

Clinical trials of Drug eluting stent for coronary artery disease in in stent restenosis

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1 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
sirolimus eluting stent vs cutting ballon angioplasty			
FOCUS <i>ongoing</i> [NCT00485004] n=NA follow-up:	sirolimus-eluting implantation cypher versus cutting balloon angioplasty	focal in-stent restenosis after drug-eluting stent	
sirolimus eluting stent vs PTCA			
CRISTAL [NCT00323895] n=NA follow-up:	sirolimus-eluting stent versus balloon re-percutaneous transluminal coronary angioplasty	Intra-Des Restenosis	
RIBS-II , 2008 n=76/74 follow-up: >1 year	sirolimus-eluting stents versus Balloon angioplasty	patients with bare metal in-stent restenosis	Parallel groups open Spanish
paclitaxel eluting balloon vs brachytherapy			
TAXUS V ISR , 2006 [NCT00287573] n=195/201 follow-up:	TAXUS Express2 versus angioplasty followed by vascular brachytherapy with a beta source	patients with restenotic lesions after prior stent implantation in native coronary arteries	Parallel groups open North America
sirolimus eluting stent vs brachytherapy			
SISR , 2007 [NCT00231257] n=259/125 follow-up: 12 months	Sirolimus-eluting stents versus brachytherapy	restenosis within a bare metal stent	Parallel groups open US and Canadian
sirolimus eluting stent vs paclitaxel eluting stent			
ISAR-DESIRE (SES vs PES) , 2005 n=100/100 follow-up: 1y	Cypher versus Taxus	In-stent restenosis. AP and/or positive test, previously stented, no AMI	Parallel groups open germany
ISAR-DESIRE-2 , 2010 [NCT00598715] n=225/225 follow-up: 1y	sirolimus-eluting stent versus paclitaxel-eluting stent	coronary restenosis in sirolimus-eluting stents	Parallel groups open Germany

continued...

Trial	Treatments	Patients	Trials design and methods
DES-ISR <i>ongoing</i> [NCT00485030] n=NA follow-up:	Cypher versus Taxus	patients Diffuse Type In-Stent Restenosis After Drug-Eluting Stents Implantation	

References

FOCUS, 0:

CRISTAL, 0:

RIBS-II, 2008:

Alfonso F, Prez-Vizcayno MJ, Hernandez R, Bethencourt A, Mart V, Lopez-Mnguez JR, Angel J, Iiguez A, Mors C, Cequier A, Sabat M, Escaned J, Jimnez-Quevedo P, Baelos C, Surez A, Macaya C Long-term clinical benefit of sirolimus-eluting stents in patients with in-stent restenosis results of the RIBS-II (Restenosis Intra-stent: Balloon angioplasty vs. elective sirolimus-eluting Stenting) study. *J Am Coll Cardiol* 2008 Nov 11;52:1621-7 [[18992651](#)]

TAXUS V ISR, 2006:

Stone GW, Ellis SG, O'Shaughnessy CD, Martin SL, Satler L, McGarry T, Turco MA, Kereiakes DJ, Kelley L, Popma JJ, Russell ME Paclitaxel-eluting stents vs vascular brachytherapy for in-stent restenosis within bare-metal stents: the TAXUS V ISR randomized trial. *JAMA* 2006 Mar 15;295:1253-63 [[16531618](#)]

Ellis SG, O'Shaughnessy CD, Martin SL, Kent K, McGarry T, Turco MA, Kereiakes DJ, Popma JJ, Friedman M, Koglin J, Stone GW Two-year clinical outcomes after paclitaxel-eluting stent or brachytherapy treatment for bare metal stent restenosis: the TAXUS V ISR trial. *Eur Heart J* 2008 Jul;29:1625-34 [[18556716](#)]

Koizumi T, Fitzgerald PJ, Honda Y, Ellis SG, Kent K, Martin SL, Brown CL, Masud AR, Patterson JB, Greenberg J, Friedman M, Uchida T, Stone GW Vascular responses to the multiple overlapped paclitaxel-eluting stents for the treatment of bare-metal in-stent restenotic lesions: angiographic and intravascular ultrasound analysis from the TAXUS-V ISR trial. *Cardiovasc Revasc Med* 2010;11:140-8 [[20599163](#)] [10.1016/j.carrev.2009.07.004](#)

SISR, 2007:

Reynolds MR, Pinto DS, Shi C, Walczak J, Berezin R, Holmes DR, Cohen DJ, Cost-effectiveness of sirolimus-eluting stents compared with vascular brachytherapy for the treatment of in-stent restenosis. *Am Heart J* 2007;154:1221-7. [[18035097](#)] [10.1016/j.ahj.2007.07.033](#)

Holmes DR Jr, Teirstein P, Satler L, Sketch M, O'Malley J, Popma JJ, Kuntz RE, Fitzgerald PJ, Wang H, Caramanica E, Cohen SA Sirolimus-eluting stents vs vascular brachytherapy for in-stent restenosis within bare-metal stents: the SISR randomized trial. *JAMA* 2006;295:1264-73 [[16531619](#)]

ISAR-DESIRE (SES vs PES), 2005:

Kastrati A, Mehilli J, von Beckerath N, Dibra A, Hausleiter J, Pache J, Schhlen H, Schmitt C, Dirschinger J, Schmig A Sirolimus-eluting stent or paclitaxel-eluting stent vs balloon angioplasty for prevention of recurrences in patients with coronary in-stent restenosis: a randomized controlled trial. *JAMA* 2005;293:165-71 [[15644543](#)]

ISAR-DESIRE-2, 2010:

Mehilli J, Byrne RA, Tiroch K, Piniack S, Schulz S, Kufner S, Massberg S, Laugwitz KL, Schmig A, Kastrati A Randomized Trial of Paclitaxel- Versus Sirolimus-Eluting Stents for Treatment of Coronary Restenosis in Sirolimus-Eluting Stents The ISAR-DESIRE 2 (Intracoronary Stenting and Angiographic Results: Drug Eluting Stents for In-Stent Restenosis 2) Study. *J Am Coll Cardiol* 2010 Mar 5;: [[20226618](#)] [10.1016/j.jacc.2010.02.009](#)

DES-ISR, 0:

2 About TrialResults-center.org

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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.

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