Song SJ, Cho DL, Kang JC Two-year clinical outcome after abciximab-coated stent implantation in patients with coronary artery disease. *Circ J* 2010;74:442-8 [20103970]

2 bioabsorbable polymer stent

Trial	Treatments	Patients	Trials design and methods
biodegradable-polymer vs BMS			
PAINT (sirolimus) , 2009 [NCT00752362] n=NA follow-up: 12 mo (angiography 9 mo)	biodegradable-polymer sirolimus-eluting (Supralimus) versus bare metal stent (matrix)	patients with de novo coronary lesions in native vessels scheduled for stent implantation	Parallel groups open
biolimus eluting stent vs sirolimus eluting stent			
LEADERS , 2008 [NCT00389220] n=857/850 follow-up: 9 months	BioMatrix III (biolimus-eluting stent with biodegradable polymer) versus Cypher SELECT (sirolimus-eluting stent with durable polymer)	patients aged 18 years or older with chronic stable coronary artery disease or acute coronary syndromes	Parallel groups open assessor-blind Europe
sirolimus biodegradable polymer vs sirolimus eluting stent			
ISAR TEST 3 (BP) , 2009 n=202/202 follow-up: 12 months	biodegradable-polymer 0.4% rapamycin stent (180 mg rapamycin/cm2) versus permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2)	Patients with de novo coronary lesions in native vessels	Parallel groups open Germany

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Trial	Treatments	Patients	Trials design and methods
ISAR-TEST-4 (biodegradable polymer) , 2009 [NCT00598676].] n=1299/1304 follow-up: 12 mo	biodegradable polymer rapamycin-eluting stent versus permanent polymer-based rapamycin-eluting or everolimus-eluting	patients with stable coronary disease or acute coronary syndromes with de novo native-vessel stent implantation	Parallel groups open Germany

References

PAINT (sirolimus), 2009:

Lemos PA, Moulin B, Perin MA, Oliveira LA, Arruda JA, Lima VC, Lima AA, Caramori PR, Medeiros CR, Barbosa MR, Brito FS Jr, Ribeiro EE, Martinez EE Randomized evaluation of two drug-eluting stents with identical metallic platform and biodegradable polymer but different agents (paclitaxel or sirolimus) compared against bare stents: 1-year results of the PAINT trial. *Catheter Cardiovasc Interv* 2009;74:665-73 [[19670303](#)]

LEADERS, 2008:

Windecker S, Serruys PW, Wandel S, Buszman P, Trznadel S, Linke A, Lenk K, Ischinger T, Klauss V, Eberli F, Corti R, Wijns W, Morice MC, di Mario C, Davies S, van Geuns RJ, Eerdmans P, van Es GA, Meier B, Jni P Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomised non-inferiority trial. *Lancet* 2008 Aug 31;: [[18765162](#)]

Stefanini GG, Kalesan B, Serruys PW, Heg D, Buszman P, Linke A, Ischinger T, Klauss V, Eberli F, Wijns W, Morice MC, Di Mario C, Corti R, Antoni D, Sohn HY, Eerdmans P, van Es GA, Meier B, Windecker S, Jni P Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4 year follow-up of a randomised non-inferiority trial. *Lancet* 2011 Dec 3;378:1940-8 [[22075451](#)] [10.1016/S0140-6736\(11\)61672-3](#)

ISAR TEST 3 (BP), 2009:

ISAR-TEST-4 (biodegradable polymer), 2009:

3 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
A vs B			
Nordic Bifurcation Study <i>ongoing</i> [NCT00376571] n=NA follow-up:	Strategy of Routine Stenting Both Main Vessel and Side Branch versus Strategy of Routine Main Vessel Stenting and Optional Treatment of Side Branch	bifurcation lesions	
paclitaxel eluting stent vs balloon angioplasty			
ISAR-DESIRE (PES vs PTCA) , 2005 n=100/100 follow-up: 1y	TAXUS versus ballon angioplasty	In-stent restenosis. AP and/or positive test, previously stented, no AMI	Parallel groups open germany
sirolimus eluting stent vs balloon angioplasty			
ISAR-DESIRE (SES vs PTCA) , 2005 n=100/100 follow-up: 1y	Cypher versus ballon angioplasty	In-stent restenosis. AP and/or positive test, previously stented, no AMI	Parallel groups open germany

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Trial	Treatments	Patients	Trials design and methods
dactinomycin eluting stent vs bare-metal stent			
ACTION , 2004 n=241/119 follow-up: 6 months	Multilink Tetra stent versus uncoated Multilink Tetra stent	Patients with stable angina pectoris or silent ischemia and a single de novo lesion in a native coronary artery ≥ 3.0 mm and ≤ 4.0 mm in diameter that could be covered by an 18-mm stent	Parallel groups single-blind worldwide
dexamethasone eluting stent vs bare-metal stent			
FEMH-93005 <i>ongoing</i> [NCT00190099] n=NA	-	-	
drug-eluting stents vs bare-metal stent			
PASEO , 2009 n=180/90 follow-up: 4.3 years	paclitaxel-eluting stents and sirolimus-eluting stents versus bare metal stent	patients with ST-elevation myocardial infarction within 12 hours from symptom onset	Parallel groups open
ISAR-CABG <i>ongoing</i> [NCT00611910] n=NA follow-up:	DES versus BMS	Bypass Graft Lesions	open
everolimus eluting stent vs bare-metal stent			
BASKET-PROVE (EES) , 2010 [ISRCTN72444640] n=774/765 follow-up: 2 years	second generation everolimus-eluting stent versus BMS	patients needing stents 3.0 mm or larger	open Switzerland, Denmark, Austria, Italy
FUTURE I , 2004 n=27/15 follow-up: 12 months	everolimus coated S-Stent versus S-Stent	de novo coronary lesions	Parallel groups single-blind Germany
FUTURE II , 2006 <i>unpublished</i> n=43/21 follow-up: 6 months	CHAMPION versus bare-metal stent	Patients with de novo lesions in vessels with a reference diameter of 2.75-4.0 mm and length ≤ 18 mm	Parallel groups double-blind
SPIRIT I , 2005 [NCT00180453] n=28/32 follow-up: 6 months (5yr)	everolimus eluting stent, XIENCE versus bare metal stent, MULTI-LINK VISION	patients with de novo native coronary artery lesions	Parallel groups single-blind
Genous stent vs bare-metal stent			
GENIUS-STEMI , 2009 n=50/50 follow-up: 6 months	endothelial progenitor cell capture stent versus cobalt chromium stent	patients with ST-elevation myocardial infarction	Parallel groups NA
TRIAS-Low-Risk <i>ongoing</i> n=NA	-	-	
paclitaxel eluting stent vs bare-metal stent			

