

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

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

## 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

## References

### 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](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>			

continued...

<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>			

continued...

<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>			

continued...

<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

continued...

<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.

continued...

<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

continued...

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

## References

### **ACTION, 2004:**

Serruys PW, Veldhof S, Stuteville M, et al Actinomycin-elutingstent improves outcome by reducing neointimal hyperplasia Transcatheter Cardiovascular Therapeutics Annual Meeting,September, 2002

Serruys PW, Ormiston JA, Sianos G, Sousa JE, Grube E, den Heijer P, de Feyter P, Buszman P, Schmig A, Marco J, Polonski L, Thuesen L, Zeiher AM, Bett JH, Suttorp MJ, Glogar HD, Pitney M, Wilkins GT, Whitbourn R, Veldhof S, Miquel K, Johnson R, Coleman L, Actinomycin-eluting stent for coronary revascularization: a randomized feasibility and safety study: the ACTION trial. J Am Coll Cardiol 2004 Oct 6;44:1363-7 [[15464314](#)]

### **FEMH-93005, 0:**

#### **FUTURE I, 2004:**

Grube E, Sonoda S, Ikeno F, Honda Y, Kar S, Chan C, Gerckens U, Lansky AJ, Fitzgerald PJ Six- and twelve-month results from first human experience using everolimus-eluting stents with bioabsorbable polymer. Circulation 2004;109:2168-71 [[15123533](#)]

#### **FUTURE II, 2006:**

Grube E, Lansky A, Mehran R, Fitzgerald P, Ho Multicenter evaluation of the bioabsorbable polymer-basedeverolimus-eluting stent: FUTURE-2 trial TranscatheterCardiovascular Therapeutic Annual Meeting, September, 2003

Tsuchiya Y, Lansky AJ, Costa RA, Mehran R, Pietras C, Shimada Y, Sonoda S, Cristea E, Negoita M, Dangas GD, Moses JW, Leon MB, Fitzgerald PJ, Mller R, Strger H, Hauptmann KE, Grube E Effect of everolimus-eluting stents in different vessel sizes (from the pooled FUTURE I and II trials). Am J Cardiol 2006 Aug 15;98:464-9 [[16893698](#)]

Grube E, Sonoda S, Ikeno F, Honda Y, Kar S, Chan C, Gerckens U, Lansky AJ, Fitzgerald PJ Six- and twelve-month results from first human experience using everolimus-eluting stents with bioabsorbable polymer. Circulation 2004 May 11;109:2168-71 [[15123533](#)]

#### **SPIRIT I, 2005:**

Serruys PW, Ong AT, Piek JJ, Neumann FJ, van der Giessen WJ, Wiemer M, Zeiher A, Grube E, Haase J, Thuesen L, Hamm C, Otto-Terlouw PC A randomized comparison of a durable polymer Everolimus-eluting stent with a bare metal coronary stent: The SPIRIT first trial. EuroIntervention 2005 May;1:58-65 [[19758878](#)]

Tsuchida K, Piek JJ, Neumann FJ, van der Giessen WJ, Wiemer M, Zeiher AM, Grube E, Haase J, Thuesen L, Hamm CW, Veldhof S, Dorange C, Serruys PW One-year results of a durable polymer everolimus-eluting stent in de novo coronary narrowings (The SPIRIT FIRST Trial). EuroIntervention 2005 Nov;1:266-72 [[19758915](#)]

Tsuchida K, Garca-Garca HM, Ong AT, Valgimigli M, Aoki J, Rademaker TA, Morel MA, van Es GA, Bruining N, Serruys PW Revisiting late loss and neointimal volumetric measurements in a drug-eluting stent trial: analysis from the SPIRIT FIRST trial. Catheter Cardiovasc Interv 2006 Feb;67:188-97 [[16400664](#)]

#### **TRIAS-Low-Risk, 0:**

**SCORE, 2004:**

Stone GW. Adverse outcomes from a taxane-loaded polymeric sleeve stent: final results from the SCORE Trial American College of Cardiology Scientific Session, March, 2002

