

Clinical trials of myocardial revascularization for coronary artery disease in all type of patient

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1 abciximab-coated stent

Trial	Treatments	Patients	Trials design and methods
abciximab-coated stent vs bare-metal stent			
Kim , 2010 n=93 follow-up: 6 mo (2y)	abciximab-coated stent versus bare metal stents	patients undergoing PCI for de novo coronary lesions	Parallel groups open Korea

References

Kim, 2010:

Kim SS, Hong YJ, Jeong MH, Kim W, Kim HK, Ko JS, Lee MG, Sim DS, Park KH, Yoon NS, Yoon HJ, Kim KH, Park HW, Kim JH, Ahn Y, Cho JG, Park JC, Song SJ, Cho DL, Kang JC Two-year clinical outcome after abciximab-coated stent implantation in patients with coronary artery disease. *Circ J* 2010;74:442-8 [20103970]

2 bioabsorbable polymer stent

Trial	Treatments	Patients	Trials design and methods
biodegradable-polymer vs BMS			
PAINT (sirolimus) , 2009 [NCT00752362] n=NA follow-up: 12 mo (angiography 9 mo)	biodegradable-polymer sirolimus-eluting (Supralimus) versus bare metal stent (matrix)	patients with de novo coronary lesions in native vessels scheduled for stent implantation	Parallel groups open
biolimus eluting stent vs sirolimus eluting stent			
LEADERS , 2008 [NCT00389220] n=857/850 follow-up: 9 months	BioMatrix III (biolimus-eluting stent with biodegradable 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 3 (BP) , 2009 n=202/202 follow-up: 12 months	biodegradable-polymer 0.4% rapamycin stent (180 mg rapamycin/cm2) versus permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2)	Patients with de novo coronary lesions in native vessels	Parallel groups open Germany

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Trial	Treatments	Patients	Trials design and methods
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

References

PAINT (sirolimus), 2009:

Lemos PA, Moulin B, Perin MA, Oliveira LA, Arruda JA, Lima VC, Lima AA, Caramori PR, Medeiros CR, Barbosa MR, Brito FS Jr, Ribeiro EE, Martinez EE Randomized evaluation of two drug-eluting stents with identical metallic platform and biodegradable polymer but different agents (paclitaxel or sirolimus) compared against bare stents: 1-year results of the PAINT trial. *Catheter Cardiovasc Interv* 2009;74:665-73 [[19670303](#)]

LEADERS, 2008:

Windecker S, Serruys PW, Wandel S, Buszman P, Trznadel S, Linke A, Lenk K, Ischinger T, Klauss V, Eberli F, Corti R, Wijns W, Morice MC, di Mario C, Davies S, van Geuns RJ, Eerdmans P, van Es GA, Meier B, Jni P Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomised non-inferiority trial. *Lancet* 2008 Aug 31;: [[18765162](#)]

Stefanini GG, Kalesan B, Serruys PW, Heg D, Buszman P, Linke A, Ischinger T, Klauss V, Eberli F, Wijns W, Morice MC, Di Mario C, Corti R, Antoni D, Sohn HY, Eerdmans P, van Es GA, Meier B, Windecker S, Jni P Long-term clinical outcomes of biodegradable polymer biolimus-eluting stents versus durable polymer sirolimus-eluting stents in patients with coronary artery disease (LEADERS): 4 year follow-up of a randomised non-inferiority trial. *Lancet* 2011 Dec 3;378:1940-8 [[22075451](#)] [10.1016/S0140-6736\(11\)61672-3](#)

ISAR TEST 3 (BP), 2009:

ISAR-TEST-4 (biodegradable polymer), 2009:

3 CABG or PCI

Trial	Treatments	Patients	Trials design and methods
CABG or PCI vs medical treatment			
BARI 2D , 2009 [NCT00006305] n=1176/1192 follow-up: 5.3 y	prompt revascularization with intensive medical therapy versus intensive medical therapy alone	patients with type 2 diabetes and heart disease	Parallel groups open US, Canada, Brazil, Mexico, Czech Republic, Austria

References

BARI 2D, 2009:

4 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
A vs B			
Nordic Bifurcation Study <i>ongoing</i> [NCT00376571] n=NA follow-up:	Strategy of Routine Stenting Both Main Vessel and Side Branch versus Strategy of Routine Main Vessel Stenting and Optional Treatment of Side Branch	bifurcation lesions	
paclitaxel eluting stent vs balloon angioplasty			
ISAR-DESIRE (PES vs PTCA) , 2005 n=100/100 follow-up: 1y	TAXUS versus ballon angioplasty	In-stent restenosis. AP and/or positive test, previously stented, no AMI	Parallel groups open germany
sirolimus eluting stent vs balloon angioplasty			
ISAR-DESIRE (SES vs PTCA) , 2005 n=100/100 follow-up: 1y	Cypher versus ballon angioplasty	In-stent restenosis. AP and/or positive test, previously stented, no AMI	Parallel groups open germany
dactinomycin eluting stent vs bare-metal stent			
ACTION , 2004 n=241/119 follow-up: 6 months	Multilink Tetra stent versus uncoated Multilink Tetra stent	Patients with stable angina pectoris or silent ischemia and a single de novo lesion in a native coronary artery ≥ 3.0 mm and ≤ 4.0 mm in diameter that could be covered by an 18-mm stent	Parallel groups single-blind worldwide
dexamethasone eluting stent vs bare-metal stent			
FEMH-93005 <i>ongoing</i> [NCT00190099] n=NA	-	-	
drug-eluting stents vs bare-metal stent			
ISAR-CABG <i>ongoing</i> [NCT00611910] n=NA follow-up:	DES versus BMS	Bypass Graft Lesions	open
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 stent, XIENCE versus bare metal stent, MULTI-LINK VISION	patients with de novo native coronary artery lesions	Parallel groups single-blind
Genous stent vs bare-metal stent			

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Trial	Treatments	Patients	Trials design and methods
TRIAS-Low-Risk <i>ongoing</i> n=NA	-	-	
paclitaxel eluting stent vs bare-metal stent			
HAAMU-STENT , 2006 <i>unpublished</i> n=70/75 follow-up: 12 months	Taxus Express versus Bare-metal-stent	AMI - STEMI patients undergoing PCI	Parallel groups open Finland
PASSION , 2006 [ISRCTN65027270] n=310/309 follow-up: 12 months (5y)	Taxus Express2 versus Express2 or Libert	Myocardial Infarction with ST-Segment Elevation	Parallel groups open The Netherlands
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 estimated stenosis >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
TAXUS V (all patients) , 2005 [NCT00301522] n=577/579 follow-up: 9 months	TAXUS versus bare metal EXPRESS-2	Stable or unstable AP, silent ischaemia with single coronary artery stenosis including complex or previously unstudied lesions (requiring 2.25-mm, 4.0-mm, and/or multiple stents)	Parallel groups double-blind United States
TAXUS VI , 2005 [NCT00297804] n=219/227 follow-up: 9 months (2y)	TAXUS versus Express2 stent	Stable or unstable AP, silent ischaemia with long, complex coronary artery lesions	Parallel groups double-blind Europe
BASKET-SAVAGE <i>ongoing</i> [NCT00595647] n=NA follow-up:	Taxus versus Libert	percutaneous coronary interventions of saphenous vein grafts	open
sirolimus eluting stent vs bare-metal stent			
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