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Trial	Treatments	Patients	Trials design and methods
Erglis , 2007 n=53/50 follow-up: 6 months	IVUS-guided paclitaxel-eluting stent (Taxus Express) after lesion pre-treatment with cutting balloon versus IVUS-guided bare-metal (Express or Liberte) after lesion pre-treatment with cutting balloon	percutaneous coronary intervention for unprotected left main artery stenosis	Parallel groups open
HAAMU-STENT , 2006 <i>unpublished</i> n=70/75 follow-up: 12 months	Taxus Express versus Bare-metal-stent	AMI - STEMI patients undergoing PCI	Parallel groups open Finland
HORIZONS-AMI Stent , 2008 n=2257/749 follow-up: 1 year	paclitaxel-eluting stents (Taxus) versus BMS (Express)	ST-elevation myocardial infarction	Factorial plan open
PASSION , 2006 [ISRCTN65027270] n=310/309 follow-up: 12 months (5y)	Taxus Express2 versus Express2 or Libert	Myocardial Infarction with ST-Segment Elevation	Parallel groups open The Netherlands
SCORE , 2004 n=126/140 follow-up: 12 months	QuaDDS stents (paclitaxel) versus uncoated control stents	patients with focal, de novo coronary lesions	Parallel groups open Worldwide
TAXUS I , 2003 n=31/30 follow-up: 12 months	TAXUS NIR versus NIR stent	Stable or unstable AP, silent ischaemia; single de novo or restenotic coronary lesions	Parallel groups double-blind Germany
TAXUS II , 2003 [NCT00299026] n=266/270 follow-up: 12 months	TAXUS versus NIR stent	Stable or unstable AP, silent ischaemia; single de novo target lesion with estimated stenosis >50% and <99% ,	Parallel groups double-blind Global
TAXUS IV , 2004 [NCT00292474] n=662/652 follow-up: 9 months	TAXUS versus EXPRESS	Stable or unstable AP, provokable ischaemia with a single, previously untreated coronary-artery stenosis (vessel diameter, 2.5 to 3.75 mm; lesion length, 10 to 28 mm)	Parallel groups double-blind United States
TAXUS V (all patients) , 2005 [NCT00301522] n=577/579 follow-up: 9 months	TAXUS versus bare metal EXPRESS-2	Stable or unstable AP, silent ischaemia with single coronary artery stenosis including complex or previously unstudied lesions (requiring 2.25-mm, 4.0-mm, and/or multiple stents)	Parallel groups double-blind United States
TAXUS VI , 2005 [NCT00297804] n=219/227 follow-up: 9 months (2y)	TAXUS versus Express2 stent	Stable or unstable AP, silent ischaemia with long, complex coronary artery lesions	Parallel groups double-blind Europe

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Trial	Treatments	Patients	Trials design and methods
BASKET-SAVAGE <i>ongoing</i> [NCT00595647] n=NA follow-up:	Taxus versus Libert	percutaneous coronary interventions of saphenous vein grafts	open
sirolimus eluting stent vs bare-metal stent			
BASKET-PROVE (SES) , 2010 [ISRCTN72444640] n=775/765 follow-up: 2 years	first-generation sirolimus-eluting stent versus BMS	patients needing stents 3.0 mm or larger	Parallel groups open Switzerland, Denmark, Austria, Italy
C-SIRIUS , 2004 [NCT00381420] n=50/50 follow-up: 9 months	coated Bx-VELOCITY versus Bx-VELOCITY	Stable or unstable AP, silent ischaemia	Parallel groups double-blind Canada
DEBATER (SES vs BMS) , 2009 n=424/446 follow-up: 1 y	sirolimus-eluting stents versus bare-metal stents	patients undergoing PCI for STEMI withon 12 hours	Factorial plan
DECODE , 2005 <i>unpublished</i> [NCT00489164] n=54/29 follow-up: 1 year	CYPHER (Up to 3 stents per patient were allowed) versus Bx VELOCITY (Up to 3 stents per patient were allowed)	Stable or unstable angina in diabetic patients with with up to 2 de novo lesions in up to 2 native coronary vessels	Parallel groups open US, Asia/Pacific
DIABETES , 2005 n=80/80 follow-up: 9 months	Cypher versus Bx Velocity/Sonic	de novo lesions in native coronary arteries in 1, 2, or 3 native vessels with symptoms or objective evidence of ischemia; vessel size smaller than 4.0 mm	Parallel groups open Spanish
E-SIRIUS , 2003 [NCT00235144] n=175/177 follow-up: 9 months	coated Bx Velocity versus Bx Velocity	Stable or unstable AP, silent ischaemia; single-vessel or multivessel coronary disease but with only one new lesion with an estimated stenosis of more than 50% but less than 100% in a major native coronary artery requiring treatment	Parallel groups open Europe
GISSOC II , 2010 [NCT00220558] n=78/74 follow-up: 8 months	Sirolimus Eluting Stent versus Bare Metal Stent	patients with Chronic Total Occlusion older than 1 month, and successful recanalization	Parallel groups open Italy
Kochiadakis , 2007 n=38/43 follow-up: 4.8 months (mean)	sirolimus-eluting stents versus bare metal stent	one-vesseldisease (>70% narrowing of the lumen of one major epicardialcoronary artery); stable coronary artery disease, age <70 years, and vessel referencediameter >=2.5 mm	Parallel groups open Greece
MISSION , 2008 [ISRCTN62825862] n=158/152 follow-up: 12 months	Cypher versus Vision	primary percutaneous coronary intervention for ST-segment elevation myocardial infarction (<9h)	Parallel groups single-blind the Netherlands