Grube E, Lansky A, Hauptmann KE, Di Mario C, Di Sciascio G, Colombo A, Silber S, Stumpf J, Reifart N, Fajadet J, Marzocchi A, Schofer J, Dumas P, Hoffmann R, Guagliumi G, Pitney M, Russell ME High-dose 7-hexanoyltaxol-eluting stent with polymer sleeves for coronary revascularization: one-year results from the SCORE randomized trial. *J Am Coll Cardiol* 2004 Oct 6;44:1368-72 [[15464315](#)]

**TAXUS I, 2003:**

Grube E, Silber S, Hauptmann KE, Mueller R, Buellesfeld L, Gerckens U, Russell ME TAXUS I: six- and twelve-month results from a randomized, double-blind trial on a slow-release paclitaxel-eluting stent for de novo coronary lesions. *Circulation* 2003;107:38-42 [[12515740](#)]

Grube E, Silber S, Hauptmann KE, Mueller R, Buellesfeld L, Gerckens U, Russell ME TAXUS I: six- and twelve-month results from a randomized, double-blind trial on a slow-release paclitaxel-eluting stent for de novo coronary lesions. *Circulation* 2003 Jan 7;107:38-42 [[12515740](#)]

**TAXUS II, 2003:**

Colombo A, Drzewiecki J, Banning A, Grube E, Hauptmann K, Silber S, Dudek D, Fort S, Schiele F, Zmudka K, Guagliumi G, Russell ME Randomized study to assess the effectiveness of slow- and moderate-release polymer-based paclitaxel-eluting stents for coronary artery lesions. *Circulation* 2003;108:788-94 [[12900339](#)]

Silber S, Colombo A, Banning AP, Hauptmann K, Drzewiecki J, Grube E, Dudek D, Baim DS Final 5-year results of the TAXUS II trial: a randomized study to assess the effectiveness of slow- and moderate-release polymer-based paclitaxel-eluting stents for de novo coronary artery lesions. *Circulation* 2009 Oct 13;120:1498-504 [[19786634](#)]

**TAXUS IV, 2004:**

Stone GW, Ellis SG, Cox DA, Hermiller J, O'Shaughnessy C, Mann JT, Turco M, Caputo R, Bergin P, Greenberg J, Popma JJ, Russell ME A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. *N Engl J Med* 2004;350:221-31 [[14724301](#)]

Ellis SG, Stone GW, Cox DA, Hermiller J, O'Shaughnessy C, Mann T, Turco M, Caputo R, Bergin PJ, Bowman TS, Baim DS Long-Term Safety and Efficacy With Paclitaxel-Eluting Stents 5-Year Final Results of the TAXUS IV Clinical Trial (TAXUS IV-SR: Treatment of De Novo Coronary Disease Using a Single Paclitaxel-Eluting Stent). *JACC Cardiovasc Interv* 2009 Dec;2:1248-59 [[20129552](#)] [10.1016/j.jcin.2009.10.003](#)

Ellis SG, Stone GW, Cox DA, Hermiller J, O'Shaughnessy C, Mann T, Turco M, Caputo R, Bergin PJ, Bowman TS, Baim DS Long-term safety and efficacy with paclitaxel-eluting stents: 5-year final results of the TAXUS IV clinical trial (TAXUS IV-SR: Treatment of De Novo Coronary Disease Using a Single Paclitaxel-Eluting Stent). *JACC Cardiovasc Interv* 2009;2:1248-59 [[20129552](#)] [10.1016/j.jcin.2009.10.003](#)

**C-SIRIUS, 2004:**

Schampaert E, Cohen EA, Schlter M, Reeves F, Traboulsi M, Title LM, Kuntz RE, Popma JJ The Canadian study of the sirolimus-eluting stent in the treatment of patients with long de novo lesions in small native coronary arteries (C-SIRIUS). *J Am Coll Cardiol* 2004;43:1110-5 [[15028375](#)]

