# 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<br>n=93<br>follow-up: 6 mo (2y) | abciximab-coated stent<br>versus<br>bare metal stents | patients undergoing PCI for de novo coronary lesions | Parallel groups<br>open<br>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<br>[NCT00752362]<br>n=NA<br>follow-up: 12 mo<br>(angiography 9 mo) | biodegradable-polymer sirolimus-eluting (Supralimus)<br>versus<br>bare metal stent (matrix) | patients with de novo coronary lesions in native vessels scheduled for stent implantation | Parallel groups<br>open |
| **biolimus eluting stent vs sirolimus eluting stent** | | | |
| LEADERS , 2008<br>[NCT00389220]<br>n=857/850<br>follow-up: 9 months | BioMatrix III (biolimus-eluting stent withbiodegradable polymer)<br>versus<br>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<br>open assessor-blind<br>Europe |
| **sirolimus biodegradable polymer vs sirolimus eluting stent** | | | |
| ISAR TEST 3 (BP) , 2009<br>n=202/202<br>follow-up: 12 months | biodegradable-polymer 0.4% rapamycin stent (180 mg rapamycin/cm2)<br>versus<br>permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2) | Patients with de novo coronary lesions in native vessels | Parallel groups<br>open<br>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 *ongoing* [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 orsilent ischemia and a single de novo lesion in a nativecoronary artery >=3.0 mm and <=4.0 mm in diameter thatcould be covered by an 18-mm stent | Parallel groups single-blind worldwide |
| **dexamethasone eluting stent vs bare-metal stent** | | | |
| FEMH-93005 *ongoing* [NCT00190099] n=NA | - | - | |
| **drug-eluting stents vs bare-metal stent** | | | |
| ISAR-CABG *ongoing* [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 *unpublished* n=43/21 follow-up: 6 months | CHAMPION versus bare-metal stent | Patients with de novo lesions in vessels with a reference diameter of 2.75-4.0 mm and length </= 18 mm | Parallel groups double-blind |
| SPIRIT I , 2005 [NCT00180453] n=28/32 follow-up: 6 months (5yr) | everolimus eluting sent, XIENCE versus bare etal stent, MULTI-LINK VISION | patients with de novo native coronary artery lesions | Parallel groups single-blind |
| **Genous stent vs bare-metal stent** | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| TRIAS-Low-Risk *ongoing*<br>n=NA | - | - | |
| **paclitaxel eluting stent vs bare-metal stent** | | | |
| HAAMU-STENT , 2006<br>*unpublished*<br>n=70/75<br>follow-up: 12 months | Taxus Express<br>versus<br>Bare-metal-stent | AMI - STEMI patients undergoing PCI | Parallel groups<br>open<br>Finland |
| PASSION , 2006<br>[ISRCTN65027270]<br>n=310/309<br>follow-up: 12 months (5y) | Taxus Express2<br>versus<br>Express2 or Libert | Myocardial Infarction with ST-Segment Elevation | Parallel groups<br>open<br>The Netherlands |
| SCORE , 2004<br>n=126/140<br>follow-up: 12 months | QuaDDS stents (paclitaxel)<br>versus<br>uncoated control stents | patients with focal, de novo coronary lesions | Parallel groups<br>open<br>Worldwide |
| TAXUS I , 2003<br>n=31/30<br>follow-up: 12 months | TAXUS NIR<br>versus<br>NIR stent | Stable or unstable AP, silent ischaemia; single de novo or restenotic coronary lesions | Parallel groups<br>double-blind<br>Germany |
| TAXUS II , 2003<br>[NCT00299026]<br>n=266/270<br>follow-up: 12 months | TAXUS<br>versus<br>NIR stent | Stable or unstable AP, silent ischaemia; single de novo target lesion with estimatedstenosis >50% and <99% , | Parallel groups<br>double-blind<br>Global |
| TAXUS IV , 2004<br>[NCT00292474]<br>n=662/652<br>follow-up: 9 months | TAXUS<br>versus<br>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<br>double-blind<br>United States |
