

# Clinical trials of everolimus

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

## 1 stable angina

Trial	Treatments	Patients	Trials design and methods
<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unpublished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 </= 18 mm	Parallel groups double-blind
<b>SPIRIT I , 2005</b> [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
<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
<b>SPIRIT II , 2006</b> <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unpublished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)
<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 m	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

continued...

Trial	Treatments	Patients	Trials design and methods
<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>everolimus eluting stent vs zotarolimus eluting stent</b>			
<b>LEFT-MAIN-2</b> <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
<b>everolimus eluting stent vs bare-metal stent</b>			
<b>BASKET-PROVE (EES) , 2010</b> [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
<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 <= 18 mm	Parallel groups double-blind

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<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>everolimus eluting stent vs everolimus eluting stent</b>			
<b>PLATINUM , 2011</b> [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
<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
<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 (maximum 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 III (small vessel subgroup) , 2009</b> 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
<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>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

continued...

Trial	Treatments	Patients	Trials design and methods
<b>RESET , 2011</b> [NCT01035450] n=NA	-	-	
<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>everolimus eluting stent vs sirolimus ES</b>			
<b>ESSENCE diabetes</b> [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
<b>everolimus eluting stent vs zotarolimus eluting stent</b>			
<b>LEFT-MAIN-2</b> <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>
- Drug eluting stent for coronary artery disease in small vessels at <http://www.trialresultscenter.org/go-Q217>

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### **RESET, 2011:**

### **SORT OUT IV, 2012:**

[22308301]

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