**E-SIRIUS, 2003:**

Schofer J, Schlter M, Gershlick AH, Wijns W, Garcia E, Schampaert E, Breithardt G Sirolimus-eluting stents for treatment of patients with long atherosclerotic lesions in small coronary arteries: double-blind, randomised controlled trial (E-SIRIUS). *Lancet* 2003;362:1093-9 [[14550694](#)]

**Kochiadakis, 2007:**

Kochiadakis GE, Marketou ME, Arfanakis DA, Sfridaki K, Skalidis EI, Igoumenidis NE, Hamilos MI, Kolyvaki S, Chlouverakis G, Kantidaki E, Castanas E, Vardas PE, Reduced systemic inflammatory response to implantation of sirolimus-eluting stents in patients with stable coronary artery disease. *Atherosclerosis* 2007;194:433-8. [[16997310](#)] [10.1016/j.atherosclerosis.2006.08.029](#)

**Ortolani et al, 2007:**

Ortolani P, Marzocchi A, Marrozzini C, Palmerini T, Saia F, Taglieri N, Aquilina M, Baldazzi F, Silenzi S, Cooke RM, Reggiani ML, Branzi A Randomized comparative trial of a thin-strut bare metal cobalt-chromium stent versus a sirolimus-eluting stent for coronary revascularization. *Catheter Cardiovasc Interv* 2007;69:790-8 [[17290437](#)]

**Pache et al, 2005:**

Pache J, Dibra A, Mehilli J, Dirschinger J, Schmig A, Kastrati A Drug-eluting stents compared with thin-strut bare stents for the reduction of restenosis: a prospective, randomized trial. *Eur Heart J* 2005;26:1262-8 [[15737962](#)]

**RAVEL, 2002:**



Morice MC, Serruys PW, Sousa JE, Fajadet J, Ban Hayashi E, Perin M, Colombo A, Schuler G, Barragan P, Guagliumi G, Molnr F, Falotico R A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. *N Engl J Med* 2002;346:1773-80 [[12050336](#)]

Morice MC, Serruys PW, Barragan P, Bode C, Van Es GA, Stoll HP, Snead D, Mauri L, Cutlip DE, Sousa E Long-term clinical outcomes with sirolimus-eluting coronary stents: five-year results of the RAVEL trial. *J Am Coll Cardiol* 2007 Oct 2;50:1299-304 [[17903626](#)]

#### **SIRIUS, 2003:**

Moses JW, Leon MB, Popma JJ, Fitzgerald PJ, Holmes DR, O'Shaughnessy C, Caputo RP, Kereiakes DJ, Williams DO, Teirstein PS, Jaeger JL, Kuntz RE Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. *N Engl J Med* 2003;349:1315-23 [[14523139](#)]

Weisz G, Moses JW, Teirstein PS, Holmes DR Jr, Raizner AE, Satler LF, Mishkel G, Wilensky RL, Wang P, Kuntz RE, Popma JJ, Leon MB Safety of sirolimus-eluting stenting and its effect on restenosis in patients with unstable angina pectoris (a SIRIUS substudy). *Am J Cardiol* 2007 Apr 15;99:1044-50 [[17437725](#)]

Holmes DR Jr, Leon MB, Moses JW, Popma JJ, Cutlip D, Fitzgerald PJ, Brown C, Fischell T, Wong SC, Midei M, Snead D, Kuntz RE Analysis of 1-year clinical outcomes in the SIRIUS trial: a randomized trial of a sirolimus-eluting stent versus a standard stent in patients at high risk for coronary restenosis. *Circulation* 2004;109:634-40 [[14769686](#)]

Weisz G, Leon MB, Holmes DR Jr, Kereiakes DJ, Popma JJ, Teirstein PS, Cohen SA, Wang H, Cutlip DE, Moses JW Five-year follow-up after sirolimus-eluting stent implantation results of the SIRIUS (Sirolimus-Eluting Stent in De-Novo Native Coronary Lesions) Trial. *J Am Coll Cardiol* 2009 Apr 28;53:1488-97 [[19389558](#)] [10.1016/j.jacc.2009.01.050](#)