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Trial	Treatments	Patients	Trials design and methods
Ortolani et al , 2007 n=NA follow-up: 9 months	Cypher versus Vision	symptomatic coronary artery disease and target vessel diameter appropriate for implantation a 3-mm stent	Parallel groups single-blind
Pache et al , 2005 n=250/250 follow-up: 12 months	Cypher versus BeStent 2	with symptomatic coronary artery disease and significant angiographic stenosis in native coronary vessels	Parallel groups open Germany
Pasceri , 2003 <i>unpublished</i> n=NA follow-up: 12 months	-	-	Parallel groups
PRISON II , 2006 [NCT00258596] n=100/100 follow-up: 6 months	Cypher versus BxVelocity	Chronic total occlusion, positive exercise stress test	Parallel groups single-blind Belgium
RAVEL , 2002 [NCT00233805] n=120/118 follow-up: 12 months	coated Bx Velocity versus Bx Velocity	Stable or unstable AP, silent ischaemia; single primary target lesion in a native coronary artery	Parallel groups double-blind Global
SCANDSTENT , 2006 [NCT00151658] n=163/159 follow-up: 7 months	Cypher versus Sonic	Stable or unstable AP, recent AMI (non ST-elevation); with one or more de novo complex lesions in native coronary vessels (occluded, bifurcational, ostial or angulated)	Parallel groups open Denmark
SCORPIUS , 2007 [NCT00495898] n=98/102 follow-up: 12 months	Cypher versus Bx-Velocity	patients with diabetes and de novo coronary artery lesions	Parallel groups open Germany
SES-SMART , 2004 n=129/128 follow-up: 8 months	Cypher versus Bx Sonic	Stable AP, ACS, silent myocardial ischaemia as shown by exercise stress test	Parallel groups single-blind Italian
SESAMI , 2007 [NCT00288210] n=160/160 follow-up: 12 months	Cypher versus BX stent, Cordis	AMI	Parallel groups open Italy
SIRIUS , 2003 [NCT00232765] n=533/525 follow-up: 9 months	SES versus Bx Velocity	Stable or unstable AP, signs of myocardial ischaemia	Parallel groups double-blind United States
TYPHOON , 2006 [NCT00232830] n=356/359 follow-up: 12 months	Cypher or CypherSelect versus any commerciallyavailable uncoated stent	AMI	Parallel groups open Worldwide (15 countries)
BASKET-PROVE , 2008 <i>ongoing</i> n=NA follow-up:	Cypher versus Vision	-	

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Trial	Treatments	Patients	Trials design and methods
zotarolimus eluting stent vs bare-metal stent			
ENDEAVOR II , 2006 n=598/599 follow-up: 12 months	AVE Zotarolimus-Eluting Driver versus Driver	single de novo native coronary artery stenosis	Parallel groups double-blind worldwide
crush stenting vs culotte stenting			
Nordic Bifurcation Stent Technique Study <i>ongoing</i> [NCT00292305] n=NA follow-up:	crush stenting versus culotte stenting	bifurcation lesions	
sirolimus eluting stent vs cutting ballon angioplasty			
FOCUS <i>ongoing</i> [NCT00485004] n=NA follow-up:	sirolimus-eluting implantation cypher versus cutting balloon angioplasty	focal in-stent restenosis after drug-eluting stent	
bioabsorbable polymer EES vs everolimus eluting stent			
EVOLVE , 2012 [NCT01135225] n=NA follow-up: 30 days	bioabsorbable polymer everolimus-eluting stent versus polymer EES	patients with a de novo lesion 28 mm in length, in a coronary artery of 2.25 to 3.5 mm diameter	Parallel groups single blind
Nevo vs paclitaxel eluting stent			
NEVO RES-ELUTION I [NCT00714883] n=202/194 follow-up: 6 months	Nevo sirolimus eluting stent with bioresorbable PLGA polymer versus paclitaxel eluting stent (Libert)	patients with single, de novo lesions	Parallel groups open Europe, Brazil, Australia, and New Zealand
DES vs CABG			
Boudriot , 2008 n=83/84 follow-up: 12 months	DES versus CABG	-	Parallel groups open
drug-eluting stents vs CABG			
Leipzig <i>ongoing</i> [NCT00176397] n=NA follow-up:	PCI With DES versus CABG	left main coronary stenosis	
paclitaxel eluting stent vs CABG			
SYNTAX , 2009 [NCT00114972] n=903/897 follow-up: 1 year	paclitaxel (taxus Express SR) versus Coronary Artery Bypass Surgery (on- or off-pump bypass)	patients with previously untreated three-vessel or left main coronary artery disease (or both) (complex lesions)	Parallel groups open
PCI vs CABG			
COMBAT <i>ongoing</i> n=NA	PCI versus CABG	-	

