

# Clinical trials of Drug eluting stent for coronary artery disease in unparticular patients

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## 1 bioabsorbable polymer stent

Trial	Treatments	Patients	Trials design and methods
<b>biolimus eluting stent vs sirolimus eluting stent</b>			
<b>LEADERS , 2008</b> [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
<b>sirolimus biodegradable polymer vs sirolimus eluting stent</b>			
<b>ISAR-TEST-4 (biodegradable polymer) , 2009</b> [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

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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](https://doi.org/10.1016/S0140-6736(11)61672-3)

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

Byrne RA, Kastrati A, Kufner S, Massberg S, Birkmeier KA, Laugwitz KL, Schulz S, Pache J, Fusaro M, Seyfarth M, Schmig A, Mehili J Randomized, non-inferiority trial of three limus agent-eluting stents with different polymer coatings: the Intracoronary Stenting and Angiographic Results: Test Efficacy of 3 Limus-Eluting Stents (ISAR-TEST-4) Trial. *Eur Heart J* 2009 Aug 30;: [19720642]

## 2 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
<b>dactinomycin eluting stent vs bare-metal stent</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>ACTION , 2004</b> 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 $\geq 3.0$ mm and $\leq 4.0$ mm in diameter that could be covered by an 18-mm stent	Parallel groups single-blind worldwide
<b>dexamethasone eluting stent vs bare-metal stent</b>			
<b>FEMH-93005</b> <i>ongoing</i> [NCT00190099] n=NA	-	-	
<b>everolimus eluting stent vs bare-metal stent</b>			
<b>FUTURE I , 2004</b> n=27/15 follow-up: 12 months	everolimus coated S-Stent versus S-Stent	de novo coronary lesions	Parallel groups single-blind Germany
<b>FUTURE II , 2006</b> <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 $\leq 18$ mm	Parallel groups double-blind
<b>SPIRIT I , 2005</b> [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
<b>Genous stent vs bare-metal stent</b>			
<b>TRIAS-Low-Risk</b> <i>ongoing</i> n=NA	-	-	
<b>paclitaxel eluting stent vs bare-metal stent</b>			
<b>SCORE , 2004</b> 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
<b>TAXUS I , 2003</b> 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
<b>TAXUS II , 2003</b> [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
<b>TAXUS IV , 2004</b> [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
<b>sirolimus eluting stent vs bare-metal stent</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>C-SIRIUS , 2004</b> [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
<b>E-SIRIUS , 2003</b> [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
<b>Kochiadakis , 2007</b> n=38/43 follow-up: 4.8 months (mean)	sirolimus-eluting stents versus bare metal stent	one-vessel disease (>70% narrowing of the lumen of one major epicardial coronary artery); stable coronary artery disease, age <70 years, and vessel referencediameter >=2.5 mm	Parallel groups open Greece
<b>Ortolani et al , 2007</b> 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
<b>Pache et al , 2005</b> 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
<b>RAVEL , 2002</b> [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
<b>SIRIUS , 2003</b> [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
<b>BASKET-PROVE , 2008</b> <i>ongoing</i> n=NA follow-up:	Cypher versus Vision	-	
<b>zotarolimus eluting stent vs bare-metal stent</b>			
<b>ENDEAVOR II , 2006</b> 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
<b>bioabsorbable polymer EES vs everolimus eluting stent</b>			
<b>EVOLVE , 2012</b> [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
<b>PCI vs CABG</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>COMBAT</b> <i>ongoing</i> n=NA	PCI versus CABG	-	
<b>Korean Randomized Study</b> <i>ongoing</i> n=NA	PCI versus CABG	-	
<b>REVASCULARIZE</b> <i>ongoing</i> n=NA	PCI versus CABG	-	
<b>sirolimus eluting stent vs CABG</b>			
<b>MIDCAB Versus DES in Proximal LAD Lesions</b> <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	
<b>Munich Study</b> <i>ongoing</i> n=NA	sirolimus versus CABG	-	
<b>zotarolimus eluting stent vs everolimus eluting stent</b>			
<b>RESOLUTE All comers , 2010</b> [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
<b>TWENTE , 2012</b> [NCT01066650] n=NA follow-up: 1 year	zotarolimus-eluting stent versus everolimus-eluting stent	"real-world" patients	Parallel groups single (patient-blinded)
<b>sirolimus eluting stent vs Firebird eluting stent</b>			
<b>Gao</b> <i>ongoing</i> [NCT00887211] n=NA follow-up:	ProStent rapamycin-eluting stent system versus Firebird drug-eluting stents	-	Parallel groups single blind
<b>CoStar stent vs paclitaxel eluting stent</b>			
<b>Costar II , 2008</b> [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
<b>everolimus eluting stent vs paclitaxel eluting stent</b>			
<b>COMPARE , 2009</b> [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