| TAXUS V (all patients) , 2005<br><br>[NCT00301522]<br>n=577/579<br>follow-up: 9 months | TAXUS<br>versus<br>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<br>double-blind<br>United States |
| TAXUS VI , 2005<br>[NCT00297804]<br>n=219/227<br>follow-up: 9 months (2y) | TAXUS<br>versus<br>Express2 stent | Stable or unstable AP, silent ischaemia with long, complex coronary artery lesions | Parallel groups<br>double-blind<br>Europe |
| BASKET-SAVAGE *ongoing*<br>[NCT00595647]<br>n=NA<br>follow-up: | Taxus<br>versus<br>Libert | percutaneous coronary interventions of saphenous vein grafts | open |
| **sirolimus eluting stent vs bare-metal stent** | | | |
| C-SIRIUS , 2004<br>[NCT00381420]<br>n=50/50<br>follow-up: 9 months | coated Bx-VELOCITY<br>versus<br>Bx-VELOCITY | Stable or unstable AP, silent ischaemia | Parallel groups<br>double-blind<br>Canada |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| DECODE , 2005 *unpublished*<br>[NCT00489164]<br>n=54/29<br>follow-up: 1 year | CYPHER (Up to 3 stents per patient were allowed)<br>versus<br>Bx VELOCITY (Up to 3 stents per patient were allowed) | Stable or unstable angina in diabetic patients with with up to 2 de novo lesions in up to 2 native coronary vessels | Parallel groups<br>open<br>US, Asia/Pacific |
| DIABETES , 2005<br>n=80/80<br>follow-up: 9 months | Cypher<br>versus<br>Bx Velocity/Sonic | de novo lesions in native coronary arteriesin 1, 2, or 3 native vessels with symptoms or objective evidence of ischemia; vessel size smaller than 4.0 mm | Parallel groups<br>open<br>Spanish |
| E-SIRIUS , 2003<br>[NCT00235144]<br>n=175/177<br>follow-up: 9 months | coated Bx Velocity<br>versus<br>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<br>open<br>Europe |
| GISSOC II , 2010<br>[NCT00220558]<br>n=78/74<br>follow-up: 8 months | Sirolimus Eluting Stent<br>versus<br>Bare Metal Stent | patients with Chronic Total Occlusion older than 1 month, and successful recanalization | Parallel groups<br>open<br>Italy |
| Kochiadakis , 2007<br>n=38/43<br>follow-up: 4.8 months (mean) | sirolimus-eluting stents<br>versus<br>bare metal stent | one-vesseldisease (>70% narrowing of the lumen of one major epicardialcoronary artery); stable coronary artery disease, age <70 years, and vessel referencediameter >=2.5 mm | Parallel groups<br>open<br>Greece |
| MISSION , 2008<br>[ISRCTN62825862]<br>n=158/152<br>follow-up: 12 months | Cypher<br>versus<br>Vision | primary percutaneous coronary intervention for ST-segment elevation myocardial infarction (<9h) | Parallel groups<br>single-blind<br>the Netherlands |
| Ortolani et al , 2007<br>n=NA<br>follow-up: 9 months | Cypher<br>versus<br>Vision | symptomatic coronary artery disease and target vessel diameter appropriate for implantation a 3-mm stent | Parallel groups<br>single-blind |
| Pache et al , 2005<br>n=250/250<br>follow-up: 12 months | Cypher<br>versus<br>BeStent 2 | with symptomatic coronary artery disease and significant angiographic stenosis in native coronary vessels | Parallel groups<br>open<br>Germany |
| Pasceri , 2003 *unpublished*<br>n=NA<br>follow-up: 12 months | - | - | Parallel groups |
| PRISON II , 2006<br>[NCT00258596]<br>n=100/100<br>follow-up: 6 months | Cypher<br>versus<br>BxVelocity | Chronic total occlusion, positive exercise stress test | Parallel groups<br>single-blind<br>Belgium |
| RAVEL , 2002<br>[NCT00233805]<br>n=120/118<br>follow-up: 12 months | coated Bx Velocity<br>versus<br>Bx Velocity | Stable or unstable AP, silent ischaemia; single primary target lesion in a native coronary artery | Parallel groups<br>double-blind<br>Global |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| SCANDSTENT , 2006<br>[NCT00151658]<br>n=163/159<br>follow-up: 7 months | Cypher<br>versus<br>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<br>open<br>Denmark |
