

# Clinical trials of myocardial revascularization for stable angina in all type of patient

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## 1 CABG or PCI

Trial	Treatments	Patients	Trials design and methods
<b>CABG or PCI vs medical treatment</b>			
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

More details on <http://www.trialresultscenter.org/godirect.asp?q=25>

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[10.1161/CIRCULATIONAHA.110.978247](https://doi.org/10.1161/CIRCULATIONAHA.110.978247)

## 2 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
<b>A vs B</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	

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Trial	Treatments	Patients	Trials design and methods
<b>dactinomycin eluting stent vs bare-metal stent</b>			
<b>ACTION</b> , 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 $\geq 3.0$ mm and $\leq 4.0$ mm in diameter that could be covered by an 18-mm stent	Parallel groups single-blind worldwide
<b>dexamethasone eluting stent vs bare-metal stent</b>			
<b>FEMH-93005</b> <i>ongoing</i> [NCT00190099] n=NA	-	-	
<b>drug-eluting stents vs bare-metal stent</b>			
<b>ISAR-CABG</b> <i>ongoing</i> [NCT00611910] n=NA follow-up:	DES versus BMS	Bypass Graft Lesions	open
<b>everolimus eluting stent vs bare-metal stent</b>			
<b>FUTURE I</b> , 2004 n=27/15 follow-up: 12 months	everolimus coated S-Stent versus S-Stent	de novo coronary lesions	Parallel groups single-blind Germany
<b>FUTURE II</b> , 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unpublished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 $\leq 18$ mm	Parallel groups double-blind
<b>SPIRIT I</b> , 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
<b>paclitaxel eluting stent vs bare-metal stent</b>			
<b>SCORE</b> , 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
<b>TAXUS I</b> , 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
<b>TAXUS II</b> , 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
<b>TAXUS IV</b> , 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

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Trial	Treatments	Patients	Trials design and methods
<b>TAXUS V (all patients) , 2005</b> [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
<b>TAXUS VI , 2005</b> [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
<b>BASKET-SAVAGE</b> <i>ongoing</i> [NCT00595647] n=NA follow-up:	Taxus versus Libert	percutaneous coronary interventions of saphenous vein grafts	open
<b>sirolimus eluting stent vs bare-metal stent</b>			
<b>C-SIRIUS , 2004</b> [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
<b>DECODE , 2005</b> <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
<b>DIABETES , 2005</b> 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
<b>E-SIRIUS , 2003</b> [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
<b>GISSOC II , 2010</b> [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
<b>Kochiadakis , 2007</b> 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 $\geq 2.5$ mm	Parallel groups open Greece
<b>Ortolani et al , 2007</b> 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

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Trial	Treatments	Patients	Trials design and methods
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
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
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
<b>zotarolimus eluting stent vs bare-metal stent</b>			
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
<b>crush stenting vs culotte stenting</b>			
Nordic Bifurcation Stent Technique Study <i>ongoing</i> [NCT00292305] n=NA follow-up:	crush stenting versus culotte stenting	bifurcation lesions	
<b>sirolimus eluting stent vs cutting balloon angioplasty</b>			

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Trial	Treatments	Patients	Trials design and methods
<b>FOCUS</b> <i>ongoing</i> [NCT00485004] n=NA follow-up:	sirolimus-eluting implantation cypher versus cutting balloon angioplasty	focal in-stent restenosis after drug-eluting stent	
<b>DES vs CABG</b>			
Boudriot , 2008 n=83/84 follow-up: 12 months	DES versus CABG	-	Parallel groups open
<b>drug-eluting stents vs CABG</b>			
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
<b>VA CARDs</b> <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
<b>FREEDOM</b> <i>ongoing</i> [NCT00086450] n=NA follow-up: 5 years	percutaneous coronary stenting versus CABG	diabetic individuals with multivessel coronary artery disease	Parallel groups open
<b>Leipzig</b> <i>ongoing</i> [NCT00176397] n=NA follow-up:	PCI With DES versus CABG	left main coronary stenosis	
<b>paclitaxel eluting stent vs CABG</b>			
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
<b>sirolimus eluting stent vs CABG</b>			
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	
<b>zotarolimus eluting stent vs everolimus eluting stent</b>			
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
<b>paclitaxel eluting stent vs medical treatment</b>			