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Trial	Treatments	Patients	Trials design and methods
Korean Randomized Study <i>ongoing</i> n=NA	PCI versus CABG	-	
REVASCULARIZE <i>ongoing</i> n=NA	PCI versus CABG	-	
sirolimus eluting stent vs CABG			
PRECOMBAT , 2011 [NCT00422968] n=300/300 follow-up:	PCI with sirolimus-eluting stents versus CABG	patients with unprotected left main coronary artery stenosis	
MIDCAB Versus DES in Proximal LAD Lesions <i>ongoing</i> [NCT00299429] n=NA follow-up:	sirolimus-coated stent versus minimally invasive bypass surgery	patients with isolated proximal left anterior descending coronary arteries	
Munich Study <i>ongoing</i> n=NA	sirolimus versus CABG	-	
everolimus eluting stent vs everolimus eluting stent			
PLATINUM , 2011 [NCT00823212] n=768/762 follow-up: 12 months	platinum chromium everolimus-eluting stent versus cobalt chromium everolimus-eluting stent	patients with up to 2 de novo atherosclerotic coronary artery lesions	Parallel groups single-blind worldwide
zotarolimus eluting stent vs everolimus eluting stent			
RESOLUTE All comers , 2010 [NCT00617084.] n=1140/1152 follow-up: 12 months (5y)	zotarolimus-eluting stent versus everolimus-eluting stent (Xience)	adult patients with chronic, stable coronary artery disease or acute coronary syndromes, including myocardial infarction with or without ST-segment elevation	Parallel groups open
TWENTE , 2012 [NCT01066650] n=NA follow-up: 1 year	zotarolimus-eluting stent versus everolimus-eluting stent	"real-world" patients	Parallel groups single (patient-blinded)
sirolimus eluting stent vs Firebird eluting stent			
Gao <i>ongoing</i> [NCT00887211] n=NA follow-up:	ProStent rapamycin-eluting stent system versus Firebird drug-eluting stents	-	Parallel groups single blind
paclitaxel eluting stent vs medical treatment			
VELETI <i>ongoing</i> [NCT00289835] n=NA follow-up:	TAXUS versus standard medical treatment	Moderate Vein Graft Lesions	

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Trial	Treatments	Patients	Trials design and methods
CoStar stent vs paclitaxel eluting stent			
CoStar II , 2008 [NCT00165035] n=989/686 follow-up: 8 months (1 year)	CoStar stent (Conor MedSystems) PES versus Taxus (Boston Scientific) PES	patient undergoing percutaneous coronary intervention for a single lesion per vessel in up to three native epicardial vessels	Parallel groups single-blind US, Germany, Belgium, and New Zealand
everolimus eluting stent vs paclitaxel eluting stent			
COMPARE , 2009 [NCT01016041] n=897/903 follow-up: 1 y (2y)	polymer based, everolimus-eluting stent (Xience V) versus polymer-based, paclitaxel-eluting stent (Taxus Liberte)	unselected patients	Parallel groups open the Netherlands
SPIRIT II , 2006 <i>unpublished</i> [NCT00180310] n=223/77 follow-up: 6 months	everolimus eluting stent, XIENCE V versus paclitaxel eluting stent, TAXUS EXPRESS2	De novo lesions (maximim two)	Parallel groups single-blind (patient)
SPIRIT III , 2008 [NCT00180479] n=669/333 follow-up: 12 months	everolimus-eluting stent, XIENCE V versus paclitaxel-eluting stent, Taxus	lesions 28 mm or less in length and with reference vessel diameter between 2.5 and 3.75 m	Parallel groups single-blind US
SPIRIT IV , 2010 [NCT00307047] n=2458/1229 follow-up: 1 y (2y)	XIENCE V Everolimus Eluting Coronary Stent System versus TAXUS EXPRESS2 Paclitaxel Eluting Coronary Stent System (TAXUS).	patients with de novo native coronary artery lesions and reference vessel diameters between 2.5 mm to 4.25 mm and lesion lengths <= 28 mm	Parallel groups 270 days (5 years) USA
Genous stent vs paclitaxel eluting stent			
TRIAS-HR , 2008 <i>unpublished</i> [ISRCTN74297220] n=98/95 follow-up: 12 months	Genous stent (antibody-coated bare-metal stent) followed by one month of dual antiplatelet therapy versus Taxus or Cypher followed by at least six months of dual antiplatelet therapy	high-risk patients (long lesions, small vessels, chronic total occlusions, or any lesion in a diabetic patient)	Parallel groups single-blind
paclitaxel eluting balloon vs paclitaxel eluting stent			
PEPCAD IV <i>ongoing</i> [NCT00462631] n=NA follow-up:	Paclitaxel-eluting PTCA-balloon dilation (SeQuent™ Please) followed by cobalt-chromium stent (Coroflex™ Blue) deployment versus Taxus Libert	patients with diabetes mellitus	open
paclitaxel eluting stent vs paclitaxel eluting stent			
PERSEUS Workhorse , 2010 <i>ongoing</i> [NCT00484315] n=NA follow-up:	platinum-chromium alloy, paclitaxel-eluting stent TAXUS Element versus paclitaxel-eluting stent TAXUS Express 2	De Novo Coronary Artery Lesions; stent patients with lesions <28 mm in length in coronary vessels between 2.75 mm and 4.0 mm in diameter	
sirolimus eluting stent vs paclitaxel eluting stent			