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Trial	Treatments	Patients	Trials design and methods
DECODE , 2005 <i>unpublished</i> [NCT00489164] n=54/29 follow-up: 1 year	CYPHER (Up to 3 stents per patient were allowed) versus Bx VELOCITY (Up to 3 stents per patient were allowed)	Stable or unstable angina in diabetic patients with up to 2 de novo lesions in up to 2 native coronary vessels	Parallel groups open US, Asia/Pacific
DIABETES , 2005 n=80/80 follow-up: 9 months	Cypher versus Bx Velocity/Sonic	de novo lesions in native coronary arteries in 1, 2, or 3 native vessels with symptoms or objective evidence of ischemia; vessel size smaller than 4.0 mm	Parallel groups open Spanish
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
GISSOC II , 2010 [NCT00220558] n=78/74 follow-up: 8 months	Sirolimus Eluting Stent versus Bare Metal Stent	patients with Chronic Total Occlusion older than 1 month, and successful recanalization	Parallel groups open Italy
Kochiadakis , 2007 n=38/43 follow-up: 4.8 months (mean)	sirolimus-eluting stents versus bare metal stent	one-vessel disease (>70% narrowing of the lumen of one major epicardial coronary artery); stable coronary artery disease, age <70 years, and vessel reference diameter >=2.5 mm	Parallel groups open Greece
MISSION , 2008 [ISRCTN62825862] n=158/152 follow-up: 12 months	Cypher versus Vision	primary percutaneous coronary intervention for ST-segment elevation myocardial infarction (<9h)	Parallel groups single-blind the Netherlands
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
Pasceri , 2003 <i>unpublished</i> n=NA follow-up: 12 months	-	-	Parallel groups
PRISON II , 2006 [NCT00258596] n=100/100 follow-up: 6 months	Cypher versus BxVelocity	Chronic total occlusion, positive exercise stress test	Parallel groups single-blind Belgium
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

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Trial	Treatments	Patients	Trials design and methods
SCANDSTENT , 2006 [NCT00151658] n=163/159 follow-up: 7 months	Cypher versus Sonic	Stable or unstable AP, recent AMI (non ST-elevation); with one or more de novo complex lesions in native coronary vessels (occluded, bifurcational, ostial or angulated)	Parallel groups open Denmark
SCORPIUS , 2007 [NCT00495898] n=98/102 follow-up: 12 months	Cypher versus Bx-Velocity	patients with diabetes and de novo coronary artery lesions	Parallel groups open Germany
SES-SMART , 2004 n=129/128 follow-up: 8 months	Cypher versus Bx Sonic	Stable AP, ACS, silent myocardial ischaemia as shown by exercise stress test	Parallel groups single-blind Italian
SESAMI , 2007 [NCT00288210] n=160/160 follow-up: 12 months	Cypher versus BX stent, Cordis	AMI	Parallel groups open Italy
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
TYPHOON , 2006 [NCT00232830] n=356/359 follow-up: 12 months	Cypher or CypherSelect versus any commerciallyavailable uncoated stent	AMI	Parallel groups open Worldwide (15 countries)
BASKET-PROVE , 2008 <i>ongoing</i> 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
crush stenting vs culotte stenting			
Nordic Bifurcation Stent Technique Study <i>ongoing</i> [NCT00292305] n=NA follow-up:	crush stenting versus culotte stenting	bifurcation lesions	
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	
bioabsorbable polymer EES vs everolimus eluting stent			

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Trial	Treatments	Patients	Trials design and methods
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
Nevo vs paclitaxel eluting stent			
NEVO RES-ELUTION I [NCT00714883] n=202/194 follow-up: 6 months	Nevo sirolimus eluting stent with bioresorbable PLGA polymer versus paclitaxel eluting stent (Libert)	patients with single, de novo lesions	Parallel groups open Europe, Brazil, Australia, and New Zealand
DES vs CABG			
Boudriot , 2008 n=83/84 follow-up: 12 months	DES versus CABG	-	Parallel groups open
drug-eluting stents vs CABG			
Leipzig ongoing [NCT00176397] n=NA follow-up:	PCI With DES versus CABG	left main coronary stenosis	
paclitaxel eluting stent vs CABG			
SYNTAX , 2009 [NCT00114972] n=903/897 follow-up: 1 year	paclitaxel (taxus Express SR) versus Coronary Artery Bypass Surgery (on- or off-pump bypass)	patients with previously untreated three-vessel or left main coronary artery disease (or both) (complex lesions)	Parallel groups open
PCI vs CABG			
AWESOME , 2001 n=222/232 follow-up: 5 years	percutaneous coronary intervention versus coronary artery bypass graft	high-risk patients with medically refractory ischemia	Parallel groups open US (Veterans Affairs Medical Centers)
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			
PRECOMBAT , 2011 [NCT00422968] n=300/300 follow-up:	PCI with sirolimus-eluting stents versus CABG	patients with unprotected left main coronary artery stenosis	

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Trial	Treatments	Patients	Trials design and methods
MIDCAB Versus DES in Proximal LAD Lesions <i>ongoing</i> [NCT00299429] n=NA follow-up:	sirolimus-coated stent versus minimally invasive bypass surgery	patients with isolated proximal left anterior descending coronary arteries	
Munich Study <i>ongoing</i> n=NA	sirolimus versus CABG	-	
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
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 <i>ongoing</i> [NCT00887211] n=NA follow-up:	ProStent rapamycin-eluting stent system versus Firebird drug-eluting stents	-	Parallel groups single blind
paclitaxel eluting stent vs medical treatment			
VELETI <i>ongoing</i> [NCT00289835] n=NA follow-up:	TAXUS versus standard medical treatment	Moderate Vein Graft Lesions	
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			
SPIRIT II , 2006 <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)

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Trial	Treatments	Patients	Trials design and methods
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
Genous stent vs paclitaxel eluting stent			
TRIAS-HR , 2008 <i>unpublished</i> [ISRCTN74297220] n=98/95 follow-up: 12 months	Genous stent (antibody-coated bare-metal stent) followed by one month of dual antiplatelet therapy versus Taxus or Cypher followed by at least six months of dual antiplatelet therapy	high-risk patients (long lesions, small vessels, chronic total occlusions, or any lesion in a diabetic patient)	Parallel groups single-blind
paclitaxel eluting balloon vs paclitaxel eluting stent			
PEPCAD IV <i>ongoing</i> [NCT00462631] n=NA follow-up:	Paclitaxel-eluting PTCA-balloon dilation (SeQuent™ Please) followed by cobalt-chromium stent (Coroflex™ Blue) deployment versus Taxus Libert	patients with diabetes mellitus	open
paclitaxel eluting stent vs paclitaxel eluting stent			
PERSEUS Workhorse , 2010 <i>ongoing</i> [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,
Cervinka , 2006 n=37/33 follow-up: 6 months	sirolimus-eluting stent versus paclitaxel-eluting stent	Complex lesions and patients. Signs and/or symptoms myocardial ischaemia, including AMI	Parallel groups open
CORPAL , 2005 <i>unpublished</i> n=331/321 follow-up:	sirolimus versus paclitaxel	Documented myocardial ischaemia, no AMI	Parallel groups open Spain
Di Lorenzo et al. , 2005 <i>unpublished</i> n=90/90 follow-up:	sirolimus versus paclitaxel	ST-segment elevation myocardial infarction	Parallel groups open