Novack V, Nguyen MC, Rooney M, Chacko R, Novack L, Pencina M, Apruzzese P, Mauri L, Cohen SA, Moses J, Leon MB, Cutlip DE Effect of coronary target lesion revascularization on late cardiac events after insertion of sirolimus-eluting or bare metal stents. *Am J Cardiol* 2010 Sep 15;106:774-9 [[20816116](#)] [10.1016/j.amjcard.2010.04.039](#)

#### **BASKET-PROVE, 2008:**

Pfisterer M, Bertel O, Bonetti PO, Brunner-La Rocca HP, Eberli FR, Erne P, Galatius S, Hornig B, Kiowski W, Pachinger O, Pedrazzini G, Rickli H, De Servi S, Kaiser C, , Drug-eluting or bare-metal stents for large coronary vessel stenting? The BASKET-PROVE (PROspective Validation Examination) trial: study protocol and design. *Am Heart J* 2008;155:609-14. [[18371466](#)] [10.1016/j.ahj.2007.11.011](#)

#### **ENDEAVOR II, 2006:**

Gruberg L. ENDEAVOR II. A randomized comparison of the Endeavor ABT-578 drug-eluting stent with a bare metal stent for coronary revascularization, powerpo <http://www.medscape.com/viewart>

Fajadet J, Wijns W, Laarman GJ, Kuck KH, Ormiston J, Mnzal T, Popma JJ, Fitzgerald PJ, Bonan R, Kuntz RE Randomized, double-blind, multicenter study of the Endeavor zotarolimus-eluting phosphorylcholine-encapsulated stent for treatment of native coronary artery lesions: clinical and angiographic results of the ENDEAVOR II trial. *Circulation* 2006 Aug 22;114:798-806 [[16908773](#)]

Fajadet J, Wijns W, Laarman GJ, Kuck KH, Ormiston J, Mnzal T, Popma JJ, Fitzgerald PJ, Bonan R, Kuntz RE Randomized, double-blind, multicenter study of the Endeavor zotarolimus-eluting phosphorylcholine-encapsulated stent for treatment of native coronary artery lesions. Clinical and angiographic results of the ENDEAVOR II Trial. *Minerva Cardioangiol* 2007 Feb;55:1-18 [[17287679](#)]

Sakurai R, Hongo Y, Yamasaki M, Honda Y, Bonneau HN, Yock PG, Cutlip D, Popma JJ, Zimetbaum P, Fajadet J, Kuntz RE, Wijns W, Fitzgerald PJ Detailed intravascular ultrasound analysis of Zotarolimus-eluting phosphorylcholine-coated cobalt-chromium alloy stent in de novo coronary lesions (results from the ENDEAVOR II trial). *Am J Cardiol* 2007 Sep 1;100:818-23 [[17719326](#)]

Eisenstein EL, Wijns W, Fajadet J, Mauri L, Edwards R, Cowper PA, Kong DF, Anstrom KJ Long-Term Clinical and Economic Analysis of the Endeavor Drug-Eluting Stent Versus the Driver Bare-Metal Stent 4-Year Results From the ENDEAVOR II Trial (Randomized Controlled Trial to Evaluate the Safety and Efficacy of the Medtronic AVE ABT-578 Eluting Driver Coronary Stent in De Novo Native Coronary Artery Lesions). *JACC Cardiovasc Interv* 2009 Dec;2:1178-87 [[20129543](#)] [10.1016/j.jcin.2009.10.011](#)

#### **EVOLVE, 2012:**

Meredith IT, Verheye S, Dubois CL, Dens J, Fajadet J, Carri D, Walsh S, Oldroyd KG, Varenne O, El-Jack S, Moreno R, Joshi AA, Allocco DJ, Dawkins KD Primary Endpoint Results of the EVOLVE Trial A Randomized Evaluation of a Novel Bioabsorbable Polymer-Coated, Everolimus-Eluting Coronary Stent. *J Am Coll Cardiol* 2012 Feb 3;: [[22341736](#)] [10.1016/j.jacc.2011.12.016](#)