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Trial	Treatments	Patients	Trials design and methods
BASKET (vs paclitaxel) , 2005 n=264/281 follow-up: 6 months	Cypher versus Taxus	Unselected patients; de-novo lesions	Parallel groups open Switzerland,
Cervinka , 2006 n=37/33 follow-up: 6 months	sirolimus-eluting stent versus paclitaxel-eluting stent	Complex lesions and patients. Signs and/or symptoms myocardial ischaemia, including AMI	Parallel groups open
CORPAL , 2005 <i>unpublished</i> n=331/321 follow-up:	sirolimus versus paclitaxel	Documented myocardial ischaemia, no AMI	Parallel groups open Spain
DES-DIABETES , 2008 n=200/200 follow-up: 9 months (1 year)	sirolimus-eluting stent versus paclitaxel-eluting stent	diabetic patients with angina pectoris and/or a positive stress test and a native coronary lesion	Factorial plan open Korea
Di Lorenzo et al. , 2005 <i>unpublished</i> n=90/90 follow-up:	sirolimus versus paclitaxel	ST-segment elevation myocardial infarction	Parallel groups open
Han , 2006 n=210/206 follow-up: 19.5 months (mean)	Cypher versus Taxus	Multivessel disease. Stable or unstable AP, no AMI	Parallel groups open China
ISAR-DESIRE (SES vs PES) , 2005 n=100/100 follow-up: 1y	Cypher versus Taxus	In-stent restenosis. AP and/or positive test, previously stented, no AMI	Parallel groups open germany
ISAR-DIABETES , 2005 n=125/125 follow-up: 9 months	Taxus versus Cypher	Diabetic patients. AP or positive stress, no AMI with clinically significant angiographic stenosis in a native coronary vessel	Parallel groups open Germany
ISAR-LEFT-MAIN , 2009 [NCT00133237] n=302/305 follow-up: 1 year	Paclitaxel-eluting stent versus Sirolimus-eluting stent	Unprotected Left Main Coronary Artery Disease	Parallel groups open
ISAR-SMART 3 , 2006 [NCT00146575] n=180/180 follow-up:	Taxus versus Cypher	Small vessels, de novo lesions in native coronary vessels with a diameter of <2.80 mm nondiabetic patients. AP or positive stress, no AMI	Parallel groups NA Germany
ISAR-TEST-1 , 2006 [NCT00140530] n=225/225 follow-up: 9 months	rapamycin-eluting stent Yukon versus Taxus	stable or unstable angina or a positive stress test, stable or unstable angina or a positive stress test	Parallel groups open Germany

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Trial	Treatments	Patients	Trials design and methods
Kim , 2008 n=85/84 follow-up: 6 months	Cypher versus Taxus	Korean diabetic patients with high-grade de novo coronary lesions (stenosis of >70 percent of the luminal diameter) requiring <3 stents	Parallel groups open Korea
LONG DES II , 2006 n=250/250 follow-up: 9 months	SES versus PES	Long lesions. AP or positive stress, no AMI	Parallel groups single-blind Korea
Pan , 2007 n=103/102 follow-up: 24 months (mean)	SES for provisional T-stenting versus PES for provisional T-stenting	patients with bifurcation lesions	Parallel groups open Spain
Petronio et al , 2007 n=50/50 follow-up: 9 months	Cypher versus Taxus	Complex lesions. Stable AP or documented ischaemia, no AMI	Parallel groups open Italy
PROSIT , 2006 n=154/154 follow-up: 1 year	SES Cordis versus PES Boston Scientific	AMI or persistent ischaemia 12-24h	Parallel groups open Korea
REALITY , 2006 [NCT00235092] n=701/685 follow-up: 12 months	Cypher versus Taxus	Relatively unselected patients. Stable or unstable documented silent ischaemia, no AMI with 1 or 2 de novo lesions (2.25-3.00 mm in diameter) in native coronary arteries	Parallel groups open Europe, Latin America, and Asiam
SIRTAX (Windecker) , 2005 n=503/509 follow-up: 9 mo (5y)	sirolimus-eluting stents (Cypher) versus paclitaxel-eluting stents (Taxus)	Unselected patients. Stable AP, ACS, including AMI. at least one lesion with stenosis of at least 50 percent in a vessel with a reference diameter between 2.25 and 4.00 mm that was suitable for stent implantation	Parallel groups single-blind Switzerland
SORT OUT II , 2008 [NCT00388934] n=1065/1033 follow-up:	Cypher stent versus Taxus stent(Boston Scientific Corp)	Unselected patients (included ST-segment elevation myocardial infarction (STEMI), non-STEMI or unstable angina pectoris, and stable angina)	Parallel groups open Denmark.
TAXi , 2005 n=102/100 follow-up: 6 months	Cypher versus Taxus	Unselected patients	Parallel groups open Switzerland.
Tomai , 2008 n=60/60 follow-up: 8 months	sirolimus-eluting stent versus paclitaxel-eluting stent	diabetic patient with multiple de novo coronary artery lesions	Cross over NA Italy
Zhang (SES vs PES) , 2006 n=246/203 follow-up: 1y	Cypher versus Taxus	Unselected patients. Stable or unstable AP, ACS with de novo coronary lesions	Parallel groups open China