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Trial	Treatments	Patients	Trials design and methods
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-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-DIABETES , 2005 n=125/125 follow-up: 9 months	Taxus versus Cypher	Diabetic patients. AP or positive stress, no AMI with clinically significant angiographic stenosis in a native coronary vessel	Parallel groups open Germany
ISAR-LEFT-MAIN , 2009 [NCT00133237] n=302/305 follow-up: 1 year	Paclitaxel-eluting stent versus Sirolimus-eluting stent	Unprotected Left Main Coronary Artery Disease	Parallel groups open
ISAR-SMART 3 , 2006 [NCT00146575] n=180/180 follow-up:	Taxus versus Cypher	Small vessels, de novo lesions in native coronary vessels with a diameter of <2.80 mm nondiabetic patients. AP or positive stress, no AMI	Parallel groups NA Germany
ISAR-TEST-1 , 2006 [NCT00140530] n=225/225 follow-up: 9 months	rapamycin-eluting stent Yukon versus Taxus	stable or unstable angina or a positive stress test, stable or unstable angina or a positive stress test	Parallel groups open Germany
LONG DES II , 2006 n=250/250 follow-up: 9 months	SES versus PES	Long lesions. AP or positive stress, no AMI	Parallel groups single-blind Korea
Pan , 2007 n=103/102 follow-up: 24 months (mean)	SES for provisional T-stenting versus PES for provisional T-stenting	patients with bifurcation lesions	Parallel groups open Spain
Petronio et al , 2007 n=50/50 follow-up: 9 months	Cypher versus Taxus	Complex lesions. Stable AP or documented ischaemia, no AMI	Parallel groups open Italy
PROSIT , 2006 n=154/154 follow-up: 1 year	SES Cordis versus PES Boston Scientific	AMI or persistent ischaemia 12-24h	Parallel groups open Korea
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

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Trial	Treatments	Patients	Trials design and methods
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.
TAXi , 2005 n=102/100 follow-up: 6 months	Cypher versus Taxus	Unselected patients	Parallel groups open Switzerland.
Tomai , 2008 n=60/60 follow-up: 8 months	sirolimus-eluting stent versus paclitaxel-eluting stent	diabetic patient with multiple de novo coronary artery lesions	Cross over NA Italy
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
DES-ISR <i>ongoing</i> [NCT00485030] n=NA follow-up:	Cypher versus Taxus	patients Diffuse Type In-Stent Restenosis After Drug-Eluting Stents Implantation	
Lipsia-Yukon-DM <i>ongoing</i> [NCT00368953] n=NA follow-up: 9 months	Yukon Choice stent system versus Taxus Libert stent system	Patients With Diabetes Mellitus	
zotarolimus eluting stent vs paclitaxel eluting stent			
ENDEAVOR IV , 2009 <i>unpublished</i> [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
ZEST AMI (vs PES) , 2009 [NCT00422565] n=108/110 follow-up: 1 year (mean)	zotarolimus-eluting stent (Endeavor) versus paclitaxel-eluting stent (Taxus Libert)	Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours	open Korea

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Trial	Treatments	Patients	Trials design and methods
ZoMaxx I , 2008 n=199/197 follow-up: 9 months	ZoMaxx zotarolimus-eluting stent versus Taxus paclitaxel-eluting stent	patients with single de novo coronary lesions and with lesion length 10-30 mm and reference vessel diameter 2.5-3.5 mm	Parallel groups open
ZoMaxx phase 2 <i>ongoing</i> [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 <i>ongoing</i> [NCT00322569] n=NA follow-up: 6 months	Corio Pimecrolimus versus CoStar	patients with de novo lesions of the native coronary arteries	
dual sirolimus, probucol eluting stent vs sirolimus eluting stent			
ISAR TEST 2 (vs SES) , 2009 [NCT00332397] n=333/335 follow-up: 12 months	dual DES (polymer-free stent consisting of probucol and rapamycin) versus SES	patients with De novo lesions in native coronary arteries	Parallel groups open Germany
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
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
paclitaxel eluting stent vs sirolimus eluting stent			
FRE-RACE <i>ongoing</i> [NCT00130546] n=NA follow-up:	Cypher select versus Taxus	de novo native coronary lesions with two or more coronary artery stenoses	Cross over
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

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Trial	Treatments	Patients	Trials design and methods
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
ZEST AMI (vs SES) , 2009 [NCT00422565] n=108/110 follow-up: 1 year (mean)	zotarolimus-eluting stent (Endeavor) versus sirolimus-eluting stents (Cypher)	Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours	Parallel groups open Korea
DIABEDES IV <i>ongoing</i> [NCT00552994] n=NA follow-up:	Cypher select plus versus Xience V	diabetic patients	
PRISON III , 2007 <i>ongoing</i> [NCT00428454] n=NA follow-up: 8 months	Endeavor versus Cypher	patients with total coronary occlusions for at least 2 weeks with evidence of ischemia related to the occluded coronary artery	Parallel groups open
dual sirolimus, probucol eluting stent vs zotarolimus eluting stent			
ISAR TEST 2 (vs ZES) , 2009 [NCT00332397] n=333/339 follow-up: 12 months	dual DES (polymer-free stent consisting of probucol and rapamycin) versus permanent polymer zotarolimus-eluting stent (Endeavor)	patients with De novo lesions in native coronary arteries	Parallel groups open Germany
ISAR TEST 5 [NCT00598533] n=2002/1000 follow-up: 1 year	polymer-free, rapamycin/probucol-eluting Dual-DES stent versus zotarolimus-eluting stent with a modified permanent polymer on a cobalt-chromium alloy platform	"all-comers" population	Parallel groups
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

References

Nordic Bifurcation Study, 0:
ISAR-DESIRE (PES vs PTCA), 2005:
ISAR-DESIRE (SES vs PTCA), 2005:
ACTION, 2004:

FEMH-93005, 0:
ISAR-CABG, 0:
FUTURE I, 2004:
FUTURE II, 2006:
SPIRIT I, 2005:
TRIAS-Low-Risk, 0:
HAAMU-STENT, 2006:
PASSION, 2006:
SCORE, 2004:
TAXUS I, 2003:
TAXUS II, 2003:
TAXUS IV, 2004:
TAXUS V (all patients), 2005:
TAXUS VI, 2005:
BASKET-SAVAGE, 0:
C-SIRIUS, 2004:
DECODE, 2005:
DIABETES, 2005:
E-SIRIUS, 2003:
GISSOC II, 2010:
Kochiadakis, 2007:
MISSION, 2008:
Ortolani et al, 2007:
Pache et al, 2005:
Pasceri, 2003:
PRISON II, 2006:
RAVEL, 2002:
SCANDSTENT, 2006:
SCORPIUS, 2007:
SES-SMART, 2004:
SESAMI, 2007:
SIRIUS, 2003:
TYPHOON, 2006:
BASKET-PROVE, 2008:
ENDEAVOR II, 2006:
Nordic Bifurcation Stent Technique Study, 0:
FOCUS, 0:
EVOLVE, 2012:
NEVO RES-ELUTION I, 0:
Boudriot, 2008:
Leipzig, 0:

SYNTAX, 2009:
AWESOME, 2001:
COMBAT, 0:
Korean Randomized Study, 0:
REVASCULARIZE, 0:
PRECOMBAT, 2011:
MIDCAB Versus DES in Proximal LAD Lesions, 0:
Munich Study, 0:
PLATINUM, 2011:
RESOLUTE All comers, 2010:
TWENTE, 2012:
Gao, :
VELETI, 0:
Costar II, 2008:
SPIRIT II, 2006:
SPIRIT III, 2008:
SPIRIT IV, 2010:
TRIAS-HR, 2008:
PEPCAD IV, 0:
PERSEUS Workhorse, 2010:
BASKET (vs paclitaxel), 2005:
Cervinka, 2006:
CORPAL, 2005:
Di Lorenzo et al., 2005:
Han, 2006:
ISAR-DESIRE (SES vs PES), 2005:
ISAR-DIABETES, 2005:
ISAR-LEFT-MAIN, 2009:
ISAR-SMART 3, 2006:
ISAR-TEST-1, 2006:
LONG DES II, 2006:
Pan, 2007:
Petronio et al, 2007:
PROSIT, 2006:
REALITY, 2006:
SIRTAX (Windecker), 2005:
SORT OUT II, 2008:
TAXi, 2005:
Tomai, 2008:
Zhang (SES vs PES), 2006:
DES-ISR, 0:

Lipsia-Yukon-DM, 0:
 ENDEAVOR IV, 2009:
 ZEST (vs PES), 2009:
 ZEST AMI (vs PES), 2009:
 ZoMaxx I, 2008:
 ZoMaxx phase 2, 0:
 GENESIS Trial CP-01, 0:
 ISAR TEST 2 (vs SES), 2009:
 ISAR-TEST 4 (EES vs SES), :
 RESET, 2011:
 SORT OUT IV, 2012:
 FRE-RACE, 0:
 ENDEAVOR III, 2006:
 PROTECT, 2012:
 ZEST (vs SES), 2009:
 ZEST AMI (vs SES), 2009:
 DIABEDES IV, 0:
 PRISON III, 2007:
 ISAR TEST 2 (vs ZES), 2009:
 ISAR TEST 5, :
 LEFT-MAIN-2, 0:

5 fractional-flow-reserve-guided

Trial	Treatments	Patients	Trials design and methods
FFR-guided PCI vs no PCI			
FAME II , 2012 [NCT01132495] n=447/441 follow-up:	fractional-flow-reserve (FFR)-guided stenting versus optimal medical therapy alone	patients patients with stable CAD found on FFR to have hemodynamically relevant disease	Parallel groups Europe, US, and Canada
FAME , 2008 [NCT00267774] n=509/496 follow-up: 1 year	FFR-guided PCI (PCI with implantation of drug-eluting stents guided by FFR measurements in addition to angiography versus angiography-PCI (PCI with implantation of drug-eluting stents guided by angiography alone)	patients with multivessel coronary artery disease	Parallel groups open USA, Europe
DEFER , 2001 n=90/91 follow-up: 24 months	PCI versus deferral (no PCI)	patients for whom PTCA was planned and who did not have documented ischemia and with fractional flow reserve >0.75	Parallel groups open

References

FAME II, 2012:

FAME, 2008:

DEFER, 2001:

6 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 <i>unpublished</i> 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
polymer-free biolimus a9-eluting stents vs paclitaxel eluting stent			
BIOFREEDOM [NCT01172119] n=NA follow-up:	polymer-free biolimus A9-eluting stent versus paclitaxel-eluting stent	patients with symptomatic ischemic heart disease, and stenosis in native coronary arteries ranging in diameter from >=2.25 mm to <=3.0 mm	
polymer free sirolimus stent vs sirolimus eluting stent			
ISAR TEST 3 (PF) , 2009 n=201/202 follow-up: 12 months	polymer free 2% rapamycin (479 mg rapamycin/cm2) stent versus permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2)	Patients with de novo coronary lesions in native vessels	open Germany

References

ASPECT, 2003:

DELIVER, 2004:

ELUTES, 2004:

PATENCY, 2002:
 BIOFREEDOM, :
 ISAR TEST 3 (PF), 2009:

7 PCI

Trial	Treatments	Patients	Trials design and methods
stent vs balloon angioplasty			
Lincoff (EPISTENT) , 1999 [NCT00271401] n=794/796 follow-up: 6 months	stent followed by aspirin 325 mg, abciximab versus balloon angioplasty followed by aspirin 325 mg, abciximab	patients with ischaemic heart disease and suitable coronary-artery lesions	Parallel groups open USA, Canada
Hoher , 1999 n=42/43 follow-up: 6 months	Wiktor versus PTCA alone	patients with a thrombolysis in myocardial infarction grade 0 chronic coronary occlusion	Parallel groups open
Serruys Benestent , 1994 n=262/258 follow-up: 7 months	Palmaz-Schatz versus balloon angioplasty, aspirin 250-500 mg + dipyridamole 75 mgx3	Stable angina	Parallel groups Open Europe
Fischman STRESS , 1994 n=205/202 follow-up: 6 months	Palmaz-Schatz versus ballon angioplasty aspirin, dipyridamol	Stable angina	Parallel groups Open USA
Eeckout , 1996 n=42/42 follow-up: 6 months	Wiktor stent implantation versus conventional balloon angioplasty	Stable angina	Parallel groups open
Sirnes , 1996 n=58/59 follow-up: 6 months	Palmaz-Schatz versus PTCA alone	patients with a satisfactory result after successful recanalization by PTCA of a chronic coronary occlusion	Parallel groups open
Versaci , 1997 n=60/60 follow-up: 12 months	Palmaz-Schatz versus standard coronary angioplasty, aspirin and diltiazem indefinitely	patients with isolated stenosis of the proximal left anterior descending coronary artery	Parallel groups open Italy
Savage , 1998 n=108/107 follow-up: 6 months	Palmaz-Schatz stent versus standard balloon angioplasty	patients with new lesions in aortocoronary-venous bypass grafts	Parallel groups open
Erbel , 1998 n=191/192 follow-up: 6 months	Palmaz-Schatz versus standard balloon angioplasty	patients with clinical and angiographic evidence of restenosis after at least one balloon angioplasty	Parallel groups open
Rubartelli , 1998 n=56/54 follow-up: 9 months	Palmaz-Schatz stent implantation versus PTCA alone	patients with recanalized total occlusion	Parallel groups open

