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
biolimus eluting stent vs sirolimus eluting stent			
LEADERS , 2008 [NCT00389220] n=857/850 follow-up: 9 months	BioMatrix III (biolimus-eluting stent withbiodegradable 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-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

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2 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
dactinomycin eluting stent vs bare-metal stent			

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Trial	Treatments	Patients	Trials design and methods
ACTION , 2004 n=241/119 follow-up: 6 months	Multilink Tetra stent versus uncoated Multilink Tetra stent	Patients with stable angina pectoris orsilent ischemia and a single de novo lesion in a nativecoronary artery >=3.0 mm and <=4.0 mm in diameter thatcould be covered by an 18-mm stent	Parallel groups single-blind worldwide
dexamethasone eluting stent vs bare-metal stent			
FEMH-93005 *ongoing* [NCT00190099] n=NA	-	-	
everolimus eluting stent vs bare-metal stent			
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FUTURE II , 2006 *unpublished* n=43/21 follow-up: 6 months	CHAMPION versus bare-metal stent	Patients with de novo lesions in vessels with a reference diameter of 2.75-4.0 mm and length 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 sent, XIENCE versus bare etal stent, MULTI-LINK VISION	patients with de novo native coronary artery lesions	Parallel groups single-blind
Genous stent vs bare-metal stent			
TRIAS-Low-Risk *ongoing* n=NA	-	-	
paclitaxel eluting stent vs bare-metal stent			
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 estimatedstenosis >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
sirolimus eluting stent vs bare-metal stent			

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Trial	Treatments	Patients	Trials design and methods
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
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
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
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
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
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
BASKET-PROVE , 2008 *ongoing* n=NA follow-up:	Cypher versus Vision	-	
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
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
PCI vs CABG			

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Trial	Treatments	Patients	Trials design and methods
COMBAT *ongoing* n=NA	PCI versus CABG	-	
Korean Randomized Study *ongoing* n=NA	PCI versus CABG	-	
REVASCULARIZE *ongoing* n=NA	PCI versus CABG	-	
sirolimus eluting stent vs CABG			
MIDCAB Versus DES in Proximal LAD Lesions *ongoing* [NCT00299429] n=NA follow-up:	sirolimus-coated stent versus minimally invasive bypass surgery	patients with isolated proximal left anterior descending coronary arteries	
Munich Study *ongoing* n=NA	sirolimus versus CABG	-	
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 *ongoing* [NCT00887211] n=NA follow-up:	ProStent rapamycin-eluting stent system versus Firebird drug-eluting stents	-	Parallel groups single blind
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

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Trial	Treatments	Patients	Trials design and methods
SPIRIT II , 2006 *unpublished* [NCT00180310] n=223/77 follow-up: 6 months	everolimus eluting stent, XIENCE V versus placitaxel 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
paclitaxel eluting stent vs paclitaxel eluting stent			
PERSEUS Workhorse , 2010 *ongoing* [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			
BASKET (vs paclitaxel) , 2005 n=264/281 follow-up: 6 months	Cypher versus Taxus	Unselected patients; de-novo lesions	Parallel groups open Switzerland,
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-TEST-1 , 2006 [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
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.

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Trial	Treatments	Patients	Trials design and methods
TAXi , 2005 n=102/100 follow-up: 6 months	Cypher versus Taxus	Unselected patients	Parallel groups open Switzerland.
Wessely , 2008 n=NA follow-up: 9 months	rapamycin polymer-coated drug-eluting stent versus paclitaxel polymer-coated drug-eluting stent	-	Parallel groups NA Germany
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
zotarolimus eluting stent vs paclitaxel eluting stent			
ENDEAVOR IV , 2009 *unpublished* [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
ZoMaxx phase 2 *ongoing* [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 *ongoing* [NCT00322569] n=NA follow-up: 6 months	Corio Pimecrolimus versus CoStar	patients with de novo lesions of the native coronary arteries	
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
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 *ongoing* [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
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
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

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SORT OUT IV, 2012:
FRE-RACE, 0:
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PROTECT, 2012:
ZEST (vs SES), 2009:

3 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 *unpublished* 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.

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