#### **COMBAT, 0:**

#### **Korean Randomized Study, 0:**

#### **REVASCULARIZE, 0:**

## **MIDCAB Versus DES in Proximal LAD Lesions, 0:**

### **Munich Study, 0:**

#### **RESOLUTE All comers, 2010:**

Serruys PW, Silber S, Garg S, van Geuns RJ, Richardt G, Buszman PE, Kelbk H, van Boven AJ, Hofma SH, Linke A, Klauss V, Wijns W, Macaya C, Garot P, Dimario C, Manoharan G, Kornowski R, Ischinger T, Bartorelli A, Rondón J, Bressers M, Gobbens P, Negoita M Comparison of Zotarolimus-Eluting and Everolimus-Eluting Coronary Stents. *N Engl J Med* 2010 Jun 16;: [20554978] [10.1056/NEJMoa1004130](https://doi.org/10.1056/NEJMoa1004130)

Silber S, Windecker S, Vranckx P, Serruys PW Unrestricted randomised use of two new generation drug-eluting coronary stents: 2-year patient-related versus stent-related outcomes from the RESOLUTE All Comers trial. *Lancet* 2011 Apr 1;: [21459430] [10.1016/S0140-6736\(11\)60395-4](https://doi.org/10.1016/S0140-6736(11)60395-4)

#### **TWENTE, 2012:**

von Birgelen C, Basalus MW, Tandjung K, van Houwelingen KG, Stoel MG, Louwerenburg JH, Linssen GC, Sad SA, Kleijne MA, Sen H, Lwik MM, van der Palen J, Verhorst PM, de Man FH A Randomized Controlled Trial in Second-Generation Zotarolimus-Eluting Resolute Stents Versus Everolimus-Eluting Xience V Stents in Real-World Patients: The TWENTE Trial. *J Am Coll Cardiol* 2012 Feb 9;: [22341737] [10.1016/j.jacc.2012.01.008](https://doi.org/10.1016/j.jacc.2012.01.008)

von Birgelen C, van der Heijden LC, Basalus MW, Kok MM, Sen H, Louwerenburg HW, van Houwelingen KG, Stoel MG, de Man FH, Linssen GC, Tandjung K, Dogge Five-Year Outcome After Implantation of Zotarolimus- and Everolimus-Eluting Stents in Randomized Trial Participants and Nonenrolled Eligible Patients: A Secondary Analysis of a Randomized Clinical Trial. *JAMA Cardiol* 2017;: [28114618]

### **Gao, :**

#### **Costar II, 2008:**

Krucoff MW, Kereiakes DJ, Petersen JL, Mehran R, Hasselblad V, Lansky AJ, Fitzgerald PJ, Garg J, Turco MA, Simonton CA 3rd, Verheye S, Dubois CL, Gammon R, Batchelor WB, O'Shaughnessy CD, Hermiller JB Jr, Schofer J, Buchbinder M, Wijns W A novel bioresorbable polymer paclitaxel-eluting stent for the treatment of single and multivessel coronary disease: primary results of the COSTAR (Cobalt Chromium Stent With Antiproliferative for Restenosis) II study. *J Am Coll Cardiol* 2008 Apr 22;51:1543-52 [18420096]

Kereiakes DJ, Petersen JL, Batchelor WB, Fitzgerald PJ, Mehran R, Lansky A, Tsujino I, Schofer J, Dubois C, Verheye S, Cristea E, Garg J, Wijns W, Krucoff MW Clinical and angiographic outcomes in diabetic patients following single or multivessel stenting in the COSTAR II randomized trial. *J Invasive Cardiol* 2008;20:335-41 [18599890]