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Trial	Treatments	Patients	Trials design and methods
Hancock , 1998 n=30/30 follow-up: 6 months	Palmaz-Schatz versus angioplasty alone	patients with a total coronary occlusion successfully treated by PTCA	Parallel groups open
Serruys Benestent 2 , 1998 n=414/413 follow-up: 12 months	Heparin-coated Palmaz-Schatz versus ballon angioplastyaspirin $\geq 100\text{mg}$ 6 month	Stable and unstable angina	Parallel groups Open Europe
Rodriguez , 1998 n=57/59 follow-up: 6 months	stent versus optimal PTCA	patients obtaining a good immediate angiographic result after percutaneous transluminal coronary angioplasty	Parallel groups open
Sievert , 1999 n=55/55 follow-up: 4 months	stent implantation versus angioplasty alone	Stable angina	Parallel groups open
Betriu , 1999 n=229/223 follow-up: 6 months (4y)	Palmaz-Schatz versus standard balloon angioplasty	Stable and unstable angina	Parallel groups open
Buller , 1999 n=202/208 follow-up: 6 months	Heparin-coated Palmaz-Schatz versus PTCA	patients with nonacute native coronary occlusions	Parallel groups open
Serruys , 2000 n=97/511 follow-up: 12 months	primary stenting versus balloon angioplasty	patients scheduled for single-vessel angioplasty	Parallel groups open
Di Marlo , 2000 n=370/365 follow-up: 12 months	elective stent implantation versus guided PTCA	Stable and unstable angina; no AMI inprevious 24 h	Parallel groups open
Kastrati , 2000 n=204/200 follow-up: 7 months	Multilink versus PTCA	Patients with symptomatic coronary artery disease with lesions situated in native coronary vessels between 2 and 2.8 mm in size	Parallel groups open
Witkowski , 2000 n=192/196 follow-up: 6 months	Palmaz-Schatz stent versus angioplasty	Symptomatic CAD; no AMI in previous 14 d	Parallel groups open
Lafont , 2000 n=125/126 follow-up: 6 months	systematic stenting versus provisional stenting (group 1, in which stenting was performed if postangioplasty coronary velocity reserve was < 2.2 and/or residual stenosis $> \text{or} = 35\%$ or as bail-out)	patients undergoing elective coronary angioplasty	Parallel groups open
Fluck , 2000 n=154/146 follow-up: 12 months	Wiktor stent versus balloon angioplasty	Symptomatic CAD; no AMI in previous 7 d	Parallel groups open
Dangas , 2000 n=31/66 follow-up: 8 months	elective stenting (Palmaz-Schatz stent) versus PTCA with prolonged perfusion balloon inflation	patients with discrete, de novo lesions in native coronary arteries $> \text{or} = 3$ mm in diameter	Parallel groups open

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Trial	Treatments	Patients	Trials design and methods
Weaver , 2000 n=229/248 follow-up: 6 months	routine stent implantation (Palmaz-Schatz) versus balloon angioplasty and provisional stenting	patients undergoing single-vessel coronary angioplasty	Parallel groups open
Lotan , 2000 n=48/48 follow-up: 6 months	stent implantation (AVE Micro Stent) versus no further treatment	with total coronary artery occlusions who had an optimal PTCA result	Parallel groups open
Park , 2000 n=60/60 follow-up: 6 months (16 m)	elective stent placement (7-cell NIR stent) versus balloon angioplasty	patients with lesions in small coronary arteries (de novo, non-ostial lesion and reference diameter <3 mm)	Parallel groups open
Koning , 2001 n=192/189 follow-up: 6 months	stent implantation (beStent Small) versus standard balloon angioplasty	symptomatic patients with de novo focal lesion located on a small coronary segment vessel (<3 mm)	Parallel groups open
Doucet , 2001 n=169/182 follow-up: 6 months	stent implantation (beStent-Artist) versus angioplasty alone	symptomatic patients needing dilatation of 1 native coronary vessel between 2.3 and 2.9 mm in size	Parallel groups open
Moer , 2001 n=74/71 follow-up: 6 months	elective stenting treatment with the heparin (Hepamed)-coated beStent versus PTCA	patients with stable or unstable angina	Parallel groups open
balloon angioplasty vs medical treatment			
RITA 2 , 1997 n=504/514 follow-up: 7y	PTCA within 3 mo of the randomisation versus medical treatment	Angina leading to admission within 90days, previous Q wave MI, no previousPTCA, no left main stem disease	Parallel groups open UK
ACME , 1992 n=105/107 follow-up: 5y	PTCA within 3 days of randomization versus medical treatment (nitrates, beta-blockers, calcium blockers)	Stable angina, history of angina, MIwithin 3 months, exercise test with STdepression >3 mm, no previous PTCA; Single or serial stenosis within sameartery 70% to 99% proximal twothirds	Parallel groups open US
ACIP , 1997 n=192/366 follow-up: 24 months	revascularization by angioplasty or bypass surgery versus angina-guided drug therapy or angina plus ischemia-guided drug therapy	clinically stable patients with angiographically documented coronary disease (50% stenosis in 1 major vessel or branch) suitable for revascularization	Parallel groups open
INSPIRE , 2006 n=104/101 follow-up: 60 months	coronary revascularization for suppressing scintigraphic ischemia versus intensive medical therapy strategy	Stable survivors of MI, total perfusion defect size 20% , ischemic defect size 10% (by adenosine SPECT), EF 35% t	Parallel groups open
SWISSI II , 2007 [NCT00387231] n=96/105 follow-up: 10.2y	Percutaneous coronary intervention aimed at full revascularization versus intensive anti-ischemic drug therapy	patients with a recent MI, silent myocardial ischemia verified by stress imaging, and 1- or 2-vessel coronary artery disease	Parallel groups open Switzerland

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Trial	Treatments	Patients	Trials design and methods
ACME 2 (Folland) , 1997 n=51/50 follow-up: 5y	PTCA versus medical therapy	Stable angina, history of angina, MI within 3 months, exercise test with ST depression >3 mm, no previous PTCA; Stenosis >70% proximal two thirds, no main artery stenosis >50% , no 3 vessel disease	Parallel groups open
MASS , 1995 n=72/72 follow-up: 5y	PTCA versus medical treatment (aspirin, nitrates, beta-blockers and calcium channel blocking	Stable angina, no Q wave MI, no left ventricular dysfunction	Parallel groups open Brazil
Sievers , 1993 n=44/44 follow-up: 2y	PTCA versus medical treatment	Previous non Q wave MI, no angina in daily life, no previous Q wave MI	Parallel groups open Germany
PCI with or without stent vs medical treatment			
TIME , 2001 n=NA follow-up:	coronary angiography and revascularisation versus optimised medical therapy	patients aged 75 years or older with chronic angina of at least Canadian Cardiac Society class II despite at least two antianginal drugs	Parallel groups open
AVERT , 1995 n=177/164 follow-up: 1.5y	angioplasty versus atorvastatin at 80 mg per day	Angina or asymptomatic, MI or unstable angina but not within 14 days, no triple vessel disease	Parallel groups open
Dakik , 1998 n=19/22 follow-up: 1y	PTCA versus intensive medical therapy	stable survivors of AMI	Parallel groups open
MASS II , 2007 n=205/203 follow-up: 5y	PCI versus medical therapy	patients with multivessel coronary artery disease with stable angina and preserved ventricular function	Parallel groups open
COURAGE , 2007 [NCT00007657] n=1149/1138 follow-up: median 4.6 y	PCI coupled with optimal medical therapy versus optimal medical therapy alone	patients with stable coronary artery disease	Parallel groups open Canada, US
ALKK , 2003 n=149/151 follow-up: 4.7y	angioplasty versus medical therapy	patients with single vessel disease of the infarct vessel and no or minor angina pectoris in the subacute phase (1 to 6 weeks) after an acute myocardial infarction	Parallel groups open Germany
Hambrecht , 2004 n=50/51 follow-up: 1y	PCI versus 12 months of exercise training (20 minutes of bicycle ergometry per day)	male patients aged 70 years	Parallel groups open
Bech , 2001 n=90/91 follow-up: 2y	PTCA versus deferral of PTCA	patients with planned PTCA and no documented ischemia and with coronary pressure derived fractional flow reserve >0.75	Parallel groups open