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Trial	Treatments	Patients	Trials design and methods
<b>VELETI</b> <i>ongoing</i> [NCT00289835] n=NA follow-up:	TAXUS versus standard medical treatment	Moderate Vein Graft Lesions	
<b>sirolimus ES vs MIDCAB</b>			
<b>Thiele , 2009</b> [NCT00299429] n=65/65 follow-up: 12 months	sirolimus-eluting stent versus MIDCAB surgery	isolated LAD disease	Parallel groups open Germany
<b>CoStar stent vs paclitaxel eluting stent</b>			
<b>Costar II , 2008</b> [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
<b>everolimus eluting stent vs paclitaxel eluting stent</b>			
<b>COMPARE , 2009</b> [NCT01016041] n=897/903 follow-up: 1 y (2y)	polymer based, everolimus-eluting stent (Xience V) versus polymer-based, paclitaxel-eluting stent (Taxus Liberte)	unselected patients	Parallel groups open the Netherlands
<b>SPIRIT II , 2006</b> <i>unpublished</i> [NCT00180310] n=223/77 follow-up: 6 months	everolimus eluting stent, XIENCE V versus placitaxel eluting stent, TAXUS EXPRESS2	De novo lesions (maximim two)	Parallel groups single-blind (patient)
<b>SPIRIT III , 2008</b> [NCT00180479] n=669/333 follow-up: 12 months	everolimus-eluting stent, XIENCE V versus paclitaxel-eluting stent, Taxus	lesions 28 mm or less in length and with reference vessel diameter between 2.5 and 3.75 m	Parallel groups single-blind US
<b>SPIRIT IV , 2010</b> [NCT00307047] n=2458/1229 follow-up: 1 y (2y)	XIENCE V Everolimus Eluting Coronary Stent System versus TAXUS EXPRESS2 Paclitaxel Eluting Coronary Stent System (TAXUS).	patients with de novo native coronary artery lesions and reference vessel diameters between 2.5 mm to 4.25 mm and lesion lengths <= 28 mm	Parallel groups 270 days (5 years) USA
<b>paclitaxel eluting balloon vs paclitaxel eluting stent</b>			
<b>PEPCAD IV</b> <i>ongoing</i> [NCT00462631] n=NA follow-up:	Paclitaxel-eluting PTCA-balloon dilation (SeQuentTM Please) followed by cobalt-chromium stent (CoroflexTM Blue) deployment versus Taxus Libert	patients with diabetes mellitus	open
<b>paclitaxel eluting stent vs paclitaxel eluting stent</b>			
<b>PERSEUS Workhorse , 2010</b> <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	

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Trial	Treatments	Patients	Trials design and methods
<b>sirolimus eluting stent vs paclitaxel eluting stent</b>			
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
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 anginaor a positive stress test, stable or unstable anginaor a positive stress test	Parallel groups open Germany
Kim , 2008 n=85/84 follow-up: 6 months	Cypher versus Taxus	Korean diabetic patients with high-grade de novo coronary lesions (stenosis of>70 percent of the luminal diameter) requiring <3 stents	Parallel groups open Korea

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Trial	Treatments	Patients	Trials design and methods
<b>LONG DES II , 2006</b> n=250/250 follow-up: 9 months	SES versus PES	Long lesions. AP or positive stress, no AMI	Parallel groups single-blind Korea
<b>Petronio et al , 2007</b> n=50/50 follow-up: 9 months	Cypher versus Taxus	Complex lesions. Stable AP or documented ischaemia, no AMI	Parallel groups open Italy
<b>REALITY , 2006</b> [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
<b>SIRTAX (Windecker) , 2005</b> 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
<b>TAXi , 2005</b> n=102/100 follow-up: 6 months	Cypher versus Taxus	Unselected patients	Parallel groups open Switzerland.
<b>Tomai , 2008</b> 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
<b>Zhang (SES vs PES) , 2006</b> 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
<b>DES-ISR ongoing</b> [NCT00485030] n=NA follow-up:	Cypher versus Taxus	patients Diffuse Type In-Stent Restenosis After Drug-Eluting Stents Implantation	
<b>Lipsia-Yukon-DM ongoing</b> [NCT00368953] n=NA follow-up: 9 months	Yukon Choice stent system versus Taxus Libert stent system	Patients With Diabetes Mellitus	
<b>zotarolimus eluting stent vs paclitaxel eluting stent</b>			
<b>ENDEAVOR IV , 2009</b> <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