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>SPiRiT II , 2006</b> <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)
<b>SPiRiT III , 2008</b> [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 mm	Parallel groups single-blind US
<b>SPiRiT IV , 2010</b> [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
<b>paclitaxel eluting stent vs paclitaxel eluting stent</b>			
<b>PERSEUS Workhorse , 2010</b> <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	
<b>sirolimus eluting stent vs paclitaxel eluting stent</b>			
<b>BASKET (vs paclitaxel) , 2005</b> n=264/281 follow-up: 6 months	Cypher versus Taxus	Unselected patients; de-novo lesions	Parallel groups open Switzerland,
<b>Han , 2006</b> n=210/206 follow-up: 19.5 months (mean)	Cypher versus Taxus	Multivessel disease. Stable or unstable AP, no AMI	Parallel groups open China
<b>ISAR-TEST-1 , 2006</b> [NCT00140530] n=225/225 follow-up: 9 months	rapamycin-eluting stent Yukon versus Taxus	stable or unstable anginaor a positive stress test, stable or unstable anginaor a positive stress test	Parallel groups open Germany
<b>REALITY , 2006</b> [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
<b>SIRTAX (Windecker) , 2005</b> 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
<b>SORT OUT II , 2008</b> [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.

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>TAXi , 2005</b> n=102/100 follow-up: 6 months	Cypher versus Taxus	Unselected patients	Parallel groups open Switzerland.
<b>Wessely , 2008</b> n=NA follow-up: 9 months	rapamycin polymer-coated drug-eluting stent versus paclitaxel polymer-coated drug-eluting stent	-	Parallel groups NA Germany
<b>Zhang (SES vs PES) , 2006</b> 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
<b>zotarolimus eluting stent vs paclitaxel eluting stent</b>			
<b>ENDEAVOR IV , 2009</b> <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
<b>ZEST (vs PES) , 2009</b> [NCT00418067] n=883/884 follow-up: 1 year	zotarolimus-eluting stents versus paclitaxel-eluting stents	Patients with coronary artery disease	NA
<b>ZoMaxx phase 2</b> <i>ongoing</i> [NCT00140101] n=NA follow-up:	ZoMaxx drug-eluting stent versus TAXUS Express2	de Novo Coronary Artery Lesions	
<b>pimecrolimus eluting stent vs pimecrolimus paclitaxel</b>			
<b>GENESIS Trial CP-01</b> <i>ongoing</i> [NCT00322569] n=NA follow-up: 6 months	Corio Pimecrolimus versus CoStar	patients with de novo lesions of the native coronary arteries	
<b>everolimus eluting stent vs sirolimus eluting stent</b>			
<b>ISAR-TEST 4 (EES vs SES)</b> 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
<b>SORT OUT IV , 2012</b> [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
<b>paclitaxel eluting stent vs sirolimus eluting stent</b>			
<b>FRE-RACE</b> <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

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Trial	Treatments	Patients	Trials design and methods
<b>zotarolimus eluting stent vs sirolimus eluting stent</b>			
<b>ENDEAVOR III , 2006</b> [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
<b>PROTECT , 2012</b> [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
<b>ZEST (vs SES) , 2009</b> [NCT00418067] n=883/878 follow-up: 1 year	zotarolimus-eluting stents versus sirolimus-eluting stents	Patients with coronary artery disease	Parallel groups Open Korea

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 FRE-RACE, 0:  
 ENDEAVOR III, 2006:  
 PROTECT, 2012:  
 ZEST (vs SES), 2009:

### 3 non-polymeric ES

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Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel, non-polymeric eluting stent vs bare-metal stent</b>			
<b>ASPECT , 2003</b> [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
<b>DELIVER , 2004</b> 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
<b>ELUTES , 2004</b> 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
<b>PATENCY , 2002</b> <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

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## 4 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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