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Trial	Treatments	Patients	Trials design and methods
ISCHEMIA <i>ongoing</i> n=NA follow-up:	invasive strategy, consisting of early routine cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) and lifestyle changes versus conservative strategy of optimal medical therapy and lifestyle changes in which invasive procedures will be performed only after failure of OMT	patients with stable ischemic heart disease and moderate to severe ischemia	Parallel groups open-label
balloon angioplasty vs CABG			
EAST , 1994 [NCT00000465] n=198/194 follow-up: 3 y	transluminal coronary angioplasty versus coronary-artery bypass grafting	patients with multivessels coronary artery disease	open USA
GABI , 1994 n=182/177 follow-up: 1 y	Percutaneous transluminal coronary angioplasty versus coronary-artery bypass grafting	patients with symptomatic multivessel coronary disease	open Germany
BARI , 1996 [NCT00000462] n=915/914 follow-up: 5.4 y	PTCA versus CABG	Patients with multivessel disease	open USA, Canada
RITA , 1993 n=510/501 follow-up: 2.5 y (6.5y)	percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery	patients with one, two, or three diseased coronary arteries	open UK
ERACI , 1992 n=63/64 follow-up: 3.8 y	Percutaneous transluminal coronary angioplasty versus coronary artery bypass grafting	patients with multivessel disease and lesions suitable for either form of therapy	open Argentina
MASS , 1995 n=72/70 follow-up: 3.2 y	percutaneous transluminal coronaryangioplasty versus mammary bypass surgery	patients with stable angina,normal ventricular function and a proximal stenosis of the leftanterior descending coronary artery >80%	open Brazil
Toulouse , 1992 n=76/76 follow-up: 2.8 y	PTCA versus CABG	patients with multivessels coronary artery disease	open France
Lausanne , 1994 n=68/66 follow-up: 3.2 y	transluminal coronary angioplasty versus Coronary artery bypass grafting	patients with isolated proximal left anterior descending artery stenosis, conserved left ventricular function, and documented ischaemia	open Switzerland
CABRI , 1995 n=541/513 follow-up: 1 y	percutaneous transluminal coronary angioplasty versus coronary artery bypass grafting	patients with symptomatic multivessel coronary disease	open Europe
PCI vs CABG			

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Trial	Treatments	Patients	Trials design and methods
AWESOME , 2001 n=222/232 follow-up: 5 years	percutaneous coronary intervention versus coronary artery bypass graft	high-risk patients with medically refractory ischemia	Parallel groups open US (Veterans Affairs Medical Centers)
COMBAT <i>ongoing</i> n=NA	PCI versus CABG	-	
Korean Randomized Study <i>ongoing</i> n=NA	PCI versus CABG	-	
REVASCULARIZE <i>ongoing</i> n=NA	PCI versus CABG	-	
PCI with drug-eluting stents vs CABG			
FREEDOM , 2012 [NCT00086450] n=953/947 follow-up: 3.8 yrs (median)	percutaneous coronary stenting versus CABG	patients with diabetes and multivessel coronary artery disease	Parallel groups open international
PCI with drug-eluting stents vs CABG			
Hong , 2005 n=119/70 follow-up: 9 months	drug-eluting stents versus invasive direct coronary artery bypass (MIDCAB) surgery	proximal left anterior descending (LAD) coronary artery stenosis	Parallel groups open
VA CARDS <i>ongoing</i> [NCT00326196] n=NA follow-up:	percutaneous coronary stenting with drug eluting stents versus CABG	angiographically significant coronary artery disease in diabetes	Parallel groups open
stent vs CABG			
ARTS , 2001 n=600/605 follow-up: 1 year	Palmaz-Schatz Crown/Cross flex (Cordis) versus Conventional CABG	Multi vessel disease with 2 or more de novo lesion in different major arteries Total occlusion <1month	parallel group open International
CARDia (PCI) , 2008 [ISRCTN19872154] n=256/254 follow-up: 1 y	PCI plus stenting (and routine abciximab) versus CABG	Patients with diabetes and symptomatic multivessel coronary artery disease or complex single-vessel disease.	Parallel groups open UK, Ireland
ERACI II , 2003 n=225/225 follow-up: 30d, 1year	Gianturco Robin II (Cook) Primary device versus Conventional CABG	multi vessel disease Angina CSS III-IV; no angina but large area of heart at risk; unstable =1 vessel to be treated Lesion>3.0mm	parallel group open Argentinad
LEMANS , 2002 [NCT00375063] n=52/53 follow-up: 1y	unprotected left main stenting versus coronary artery bypass grafting	patients with unprotected left main coronary artery stenosis	Parallel groups open Poland

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Trial	Treatments	Patients	Trials design and methods
MASS II , 2007 n=205/203 follow-up: 5y (1y)	PCI (73% stent) versus CABG	patients with multivessel coronary artery disease with stable angina and preserved ventricular function	Parallel groups open South America
Myoprotect , 2004 n=23/21 follow-up: 1 year	percutaneous transluminal coronary angioplasty/stent versus CABG	patients with symptomatic main-stem and main-stem-equivalent lesions with substantially increased risk for bypass surgery	Parallel groups open Europe
SOS , 2002 [NCT00475449] n=488/500 follow-up: 3 years	Stent versus CABG	multiple vessel disease Symptomatic 1 or more vessel suitable for stenting	parallel group open Canada, United Kingdom, Europe
stent vs E-ACAB			
Cisowski n=50/50 follow-up: 2 years	Tristar, Tera, Penta (Guidant) (Cordis) versus endoscopic atraumatic coronary artery bypass grafting	single vessel disease ACC/AHA A or B lesion in proximal LAD Angina CCS II or higher Lesion diameter 3 mm or greater/length 20mm or greater	parallel group open Poland
angioplasty vs MIDCAB			
AMIST (Reeves) , 2004 n=50/50 follow-up: 12 months	percutaneous transluminal coronary angioplasty (PTCA) with or without stenting versus minimally invasive direct coronary artery bypass grafting (MIDCAB)	single-vessel disease (at least 50% stenosis) of the left anterior descending coronary artery (LAD).	Parallel groups open England
PCI with sirolimus ES vs MIDCAB			
Thiele , 2009 [NCT00299429] n=65/65 follow-up: 12 months	sirolimus-eluting stent versus MIDCAB surgery	isolated LAD disease	Parallel groups open Germany
stent vs MIDCAB			
Diegeler , 2002 n=110/110 follow-up: 5 years	Various stents versus minimally invasive direct coronary artery bypass (off-pump procedure)	single vessel disease Lesion =75% stenosis in proximal LAD or between origin of left circumflex and 1st septal branch	parallel group open Germany
Drenth , 2002 n=51/51 follow-up: 6 months, 3 years	Stent type not reported versus minimally invasive direct coronary artery bypass (off-pump procedure)	single vessel disease Angina II Lesion (Grade B2 or C) of proximal LAD Suitable for CABG or stenting	parallel group open Netherlands
Grip , 2001 n=28/25 follow-up:	Stent type not reported versus minimally invasive direct coronary artery bypass (off-pump procedure)	single vessel disease engaging LAD Stable or unstable angina	parallel group open Sweden
Kim , 2005 n=50/50 follow-up: 2 years	Stent versus MIDCAB using ministernotomy	patients with isolated proximal left anterior descending artery disease	Parallel groups open Korea