#### **COMPARE, 2009:**

Kedhi E, Joesoef KS, McFadden E, Wassing J, van Mieghem C, Goedhart D, Smits PC Second-generation everolimus-eluting and paclitaxel-eluting stents in real-life practice (COMPARE): a randomised trial. *Lancet* 2010 Jan 16;375:201-9 [20060578] [10.1016/S0140-6736\(09\)62127-9](https://doi.org/10.1016/S0140-6736(09)62127-9)

Smits PC, Kedhi E, Royaards KJ, Joesoef KS, Wassing J, Rademaker-Havinga TA, McFadden E 2-Year Follow-Up of a Randomized Controlled Trial of Everolimus- and Paclitaxel-Eluting Stents for Coronary Revascularization in Daily Practice The COMPARE (Comparison of the everolimus eluting XIENCE-V stent with the paclitaxel eluting TAXUS LIBERTE? stent in all-comers: a randomized open label trial) Trial. *J Am Coll Cardiol* 2011 Apr 15;: [21514083] [10.1016/j.jacc.2011.02.023](https://doi.org/10.1016/j.jacc.2011.02.023)

#### **SPIRIT II, 2006:**

Garg S, Serruys P, Onuma Y, Dorange C, Veldhof S, Miquel-Hbert K, Sudhir K, Boland J, Huber K, Garcia E, Te Riele JA 3-Year Clinical Follow-Up of the XIENCE V Everolimus-Eluting Coronary Stent System in the Treatment of Patients With De Novo Coronary Artery Lesions The SPIRIT II Trial (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Native Coronary Artery Lesions). *JACC Cardiovasc Interv* 2009 Dec;2:1190-8 [20129545] [10.1016/j.jcin.2009.10.002](https://doi.org/10.1016/j.jcin.2009.10.002)

Onuma Y, Tanimoto S, Ruygrok P, Neuzner J, Piek JJ, Seth A, Schofer JJ, Richardt G, Wiemer M, Carri D, Thuesen L, Dorange C, Miquel-Hebert K, Veldhof S, Serruys PW Efficacy of everolimus eluting stent implantation in patients with calcified coronary culprit lesions: two-year angiographic and three-year clinical results from the SPIRIT II study. *Catheter Cardiovasc Interv* 2010;76:634-42 [20690152] [10.1002/ccd.22541](https://doi.org/10.1002/ccd.22541)

#### **SPIRIT III, 2008:**

Stone GW, Midei M, Newman W, Sanz M, Hermiller JB, Williams J, Farhat N, Mahaffey KW, Cutlip DE, Fitzgerald PJ, Sood P, Su X, Lansky AJ, , Comparison of an everolimus-eluting stent and a paclitaxel-eluting stent in patients with coronary artery disease: a randomized trial. *JAMA* 2008;299:1903-13. [18430909] [10.1001/jama.299.16.1903](https://doi.org/10.1001/jama.299.16.1903)

#### **SPIRIT IV, 2010:**

#### **PERSEUS Workhorse, 2010:**

#### **BASKET (vs paclitaxel), 2005:**

Han, 2006:  
 ISAR-TEST-1, 2006:  
 REALITY, 2006:  
 SIRTAX (Windecker), 2005:  
 SORT OUT II, 2008:  
 TAXi, 2005:  
 Wessely, 2008:  
 Zhang (SES vs PES), 2006:  
 ENDEAVOR IV, 2009:  
 ZEST (vs PES), 2009:  
 ZoMaxx phase 2, 0:  
 GENESIS Trial CP-01, 0:  
 ISAR-TEST 4 (EES vs SES), :  
 SORT OUT IV, 2012:  
 FRE-RACE, 0:  
 ENDEAVOR III, 2006:  
 PROTECT, 2012:  
 ZEST (vs SES), 2009:

### 3 non-polymeric ES

11

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

## References

**ASPECT, 2003:**  
**DELIVER, 2004:**  
**ELUTES, 2004:**  
**PATENCY, 2002:**

## 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.

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