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Trial	Treatments	Patients	Trials design and methods
ZoMaxx phase 2 <i>ongoing</i> [NCT00140101] n=NA follow-up:	ZoMaxx drug-eluting stent versus TAXUS Express2	de Novo Coronary Artery Lesions	
<b>pimecrolimus eluting stent vs pimecrolimus paclitaxel</b>			
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	
<b>biolimus eluting stent vs sirolimus eluting stent</b>			
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
<b>everolimus eluting stent vs sirolimus eluting stent</b>			
SORT OUT IV [NCT00552877] n=1390/1384 follow-up: 9 months (3 years)	everolimus-eluting stents versus sirolimus-eluting stents	unselected patients with coronary artery disease	Parallel groups open Denmark
<b>paclitaxel eluting stent vs sirolimus eluting stent</b>			
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
<b>sirolimus biodegradable polymer vs sirolimus eluting stent</b>			
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
<b>zotarolimus eluting stent vs sirolimus eluting stent</b>			
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
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

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Trial	Treatments	Patients	Trials design and methods
<b>DIABEDES IV</b> <i>ongoing</i> [NCT00552994] n=NA follow-up:	Cypher select plus versus Xience V	diabetic patients	
<b>PRISON III , 2007</b> <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
<b>PROTECT</b> <i>ongoing</i> [NCT00476957] n=NA follow-up:	Medtronic Endeavor Zotarolimus Eluting Coronary Stent System versus Cordis Cypher Sirolimus-eluting Coronary Stent	unselected patients	
<b>everolimus eluting stent vs zotarolimus eluting stent</b>			
<b>LEFT-MAIN-2</b> <i>ongoing</i> [NCT00598637] n=NA follow-up:	Xience versus Endeavor Resolute	unprotected left main coronary artery disease	open

More details on <http://www.trialresultscenter.org/godirect.asp?q=25>

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**Boudriot, 2008:**

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COMPARE, 2009:  
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ENDEAVOR III, 2006:  
ZEST (vs SES), 2009:  
DIABEDES IV, 0:  
PRISON III, 2007:  
PROTECT, 0:  
LEFT-MAIN-2, 0:

### 3 non-polymeric ES

Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel, non-polymeric eluting stent vs bare-metal stent</b>			
<b>ASPECT , 2003</b> [NCT00196079] n=117/58 follow-up: 6 months	coated Supra-G stent versus Supra-G stent	patients with discrete coronary lesions (<15 mm in length, 2.25 to 3.5 mm in diameter)	Parallel groups double-blind
<b>DELIVER , 2004</b> 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
<b>ELUTES , 2004</b> 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 native coronary artery	Parallel groups open Europe
<b>PATENCY , 2002</b> <i>unpublished</i> n=24/26 follow-up: 9 months	Logic PTX paclitaxel Eluting Coronary Stents 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

More details on <http://www.trialresultscenter.org/godirect.asp?q=25>

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**PATENCY, 2002:**

### 4 PCI

Trial	Treatments	Patients	Trials design and methods
<b>stent vs balloon angioplasty</b>			
<b>Lincoff (EPISTENT) , 1999</b> [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
<b>Hoher , 1999</b> 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

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Trial	Treatments	Patients	Trials design and methods
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 balloon angioplasty aspirin, dipyridamol	Stable angina	Parallel groups Open USA
Eckout , 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
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 balloon angioplasty aspirin $\geq 100\text{mg}$ 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

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Trial	Treatments	Patients	Trials design and methods
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 in previous 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 >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 >or =3 mm in diameter	Parallel groups open
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

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Trial	Treatments	Patients	Trials design and methods
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
<b>balloon angioplasty vs medical treatment</b>			
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 previous PTCA, 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, MI within 3 months, exercise test with ST depression >3 mm, no previous PTCA; Single or serial stenosis within same artery 70% to 99% proximal two thirds	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
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
<b>PCI with or without stent vs medical treatment</b>			
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