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Trial	Treatments	Patients	Trials design and methods
SIMA , 2000 n=62/59 follow-up: 2.4 years	Any CE marked, but Palmaz-Schatz recommended versus Conventional CABG or minimally invasive direct coronary artery bypass (off-pump proceedure) (10% of surgical procedures)	single vessel disease Symptomatic or silent ischaemia 1 LAD lesion Ejection fraction >45% Vessel >3.0mm	parallel group open Europe
stent vs OPCAB			
OCTOSTENT , 2003 [NCT00975858] n=138/142 follow-up: 1 year	Stent type not reported versus off-pump coronary artery bypass	multi or single vessel disease Moderate LV function CABG or stenting to be considered feasible	Parallel groups open Europe

References

Lincoff (EPISTENT), 1999:

Hoher, 1999:

Serruys Benestent, 1994:

Fischman STRESS, 1994:

Eeckout, 1996:

Sirnes, 1996:

Versaci , 1997:

Savage, 1998:

Erbel, 1998:

Rubartelli, 1998:

Hancock, 1998:

Serruys Benestent 2, 1998:

Rodriguez, 1998:

Sievert, 1999:

Betriu, 1999:

Buller, 1999:

Serruys, 2000:

Di Marlo, 2000:

Kastrati, 2000:

Witkowski, 2000:

Lafont, 2000:

Fluck, 2000:

Dangas, 2000:

Weaver, 2000:

Lotan, 2000:

Park, 2000:

Koning, 2001:

Doucet, 2001:

Moer, 2001:
RITA 2, 1997:
ACME, 1992:
ACIP, 1997:
INSPIRE, 2006:
SWISSI II, 2007:
ACME 2 (Folland), 1997:
MASS, 1995:
Sievers, 1993:
TIME, 2001:
AVERT, 1995:
Dakik, 1998:
MASS II, 2007:
COURAGE, 2007:
ALKK, 2003:
Hambrecht, 2004:
Bech, 2001:
ISCHEMIA, :
EAST, 1994:
GABI, 1994:
BARI, 1996:
RITA, 1993:
ERACI, 1992:
MASS, 1995:
Toulouse, 1992:
Lausanne, 1994:
CABRI, 1995:
AWESOME, 2001:
COMBAT, 0:
Korean Randomized Study, 0:
REVASCULARIZE, 0:
FREEDOM, 2012:
Hong, 2005:
VA CARDS, 0:
ARTS, 2001:
CARDia (PCI), 2008:
ERACI II, 2003:
LEMANS, 2002:
MASS II, 2007:
Myoprotect, 2004:
SOS, 2002:

Cisowski, 0:
 AMIST (Reeves), 2004:
 Thiele, 2009:
 Diegeler, 2002:
 Drenth, 2002:
 Grip, 2001:
 Kim, 2005:
 SIMA, 2000:
 OCTOSTENT, 2003:

8 provisional T-stenting with drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
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,
Cervinka , 2006 n=37/33 follow-up: 6 months	sirolimus-eluting stent versus paclitaxel-eluting stent	Complex lesionsand patients. Signs and/or symptoms myocardial ischaemia, including AMI	Parallel groups open
CORPAL , 2005 <i>unpublished</i> n=331/321 follow-up:	sirolimus versus paclitaxel	Documented myocardial ischaemia, no AMI	Parallel groups open Spain
Di Lorenzo et al. , 2005 <i>unpublished</i> n=90/90 follow-up:	sirolimus versus paclitaxel	ST-segment elevation myocardial infarction	Parallel groups open
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-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-DIABETES , 2005 n=125/125 follow-up: 9 months	Taxus versus Cypher	Diabetic patients. AP or positive stress, no AMI with clinically significant angiographic stenosis in a native coronary vessel	Parallel groups open Germany

continued...

Trial	Treatments	Patients	Trials design and methods
ISAR-LEFT-MAIN , 2009 [NCT00133237] n=302/305 follow-up: 1 year	Paclitaxel-eluting stent versus Sirolimus-eluting stent	Unprotected Left Main Coronary Artery Disease	Parallel groups open
ISAR-SMART 3 , 2006 [NCT00146575] n=180/180 follow-up:	Taxus versus Cypher	Small vessels, de novo lesions in native coronary vessels with a diameter of <2.80 mm nondiabetic patients. AP or positive stress, no AMI	Parallel groups NA Germany
ISAR-TEST-1 , 2006 [NCT00140530] n=225/225 follow-up: 9 months	rapamycin-eluting stent Yukon versus Taxus	stable or unstable angina or a positive stress test, stable or unstable angina or a positive stress test	Parallel groups open Germany
LONG DES II , 2006 n=250/250 follow-up: 9 months	SES versus PES	Long lesions. AP or positive stress, no AMI	Parallel groups single-blind Korea
Pan , 2007 n=103/102 follow-up: 24 months (mean)	SES for provisional T-stenting versus PES for provisional T-stenting	patients with bifurcation lesions	Parallel groups open Spain
Petronio et al , 2007 n=50/50 follow-up: 9 months	Cypher versus Taxus	Complex lesions. Stable AP or documented ischaemia, no AMI	Parallel groups open Italy
PROSIT , 2006 n=154/154 follow-up: 1 year	SES Cordis versus PES Boston Scientific	AMI or persistent ischaemia 12-24h	Parallel groups open Korea
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.
TAXi , 2005 n=102/100 follow-up: 6 months	Cypher versus Taxus	Unselected patients	Parallel groups open Switzerland.

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Trial	Treatments	Patients	Trials design and methods
Tomai , 2008 n=60/60 follow-up: 8 months	sirolimus-eluting stent versus paclitaxel-eluting stent	diabetic patient with multiple de novo coronary artery lesions	Cross over NA Italy
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
DES-ISR <i>ongoing</i> [NCT00485030] n=NA follow-up:	Cypher versus Taxus	patients Diffuse Type In-Stent Restenosis After Drug-Eluting Stents Implantation	
Lipsia-Yukon-DM <i>ongoing</i> [NCT00368953] n=NA follow-up: 9 months	Yukon Choice stent system versus Taxus Libert stent system	Patients With Diabetes Mellitus	

References

BASKET (vs paclitaxel), 2005:
Cervinka, 2006:
CORPAL, 2005:
Di Lorenzo et al., 2005:
Han, 2006:
ISAR-DESIRE (SES vs PES), 2005:
ISAR-DIABETES, 2005:
ISAR-LEFT-MAIN, 2009:
ISAR-SMART 3, 2006:
ISAR-TEST-1, 2006:
LONG DES II, 2006:
Pan, 2007:
Petronio et al, 2007:
PROSIT, 2006:
REALITY, 2006:
SIRTAX (Windecker), 2005:
SORT OUT II, 2008:
TAXi, 2005:
Tomai, 2008:
Zhang (SES vs PES), 2006:
DES-ISR, 0:
Lipsia-Yukon-DM, 0:

9 resorbable

Trial	Treatments	Patients	Trials design and methods
sirolimus biodegradable polymer vs sirolimus eluting stent			
ISAR TEST 3 (BP) , 2009 n=202/202 follow-up: 12 months	biodegradable-polymer 0.4% rapamycin stent (180 mg rapamycin/cm2) versus permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2)	Patients with de novo coronary lesions in native vessels	Parallel groups open Germany
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

References

ISAR TEST 3 (BP), 2009:

ISAR-TEST-4 (biodegradable polymer), 2009:

10 surgery

Trial	Treatments	Patients	Trials design and methods
CABG+surgical ventricular reconstruction vs CABG			
STICH (ventricular reconstruction) , 2009 [NCT00023595] n=501/499 follow-up: 48 months	CABG with surgical ventricular reconstruction versus CABG	patients with anterior-apical regional left ventricular dysfunction	Parallel groups open
CABG vs medical treatment			
STICH (vs med) , 2011 [NCT00023595] n=602/610 follow-up: 56 months	CABG versus medical therapy	patients with congestive heart failure and severe LV dysfunction	Parallel groups open 26 countries
ECSS (European) , 1988 n=394/373 follow-up: 12 y	early coronary bypass surgery versus medical therapy	men with midl or moderate angina pectoris of at least 3 months duration and an obstruction of 50% or more in at least 2 major coronary arteries in the absence of marked LV dysfunction	Parallel groups open Europe (6 countries)
CASS , 1983 [NCT00000489] n=390/390 follow-up: 5y	surgical versus nonsurgical	patients with stable ischemic heart disease	Parallel groups open USA, Canada

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Trial	Treatments	Patients	Trials design and methods
VA , 1984 n=332/354 follow-up: 7 y	coronary-artery bypass grafting versus medical treatment	patients with stable angina	Parallel groups open
Texas , 1977 n=56/60 follow-up:	-	-	
Oregon , 1979 n=51/49 follow-up:	surgical treatment versus medical treatment	patients with stable, disabling angina	
New zealand 1 , 1981 n=50/50 follow-up: 4.5 y	surgical versus nonsurgical	men 60 years of age or younger who had recovered from a recurrent myocardial infarction	
MASS II , 2007 n=203/203 follow-up: 5 years	coronary artery bypass graft (CABG) versus medical therapy	multivessel coronary artery disease with stable angina and preserved ventricular function.	Parallel groups open

References

STICH (ventricular reconstruction), 2009:

STICH (vs med), 2011:

ECSS (European), 1988:

CASS, 1983:

VA, 1984:

Texas, 1977:

Oregon, 1979:

New zealand 1, 1981:

MASS II, 2007:

11 titanium-nitride-oxide coated stent

Trial	Treatments	Patients	Trials design and methods
titanium-nitride-oxide coated stent vs bare-metal stent			
TINOX , 2005 n=45/47 follow-up: 6 mo	titanium-nitride-oxide coated stents versus stainless steel stents of similar design	-	Parallel groups open Switzerland, Germany

References

TINOX, 2005:

12 transmyocardial revascularization

Trial	Treatments	Patients	Trials design and methods
TMR+CABG vs CABG			
Allen , 2000 n=132/131 follow-up:	coronary bypass of suitable vessels plus transmyocardial revascularization to areas not graftable versus coronary bypass alone with nongraftable areas left unrevascularized	patients whose standard of care was coronary artery bypass grafting and who had one or more ischemic areas not amenable to bypass grafting	single blind
Loubani , 2003 n=10/10 follow-up: 36 months	coronary artery bypass grafting plus transmyocardial laser revascularization with a holmium:YAG (yttrium-aluminum-garnet) laser to nongraftable areas versus coronary artery bypass grafting	Patients who had elective coronary artery bypass with one or more nongraftable coronary arteries	Parallel groups open UK
Zhao , 2006 n=40/40 follow-up: 3.4y	transmyocardial laser revascularization (holmium: YAG) combined with off-pump coronary artery bypass versus off-pump coronary artery bypass	patients with diffusely diseased target vessels	Parallel groups open China
TMR vs placebo			
Leon (high dose) , 2005 n=98/102 follow-up: 6 months	high-dose myocardial laser channels versus placebo (sham procedure)	patients with severe angina	Parallel groups double blind US
Leon (low dose) , 2005 n=98/102 follow-up: 6 months	low-dose myocardial laser channels versus placebo (sham procedure)	patients with severe angina	Parallel groups double blind US
TMR vs medical treatment			
Aaberge , 2000 n=50/50 follow-up: 12 months	transmyocardial revascularization with CO2-laser versus continued optimal medical treatment	patients with refractory angina not eligible for conventional revascularization	Parallel groups open Norway
Allen , 1999 n=132/143 follow-up: 1 y	transmyocardial revascularization versus medical therapy alone	patients with medically refractory class IV angina and coronary disease that could not be treated with percutaneous or surgical revascularization	Parallel groups open US
ATLANTIC (Burkhoff) , 1999 n=92/90 follow-up: 1 y	Transmyocardial revascularisation versus medical treatment alone	patients with Canadian Cardiovascular Society Angina (CCSA) score III or IV, reversible ischaemia, and incomplete response to other therapies	Parallel groups open US

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Trial	Treatments	Patients	Trials design and methods
Frazier , 1999 n=91/101 follow-up: 12 months (4y)	transmyocardial revascularization versus continued medical treatment	patients with end-stage coronary artery disease	Parallel groups open US
Gray , 2003 n=36/37 follow-up: 12 months	percutaneous myocardial laser revascularization versus medical therapy alone	with stable angina pectoris (class III or IV) who were unsuitable for conventional revascularization and had evidence of reversible ischemia by thallium-201 scintigraphy, ejection fraction of $\geq 25\%$, and myocardial wall thickness ≥ 8 mm	Parallel groups open
Huikeshoven , 2003 n=30 follow-up: 1y	XeCl excimer transmyocardial laser revascularization versus optimal cardiac medication	-	Parallel groups open
March , 1999 n=198 follow-up: 12 months	Transmyocardial laser revascularization versus continued medical management	patients with symptomatic end-stage coronary artery disease	Parallel groups open
PACIFIC , 2000 n=110/111 follow-up: 12 months	Percutaneous transmyocardial laser revascularisation versus medical treatment only	patients with reversible ischaemia of Canadian Cardiovascular Society angina class III or IV and incomplete response to other therapies	Parallel groups open US, UK
Salem , 2004 n=40/42 follow-up: 12 months	percutaneous myocardial laser revascularization versus optimal medical therapy	patients with stable angina pectoris (class III or IV) not amenable to conventional revascularization and with evidence of reversible ischemia, ejection fraction $\geq 25\%$, and myocardial wall thickness ≥ 8 mm	Parallel groups double blind Norway
Schofield , 1999 n=94/94 follow-up: 1 y	Transmyocardial laser revascularisation versus medical management alone	patients with refractory angina	Parallel groups open
Stone , 2002 n=71/70 follow-up: 6 months	percutaneous transmyocardial revascularization versus maximal medical therapy	patients with class III or IV angina caused by one or more chronically occluded native coronary arteries in which a percutaneous coronary intervention had failed	Parallel groups single blind (patient) US
van der Sloot , 2004 n=15/15 follow-up: 12 months	XeCl excimer transmyocardial laser revascularization versus maximal medication	patients with refractory angina	Parallel groups open the Netherlands
TMR vs thoracic sympathectomy			
Galianes , 2004 n=10/10 follow-up: 42 months	Transmyocardial laser revascularization by holmium: yttrium aluminum garnet laser versus thoracic sympathectomy	patients with nonrevascularizable coronary arteries and intractable angina	Parallel groups open

References

Allen, 2000:

Loubani, 2003:

Zhao, 2006:
Leon (high dose), 2005:
Leon (low dose), 2005:
Aaberge, 2000:
Allen, 1999:
ATLANTIC (Burkhoff), 1999:
Frazier, 1999:
Gray, 2003:
Huikeshoven, 2003:
March, 1999:
PACIFIC, 2000:
Salem, 2004:
Schofield, 1999:
Stone, 2002:
van der Sloot, 2004:
Galianes, 2004:

13 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.

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