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Trial	Treatments	Patients	Trials design and methods
DES-ISR <i>ongoing</i> [NCT00485030] n=NA follow-up:	Cypher versus Taxus	patients Diffuse Type In-Stent Restenosis After Drug-Eluting Stents Implantation	
Lipsia-Yukon-DM <i>ongoing</i> [NCT00368953] n=NA follow-up: 9 months	Yukon Choice stent system versus Taxus Libert stent system	Patients With Diabetes Mellitus	
zotarolimus eluting stent vs paclitaxel eluting stent			
ENDEAVOR IV , 2009 <i>unpublished</i> [NCT00217269] n=773/775 follow-up: mean 36 mo	zotarolimus-eluting stent (Endeavor) versus paclitaxel-eluting stent (Taxus)	single de novo lesions in native coronary arteries with a reference vessel diameter of 2.5-3.5 mm	Parallel groups open US
ZEST (vs PES) , 2009 [NCT00418067] n=883/884 follow-up: 1 year	zotarolimus-eluting stents versus paclitaxel-eluting stents	Patients with coronary artery disease	NA
ZEST AMI (vs PES) , 2009 [NCT00422565] n=108/110 follow-up: 1 year (mean)	zotarolimus-eluting stent (Endeavor) versus paclitaxel-eluting stent (Taxus Libert)	Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours	open Korea
ZoMaxx I , 2008 n=199/197 follow-up: 9 months	ZoMaxx zotarolimus-eluting stent versus Taxus paclitaxel-eluting stent	patients with single de novo coronary lesions and with lesion length 10-30 mm and reference vessel diameter 2.5-3.5 mm	Parallel groups open
ZoMaxx phase 2 <i>ongoing</i> [NCT00140101] n=NA follow-up:	ZoMaxx drug-eluting stent versus TAXUS Express2	de Novo Coronary Artery Lesions	
pimecrolimus eluting stent vs pimecrolimus paclitaxel			
GENESIS Trial CP-01 <i>ongoing</i> [NCT00322569] n=NA follow-up: 6 months	Corio Pimecrolimus versus CoStar	patients with de novo lesions of the native coronary arteries	
dual sirolimus, probucol eluting stent vs sirolimus eluting stent			
ISAR TEST 2 (vs SES) , 2009 [NCT00332397] n=333/335 follow-up: 12 months	dual DES (polymer-free stent consisting of probucol and rapamycin) versus SES	patients with De novo lesions in native coronary arteries	Parallel groups open Germany
everolimus eluting stent vs sirolimus eluting stent			
ISAR-TEST 4 (EES vs SES) n=652/652 follow-up: 2 years	everolimus-eluting stent versus sirolimus-eluting stent	patients with de novo coronary artery stenosis >50% and symptoms or objective evidence of ischemia	Parallel groups

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Trial	Treatments	Patients	Trials design and methods
RESET , 2011 [NCT01035450] n=NA	-	-	
SORT OUT IV , 2012 [NCT00552877] n=1390/1384 follow-up: 9 months (3 years)	everolimus-eluting stents versus sirolimus-eluting stents	unselected patients with coronary artery disease	Parallel groups open Denmark
paclitaxel eluting stent vs sirolimus eluting stent			
FRE-RACE <i>ongoing</i> [NCT00130546] n=NA follow-up:	Cypher select versus Taxus	de novo native coronary lesions with two or more coronary artery stenoses	Cross over
zotarolimus eluting stent vs sirolimus eluting stent			
ENDEAVOR III , 2006 [NCT00217256] n=327/109 follow-up: 12 months (and 24 months)	ABT-578 coated Endeavor versus Cypher	single de novo lesions in native coronary arteries 2.5-3.5 mm in diameter	Parallel groups open US
PROTECT , 2012 [NCT00476957] n=4357/4352 follow-up:	Medtronic Endeavor Zotarolimus Eluting Coronary Stent System versus Cordis Cypher Sirolimus-eluting Coronary Stent	unselected patients (patients 18 years or older who were undergoing stenting for elective, unplanned, or emergency procedures in native coronary arteries)	Parallel groups open-label
SORT-OUT-3 , 2010 [NCT00660478] n=1162/1171 follow-up: 9 months (18 mo,3yrs)	Zotarolimus-eluting stents versus sirolimus-eluting stents (SES)	Patients With Coronary Artery Disease undergoing PCI for any indication	open
ZEST (vs SES) , 2009 [NCT00418067] n=883/878 follow-up: 1 year	zotarolimus-eluting stents versus sirolimus-eluting stents	Patients with coronary artery disease	Parallel groups Open Korea
DIABEDES IV <i>ongoing</i> [NCT00552994] n=NA follow-up:	Cypher select plus versus Xience V	diabetic patients	
PRISON III , 2007 <i>ongoing</i> [NCT00428454] n=NA follow-up: 8 months	Endeavor versus Cypher	patients with total coronary occlusions for at least 2 weeks with evidence of ischemia related to the occluded coronary artery	Parallel groups open
dual sirolimus, probucol eluting stent vs zotarolimus eluting stent			

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Trial	Treatments	Patients	Trials design and methods
ISAR TEST 2 (vs ZES) , 2009 [NCT00332397] n=333/339 follow-up: 12 months	dual DES (polymer-free stent consisting of probucol and rapamycin) versus permanent polymer zotarolimus-eluting stent (Endeavor)	patients with De novo lesions in native coronary arteries	Parallel groups open Germany
ISAR TEST 5 [NCT00598533] n=2002/1000 follow-up: 1 year	polymer-free, rapamycin/probucol-eluting Dual-DES stent versus zotarolimus-eluting stent with a modified permanent polymer on a cobalt-chromium alloy platform	"all-comers" population	Parallel groups
everolimus eluting stent vs zotarolimus eluting stent			
LEFT-MAIN-2 <i>ongoing</i> [NCT00598637] n=NA follow-up:	Xience versus Endeavor Resolute	unprotected left main coronary artery disease	open

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ISAR-DESIRE (PES vs PTCA), 2005:
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ACTION, 2004:
FEMH-93005, 0:
PASEO, 2009:
ISAR-CABG, 0:
BASKET-PROVE (EES), 2010:
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SPIRIT I, 2005:
GENIUS-STEMI, 2009:
TRIAS-Low-Risk, 0:
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HAAMU-STENT, 2006:
HORIZONS-AMI Stent, 2008:
PASSION, 2006:
SCORE, 2004:
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TAXUS II, 2003:
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TAXUS VI, 2005:

BASKET-SAVAGE, 0:
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C-SIRIUS, 2004:
DEBATER (SES vs BMS), 2009:
DECODE, 2005:
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Korean Randomized Study, 0:
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MIDCAB Versus DES in Proximal LAD Lesions, 0:
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Costar II, 2008:
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SPIRIT II, 2006:
SPIRIT III, 2008:
SPIRIT IV, 2010:
TRIAS-HR, 2008:
PEPCAD IV, 0:
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ISAR-TEST 4 (EES vs SES), :
RESET, 2011:

SORT OUT IV, 2012:
 FRE-RACE, 0:
 ENDEAVOR III, 2006:
 PROTECT, 2012:
 SORT-OUT-3, 2010:
 ZEST (vs SES), 2009:
 DIABEDES IV, 0:
 PRISON III, 2007:
 ISAR TEST 2 (vs ZES), 2009:
 ISAR TEST 5, :
 LEFT-MAIN-2, 0:

4 non-polymeric ES

Trial	Treatments	Patients	Trials design and methods
paclitaxel, non-polymeric eluting stent vs bare-metal stent			
ASPECT , 2003 [NCT00196079] n=117/58 follow-up: 6 months	coated Supra-G stent versus Supra-G stent	patientswith discrete coronary lesions (<15 mm in length, 2.25 to 3.5 mm in diameter)	Parallel groups double-blind
DELIVER , 2004 n=524/519 follow-up: 9 months	non-polymer-based paclitaxel-coated ACHIEVE stent versus stainless steel Multi-Link (ML) PENTA stent	patients with focal de novo coronary lesions, <25 mm in length, in 2.5- to 4.0-mm vessels	Parallel groups single-blind US
ELUTES , 2004 n=152/38 follow-up: 12 months	coated V-Flex Plus versus V-Flex Plus	single de novo type A or type B1 lesions 15 mm length in a nativecoronary artery	Parallel groups open Europe
PATENCY , 2002 <i>unpublished</i> n=24/26 follow-up: 9 months	Logic PTX paclitaxel Eluting CoronaryStents versus uncoated control stents	Patients with de novo lesions of 2.7- to 4.0-mm diameter and 25-mm length received 3.0, 3.5, or 4.0 mm 10- or 15-mm	Parallel groups double blind
polymer-free biolimus a9-eluting stents vs paclitaxel eluting stent			
BIOFREEDOM [NCT01172119] n=NA follow-up:	polymer-free biolimus A9-eluting stent versus paclitaxel-eluting stent	patients with symptomatic ischemic heart disease, and stenosis in native coronary arteries ranging in diameter from >=2.25 mm to <=3.0 mm	
polymer free sirolimus stent vs sirolimus eluting stent			

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Trial	Treatments	Patients	Trials design and methods
ISAR TEST 3 (PF) , 2009 n=201/202 follow-up: 12 months	polymer free 2% rapamycin (479 mg rapamycin/cm2) stent versus permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2)	Patients with de novo coronary lesions in native vessels	open Germany

References

ASPECT, 2003:
DELIVER, 2004:
ELUTES, 2004:
PATENCY, 2002:
BIOFREEDOM, :
ISAR TEST 3 (PF), 2009:

5 PCI

Trial	Treatments	Patients	Trials design and methods
PCI with drug-eluting stents vs CABG			
FREEDOM , 2012 [NCT00086450] n=953/947 follow-up: 3.8 yrs (median)	percutaneous coronary stenting versus CABG	patients with diabetes and multivessel coronary artery disease	Parallel groups open international
PCI with drug-eluting stents vs CABG			
Hong , 2005 n=119/70 follow-up: 9 months	drug-eluting stents versus invasive direct coronary artery bypass (MIDCAB) surgery	proximal left anterior descending (LAD) coronary artery stenosis	Parallel groups open
VA CARDS ongoing [NCT00326196] n=NA follow-up:	percutaneous coronary stenting with drug eluting stents versus CABG	angiographically significant coronary artery disease in diabetes	Parallel groups open
PCI with sirolimus ES vs MIDCAB			
Thiele , 2009 [NCT00299429] n=65/65 follow-up: 12 months	sirolimus-eluting stent versus MIDCAB surgery	isolated LAD disease	Parallel groups open Germany

References

FREEDOM, 2012:
Hong, 2005:

VA CARDS, 0:
Thiele, 2009:

6 provisional T-stenting with drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
sirolimus eluting stent vs paclitaxel eluting stent			
BASKET (vs paclitaxel) , 2005 n=264/281 follow-up: 6 months	Cypher versus Taxus	Unselected patients; de-novo lesions	Parallel groups open Switzerland,
Cervinka , 2006 n=37/33 follow-up: 6 months	sirolimus-eluting stent versus paclitaxel-eluting stent	Complex lesions and patients. Signs and/or symptoms myocardial ischaemia, including AMI	Parallel groups open
CORPAL , 2005 <i>unpublished</i> n=331/321 follow-up:	sirolimus versus paclitaxel	Documented myocardial ischaemia, no AMI	Parallel groups open Spain
DES-DIABETES , 2008 n=200/200 follow-up: 9 months (1 year)	sirolimus-eluting stent versus paclitaxel-elutingstent	diabetic patients with angina pectoris and/or a positive stress test and a native coronary lesion	Factorial plan open Korea
Di Lorenzo et al. , 2005 <i>unpublished</i> n=90/90 follow-up:	sirolimus versus paclitaxel	ST-segment elevation myocardial infarction	Parallel groups open
Han , 2006 n=210/206 follow-up: 19.5 months (mean)	Cypher versus Taxus	Multivessel disease. Stable or unstable AP, no AMI	Parallel groups open China
ISAR-DESIRE (SES vs PES) , 2005 n=100/100 follow-up: 1y	Cypher versus Taxus	In-stent restenosis. AP and/or positive test, previously stented, no AMI	Parallel groups open germany
ISAR-DIABETES , 2005 n=125/125 follow-up: 9 months	Taxus versus Cypher	Diabetic patients. AP or positive stress, no AMI with clinically significant angiographic stenosis in a native coronary vessel	Parallel groups open Germany
ISAR-LEFT-MAIN , 2009 [NCT00133237] n=302/305 follow-up: 1 year	Paclitaxel-eluting stent versus Sirolimus-eluting stent	Unprotected Left Main Coronary Artery Disease	Parallel groups open

