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FUTURE II , 2006 *unpublished* n=43/21 follow-up: 6 months	CHAMPION versus bare-metal stent	Patients with de novo lesions in vessels with a reference diameter of 2.75-4.0 mm and length 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
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SPIRIT II , 2006 *unpublished* [NCT00180310] n=223/77 follow-up: 6 months	everolimus eluting stent, XIENCE V versus placitaxel eluting stent, TAXUS EXPRESS2	De novo lesions (maximim two)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

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 *ongoing* [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

References

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:

unpublished

Grube E, Lansky A, Mehran R, Fitzgerald P, Ho Multicenter evaluation of the bioabsorbable polymer-basedeverolimus-eluting stent: FUTURE-2 trial Transcatheter-Cardiovascular 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]

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

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

SPIRIT II, 2006:

unpublished

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

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

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

Stone GW, Midei M, Newman W, Sanz M, Hermiller JB, Williams J, Farhat N, Caputo R, Xenopoulos N, Applegate R, Gordon P, White RM, Sudhir K, Cutlip DE, Petersen JL Circulation 2009;119:680-6 [19171853]

Applegate RJ, Hermiller JJ, Sanz M, Doostzadeh J, Pierson W, Su X, Lansky AJ, Sudhir K, Stone GW Comparison of everolimus-eluting and paclitaxel-eluting coronary stents in patients with two treated vessels: 2-year results from the SPIRIT III randomised trial. EuroIntervention 2010;6:437-46 [20884430] 10.4244/EIJ30V6I4A75

SPIRIT IV, 2010:

Nikolsky E, Lansky AJ, Sudhir K, Doostzadeh J, Cutlip DE, Piana R, Su X, White R, Simonton CA, Stone GW SPIRIT IV trial design: a large-scale randomized comparison of everolimus-eluting stents and paclitaxel-eluting stents in patients with coronary artery disease. Am Heart J 2009;158:520-526.e2 [19781409]

Stone GW, Rizvi A, Newman W, Mastali K, Wang JC, Caputo R, Doostzadeh J, Cao S, Simonton CA, Sudhir K, Lansky AJ, Cutlip DE, Kereiakes DJ Everolimus-eluting versus paclitaxel-eluting stents in coronary artery disease. N Engl J Med 2010 May 6;362:1663-74 [20445180] 10.1056/NEJMoa0910496

Kereiakes DJ, Cutlip DE, Applegate RJ, Wang J, Yaqub M, Sood P, Su X, Su G, Farhat N, Rizvi A, Simonton CA, Sudhir K, Stone GW Outcomes in diabetic and nondiabetic patients treated with everolimus- or paclitaxel-eluting stents: results from the SPIRIT IV clinical trial (Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System). J Am Coll Cardiol 2010;56:2084-9 [21144968] 10.1016/j.jacc.2010.10.006

Stone GW, Rizvi A, Sudhir K, Newman W, Applegate RJ, Cannon LA, Maddux JT, Cutlip DE, Simonton CA, Sood P, Kereiakes DJ Randomized Comparison of

Everolimus- and Paclitaxel-Eluting Stents 2-Year Follow-Up From the SPIRIT (Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System) IV Trial. J Am Coll Cardiol 2011 Apr 15;: [21514084] 10.1016/j.jacc.2011.02.022

ISAR-TEST 4 (EES vs SES), :

Byrne RA, Kastrati A, Kufner S, Massberg S, Birkmeier KA, Laugwitz KL, Schulz S, Pache J, Fusaro M, Seyfarth M, Schmig A, Mehilli 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 Oct;30:2441-9 [19720642] 10.1093/eurheartj/ehp352

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]

Jensen LO, Thayssen P, Christiansen EH, Tilsted HH, Maeng M, Hansen KN, Kaltoft A, Hansen HS, Btker HE, Krusell LR, Ravkilde J, Madsen M, Thuesen L, Lassen JF 2-Year Patient-Related Versus Stent-Related Outcomes: The SORT OUT IV (Scandinavian Organization for Randomized Trials With Clinical Outcome IV) Trial. J Am Coll Cardiol 2012;60:1140-7 [22958957]

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 *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

continued...

Trial	Treatments	Patients	Trials design and methods
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 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 *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 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 *ongoing* [NCT00598637] n=NA follow-up:	Xience versus Endeavor Resolute	unprotected left main coronary artery disease	open

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

References

BASKET-PROVE (EES), 2010:

Kaiser C, Galatius S, Erne P, Eberli F, Alber H, Rickli H, Pedrazzini G, Hornig B, Bertel O, Bonetti P, De Servi S, Brunner-La Rocca HP, Ricard I, Pfisterer M Drug-Eluting versus Bare-Metal Stents in Large Coronary Arteries. N Engl J Med 2010 Nov 16;: [21080780] 10.1056/NEJMoa1009406

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:

unpublished

Grube E, Lansky A, Mehran R, Fitzgerald P, Ho Multicenter evaluation of the bioabsorbable polymer-basedeverolimus-eluting stent: FUTURE-2 trial Transcatheter-Cardiovascular 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]

PLATINUM, 2011:

Stone GW, Teirstein PS, Meredith IT, Farah B, Dubois CL, Feldman RL, Dens J, Hagiwara N, Allocco DJ, Dawkins KD A Prospective, Randomized Evaluation of a Novel Everolimus-Eluting Coronary Stent The PLATINUM (A Prospective, Randomized, Multicenter Trial to Assess an Everolimus-Eluting Coronary Stent System [PROMUS Element] for the Treatment of up to Two De Novo Coronary Artery Lesions) Trial. J Am Coll Cardiol 2011 Mar 17;: [21470815] 10.1016/j.jacc.2011.02.016

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

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

SPIRIT II, 2006:

unpublished

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

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

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

Stone GW, Midei M, Newman W, Sanz M, Hermiller JB, Williams J, Farhat N, Caputo R, Xenopoulos N, Applegate R, Gordon P, White RM, Sudhir K, Cutlip DE, Petersen JL Circulation 2009;119:680-6 [19171853]

Applegate RJ, Hermiller JJ, Sanz M, Doostzadeh J, Pierson W, Su X, Lansky AJ, Sudhir K, Stone GW Comparison of everolimus-eluting and paclitaxel-eluting coronary stents in patients with two treated vessels: 2-year results from the SPIRIT III randomised trial. EuroIntervention 2010;6:437-46 [20884430] 10.4244/EIJ30V6I4A75

SPIRIT III (small vessel subgroup), 2009:

Hermiller JB, Fergus T, Pierson W, Su X, Sood P, Sudhir K, Stone GW Clinical and angiographic comparison of everolimus-eluting and paclitaxel-eluting stents in small coronary arteries: a post hoc analysis of the SPIRIT III randomized trial. Am Heart J 2009 Dec;158:1005-10 [19958868] 10.1016/j.ahj.2009.09.018

SPIRIT IV, 2010:

Nikolsky E, Lansky AJ, Sudhir K, Doostzadeh J, Cutlip DE, Piana R, Su X, White R, Simonton CA, Stone GW SPIRIT IV trial design: a large-scale randomized comparison of everolimus-eluting stents and paclitaxel-eluting stents in patients with coronary artery disease. Am Heart J 2009;158:520-526.e2 [19781409]

Stone GW, Rizvi A, Newman W, Mastali K, Wang JC, Caputo R, Doostzadeh J, Cao S, Simonton CA, Sudhir K, Lansky AJ, Cutlip DE, Kereiakes DJ Everolimus-eluting versus paclitaxel-eluting stents in coronary artery disease. N Engl J Med 2010 May 6;362:1663-74 [20445180] 10.1056/NEJMoa0910496

Kereiakes DJ, Cutlip DE, Applegate RJ, Wang J, Yaqub M, Sood P, Su X, Su G, Farhat N, Rizvi A, Simonton CA, Sudhir K, Stone GW Outcomes in diabetic and nondiabetic patients treated with everolimus- or paclitaxel-eluting stents: results from the SPIRIT IV clinical trial (Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System). J Am Coll Cardiol 2010;56:2084-9 [21144968] 10.1016/j.jacc.2010.10.006

Stone GW, Rizvi A, Sudhir K, Newman W, Applegate RJ, Cannon LA, Maddux JT, Cutlip DE, Simonton CA, Sood P, Kereiakes DJ Randomized Comparison of Everolimus- and Paclitaxel-Eluting Stents 2-Year Follow-Up From the SPIRIT (Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System) IV Trial. J Am Coll Cardiol 2011 Apr 15;: [21514084] 10.1016/j.jacc.2011.02.022

ISAR-TEST 4 (EES vs SES), :

Byrne RA, Kastrati A, Kufner S, Massberg S, Birkmeier KA, Laugwitz KL, Schulz S, Pache J, Fusaro M, Seyfarth M, Schmig A, Mehilli 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 Oct;30:2441-9 [19720642] 10.1093/eurheartj/ehp352

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]

Jensen LO, Thayssen P, Christiansen EH, Tilsted HH, Maeng M, Hansen KN, Kaltoft A, Hansen HS, Btker HE, Krusell LR, Ravkilde J, Madsen M, Thuesen L, Lassen JF 2-Year Patient-Related Versus Stent-Related Outcomes: The SORT OUT IV (Scandinavian Organization for Randomized Trials With Clinical Outcome IV)

Trial. J Am Coll Cardiol 2012;60:1140-7 [22958957]

ESSENCE diabetes, :

Kim WJ, Lee SW, Park SW, Kim YH, Yun SC, Lee JY, Park DW, Kang SJ, Lee CW, Lee JH, Choi SW, Seong IW, Lee BK, Lee NH, Cho YH, Shin WY, Lee SJ, Lee SW, Hyon MS, Bang DW, Park WJ, Kim HS, Chae JK, Lee K, Park HK, Park CB, Lee SG, Kim MK, Park KH, Choi YJ, C Randomized Comparison of Everolimus-Eluting Stent Versus Sirolimus-Eluting Stent Implantation for De Novo Coronary Artery Disease in Patients With Diabetes Mellitus (ESSENCE-DIABETES): Results From the ESSENCE-DIABETES Trial. Circulation 2011 Aug 23;124:886-892 [21810659] 10.1161/CIRCULATIONAHA.110.015453

LEFT-MAIN-2, 0:

ongoing trial NCT00598637

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,