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Trial	Treatments	Patients	Trials design and methods
<b>AVERT , 1995</b> 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
<b>Dakik , 1998</b> n=19/22 follow-up: 1y	PTCA versus intensive medical therapy	stable survivors of AMI	Parallel groups open
<b>MASS II , 2007</b> 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
<b>COURAGE , 2007</b> [NCT00007657] n=1149/1138 follow-up: median 4.6 y	PCI coupled with optimal medical therapy versus optimal medical therapy aloneitm	patients with stable coronary artery disease	Parallel groups open Canada, US
<b>ALKK , 2003</b> 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
<b>Hambrecht , 2004</b> 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
<b>Bech , 2001</b> n=90/91 follow-up: 2y	PTCA versus deferral of PTCA	patients with planned PTCA and no documented ischemia and with coronary pressurederived fractional flow reserve >0.75	Parallel groups open
<b>balloon angioplasty vs CABG</b>			
<b>EAST , 1994</b> [NCT00000465] n=198/194 follow-up: 3 y	transluminal coronary angioplasty versus coronary-artery bypass grafting	patients with multivessels coronary artery disease	open USA
<b>GABI , 1994</b> n=182/177 follow-up: 1 y	Percutaneous transluminal coronary angioplasty versus coronary-artery bypass grafting	patients with symptomatic multivessel coronary disease	open Germany
<b>BARI , 1996</b> [NCT00000462] n=915/914 follow-up: 5.4 y	PTCA versus CABG	Patients with multivessel disease	open USA, Canada
<b>RITA , 1993</b> 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
<b>ERACI , 1992</b> 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

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Trial	Treatments	Patients	Trials design and methods
<b>MASS , 1995</b> 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
<b>Toulouse , 1992</b> n=76/76 follow-up: 2.8 y	PTCA versus CABG	patients with multivessels coronary artery disease	open France
<b>Lausanne , 1994</b> 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
<b>CABRI , 1995</b> n=541/513 follow-up: 1 y	percutaneous transluminal coronary angioplasty versus coronary artery bypass grafting	patients with symptomatic multivessel coronary disease	open Europe
<b>PCI vs CABG</b>			
<b>AWESOME , 2001</b> 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)
<b>stent vs CABG</b>			
<b>LEMANS , 2002</b> [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
<b>CARDia (PCI) , 2008</b> [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
<b>ARTS , 2001</b> 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
<b>ERACI II , 2003</b> 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
<b>MASS II , 2007</b> 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
<b>Myoprotect , 2004</b> 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

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Trial	Treatments	Patients	Trials design and methods
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
<b>stent vs E-ACAB</b>			
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
<b>angioplasty vs MIDCAB</b>			
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
<b>stent vs MIDCAB</b>			
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
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
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
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
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 procedure) (10% of surgical procedures)	single vessel disease Symptomatic or silent ischaemia 1 LAD lesion Ejection fraction >45% Vessel >3.0mm	parallel group open Europe
<b>stent vs OPCAB</b>			
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

More details on <http://www.trialresultscenter.org/godirect.asp?q=25>

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## 5 surgery

Trial	Treatments	Patients	Trials design and methods
<b>CABG+surgical ventricular reconstruction vs CABG</b>			
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

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Trial	Treatments	Patients	Trials design and methods
<b>CABG vs medical treatment</b>			
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
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

More details on <http://www.trialresultscenter.org/godirect.asp?q=25>

## References

STICH (ventricular reconstruction), 2009:

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CASS, 1983:

VA, 1984:

Texas, 1977:

Oregon, 1979:

New zealand 1, 1981:

MASS II, 2007:

## 6 transmyocardial revascularization

Trial	Treatments	Patients	Trials design and methods
<b>TMR+CABG vs CABG</b>			
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 unvascularized	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
<b>TMR vs placebo</b>			
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
<b>TMR vs medical treatment</b>			
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
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

continued...

Trial	Treatments	Patients	Trials design and methods
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 >or =25% , and myocardial wall thickness >or =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 >/=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
<b>TMR vs thoracic sympathectomy</b>			
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

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## References

- Allen, 2000:
- Loubani, 2003:
- Zhao, 2006:

**Leon (high dose), 2005:**  
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**Galianes, 2004:**

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