

Clinical trials of everolimus

TrialResults-center www.trialresultscenter.org

1 stable angina

Trial	Treatments	Patients	Trials design and methods
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 <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unpublished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 sent, XIENCE versus bare etal stent, MULTI-LINK VISION	patients with de novo native coronary artery lesions	Parallel groups single-blind
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unpublished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 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

continued...

Trial	Treatments	Patients	Trials design and methods
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
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

More details and results :

- myocardial revascularization for stable angina in all type of patient at <http://www.trialresultscenter.org/go-Q25>

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LEFT-MAIN-2, 0:

ongoing trial NCT00598637

2 coronary artery disease

Trial	Treatments	Patients	Trials design and methods
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

continued...

Trial	Treatments	Patients	Trials design and methods
SPIRIT I , 2005 [NCT00180453] n=28/32 follow-up: 6 months (5yr)	everolimus eluting stent, XIENCE versus bare etal stent, MULTI-LINK VISION	patients with de novo native coronary artery lesions	Parallel groups single-blind
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
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 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 III (small vessel subgroup) , 2009 n=160/59 follow-up: 9 months	2.5-mm everolimus-eluting stent versus 2.5-mm paclitaxel-eluting stent	patients included in SPIRIT III that received at least one 2.5-mm stent	Parallel groups open
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
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

continued...

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
everolimus eluting stent vs sirolimus ES			
ESSENCE diabetes [NCT00997763] n=149/151 follow-up: 1y for clinical events	everolimus-eluting stent versus sirolimus-eluting stent	diabetic patients with angina or documented ischemia	Parallel groups open South Korea
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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More details and results :

- myocardial revascularization for coronary artery disease in all type of patient at <http://www.trialresultscenter.org/go-Q26>
- myocardial revascularization for coronary artery disease in diabetic patients at <http://www.trialresultscenter.org/go-Q30>
- Drug eluting stent for coronary artery disease in all type of patients at <http://www.trialresultscenter.org/go-Q206>
- Drug eluting stent for coronary artery disease in unprotected left main artery stenosis at <http://www.trialresultscenter.org/go-Q212>
- Drug eluting stent for coronary artery disease in unparticular patients at <http://www.trialresultscenter.org/go-Q215>
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RESET, 2011:

SORT OUT IV, 2012:

[22308301]

Jensen LO, Thayssen P, Hansen HS, Christiansen EH, Tilsted HH, Krusell LR, Villadsen AB, Junker A, Hansen KN, Kaltoft A, Maeng M, Pedersen KE, Kristensen SD, Btker HE, Ravkilde J, Sanchez R, Aare J, Madsen M, Srensen HT, Thuesen L, Lassen JF Randomized comparison of everolimus-eluting and sirolimus-eluting stents in patients treated with percutaneous coronary intervention: the Scandinavian Organization for Randomized Trials with Clinical Outcome IV (SORT OUT IV). *Circulation* 2012 Mar 13;125:1246-55 [22308301]

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LEFT-MAIN-2, 0:

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Entry terms: everolimus eluting stent, XIENCE V, Guidant XIENCE V, Abbott XIENCE V, XIENCE 5, SDZ RAD, SDZ-RAD, 40-O-(2-hydroxyethyl)-rapamycin, RAD 001, RAD001, Afinitor, Certican,