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Trial	Treatments	Patients	Trials design and methods
ISAR-SMART 3 , 2006 [NCT00146575] n=180/180 follow-up:	Taxus versus Cypher	Small vessels, de novo lesions in native coronary vessels with a diameter of <2.80 mm nondiabetic patients. AP or positive stress, no AMI	Parallel groups NA Germany
ISAR-TEST-1 , 2006 [NCT00140530] n=225/225 follow-up: 9 months	rapamycin-eluting stent Yukon versus Taxus	stable or unstable angina or a positive stress test, stable or unstable angina or a positive stress test	Parallel groups open Germany
Kim , 2008 n=85/84 follow-up: 6 months	Cypher versus Taxus	Korean diabetic patients with high-grade de novo coronary lesions (stenosis of >70 percent of the luminal diameter) requiring <3 stents	Parallel groups open Korea
LONG DES II , 2006 n=250/250 follow-up: 9 months	SES versus PES	Long lesions. AP or positive stress, no AMI	Parallel groups single-blind Korea
Pan , 2007 n=103/102 follow-up: 24 months (mean)	SES for provisional T-stenting versus PES for provisional T-stenting	patients with bifurcation lesions	Parallel groups open Spain
Petronio et al , 2007 n=50/50 follow-up: 9 months	Cypher versus Taxus	Complex lesions. Stable AP or documented ischaemia, no AMI	Parallel groups open Italy
PROSIT , 2006 n=154/154 follow-up: 1 year	SES Cordis versus PES Boston Scientific	AMI or persistent ischaemia 12-24h	Parallel groups open Korea
REALITY , 2006 [NCT00235092] n=701/685 follow-up: 12 months	Cypher versus Taxus	Relatively unselected patients. Stable or unstable documented silent ischaemia, no AMI with 1 or 2 de novo lesions (2.25-3.00 mm in diameter) in native coronary arteries	Parallel groups open Europe, Latin America, and Asiam
SIRTAX (Windecker) , 2005 n=503/509 follow-up: 9 mo (5y)	sirolimus-eluting stents (Cypher) versus paclitaxel-eluting stents (Taxus)	Unselected patients. Stable AP, ACS, including AMI. at least one lesion with stenosis of at least 50 percent in a vessel with a reference diameter between 2.25 and 4.00 mm that was suitable for stent implantation	Parallel groups single-blind Switzerland
SORT OUT II , 2008 [NCT00388934] n=1065/1033 follow-up:	Cypher stent versus Taxus stent(Boston Scientific Corp)	Unselected patients (included ST-segment elevation myocardial infarction (STEMI), non-STEMI or unstable angina pectoris, and stable angina)	Parallel groups open Denmark.
TAXi , 2005 n=102/100 follow-up: 6 months	Cypher versus Taxus	Unselected patients	Parallel groups open Switzerland.

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Trial	Treatments	Patients	Trials design and methods
Tomai , 2008 n=60/60 follow-up: 8 months	sirolimus-eluting stent versus paclitaxel-eluting stent	diabetic patient with multiple de novo coronary artery lesions	Cross over NA Italy
Zhang (SES vs PES) , 2006 n=246/203 follow-up: 1y	Cypher versus Taxus	Unselected patients. Stable or unstable AP, ACS with de novo coronary lesions	Parallel groups open China
DES-ISR <i>ongoing</i> [NCT00485030] n=NA follow-up:	Cypher versus Taxus	patients Diffuse Type In-Stent Restenosis After Drug-Eluting Stents Implantation	
Lipsia-Yukon-DM <i>ongoing</i> [NCT00368953] n=NA follow-up: 9 months	Yukon Choice stent system versus Taxus Libert stent system	Patients With Diabetes Mellitus	

References

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SORT OUT II, 2008:
TAXi, 2005:
Tomai, 2008:
Zhang (SES vs PES), 2006:
DES-ISR, 0:
Lipsia-Yukon-DM, 0:

7 resorbable

Trial	Treatments	Patients	Trials design and methods
sirolimus biodegradable polymer vs sirolimus eluting stent			
ISAR TEST 3 (BP) , 2009 n=202/202 follow-up: 12 months	biodegradable-polymer 0.4% rapamycin stent (180 mg rapamycin/cm2) versus permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2)	Patients with de novo coronary lesions in native vessels	Parallel groups open Germany
ISAR-TEST-4 (biodegradable polymer) , 2009 [NCT00598676].] n=1299/1304 follow-up: 12 mo	biodegradable polymer rapamycin-eluting stent versus permanent polymer-based rapamycin-eluting or everolimus-eluting	patients with stable coronary disease or acute coronary syndromes with de novo native-vessel stent implantation	Parallel groups open Germany

References

ISAR TEST 3 (BP), 2009:

ISAR-TEST-4 (biodegradable polymer), 2009:

8 titanium-nitride-oxide coated stent

Trial	Treatments	Patients	Trials design and methods
titanium-nitride-oxide coated stent vs bare-metal stent			
TINOX , 2005 n=45/47 follow-up: 6 mo	titanium-nitride-oxide coated stents versus stainless steel stents of similar design	-	Parallel groups open Switzerland, Germany

References

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9 About TrialResults-center.org

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