| SCORPIUS , 2007<br>[NCT00495898]<br>n=98/102<br>follow-up: 12 months | Cypher<br>versus<br>Bx-Velocity | patients with diabetes and de novo coronary artery lesions | Parallel groups<br>open<br>Germany |
| SES-SMART , 2004<br>n=129/128<br>follow-up: 8 months | Cypher<br>versus<br>Bx Sonic | Stable AP, ACS, silent myocardial ischaemia as shown by exercise stress test | Parallel groups<br>single-blind<br>Italian |
| SESAMI , 2007<br>[NCT00288210]<br>n=160/160<br>follow-up: 12 months | Cypher<br>versus<br>BX stent, Cordis | AMI | Parallel groups<br>open<br>Italy |
| SIRIUS , 2003<br>[NCT00232765]<br>n=533/525<br>follow-up: 9 months | SES<br>versus<br>Bx Velocity | Stable or unstable AP, signs of myocardial ischaemia | Parallel groups<br>double-blind<br>United States |
| TYPHOON , 2006<br>[NCT00232830]<br>n=356/359<br>follow-up: 12 months | Cypher or CypherSelect<br>versus<br>any commerciallyavailable uncoated stent | AMI | Parallel groups<br>open<br>Worldwide (15 countries) |
| BASKET-PROVE , 2008<br>*ongoing*<br>n=NA<br>follow-up: | Cypher<br>versus<br>Vision | - | |
| **zotarolimus eluting stent vs bare-metal stent** | | | |
| ENDEAVOR II , 2006<br>n=598/599<br>follow-up: 12 months | AVE Zotarolimus-Eluting Driver<br>versus<br>Driver | single de novo native coronary artery stenosis | Parallel groups<br>double-blind<br>worldwide |
| **crush stenting vs culotte stenting** | | | |
| Nordic Bifurcation Stent Technique Study *ongoing*<br>[NCT00292305]<br>n=NA<br>follow-up: | crush stenting<br>versus<br>culotte stenting | bifurcation lesions | |
| **sirolimus eluting stent vs cutting ballon angioplasty** | | | |
| FOCUS *ongoing*<br>[NCT00485004]<br>n=NA<br>follow-up: | sirolimus-eluting implantation cypher<br>versus<br>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<br>[NCT01135225]<br>n=NA<br>follow-up: 30 days | bioabsorbable polymer everolimus-eluting stent<br>versus<br>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<br>single blind |
| **Nevo vs paclitaxel eluting stent** | | | |
| NEVO RES-ELUTION I<br>[NCT00714883]<br>n=202/194<br>follow-up: 6 months | Nevo sirolimus eluting stent with bioresordable PLGA polymer<br>versus<br>placlitaxel eluting stent (Libert) | patients with single, de novo lesions | Parallel groups<br>open<br>Europe, Brazil, Australia, and New Zealand |
| **DES vs CABG** | | | |
| Boudriot , 2008<br>n=83/84<br>follow-up: 12 months | DES<br>versus<br>CABG | - | Parallel groups<br>open |
| **drug-eluting stents vs CABG** | | | |
| Leipzig *ongoing*<br>[NCT00176397]<br>n=NA<br>follow-up: | PCI With DES<br>versus<br>CABG | left main coronary stenosis | |
| **paclitaxel eluting stent vs CABG** | | | |
| SYNTAX , 2009<br>[NCT00114972]<br>n=903/897<br>follow-up: 1 year | paclitaxel (taxus Express SR)<br>versus<br>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<br>open |
| **PCI vs CABG** | | | |
| AWESOME , 2001<br>n=222/232<br>follow-up: 5 years | percutaneous coronary intervention<br>versus<br>coronary artery bypass graft | high-risk patients with medically refractory ischemia | Parallel groups<br>open<br>US (Veterans Affairs Medical Centers) |
| COMBAT *ongoing*<br>n=NA | PCI<br>versus<br>CABG | - | |
| Korean Randomized Study *ongoing*<br>n=NA | PCI<br>versus<br>CABG | - | |
| REVASCULARIZE *ongoing*<br>n=NA | PCI<br>versus<br>CABG | - | |
| **sirolimus eluting stent vs CABG** | | | |
| PRECOMBAT , 2011<br>[NCT00422968]<br>n=300/300<br>follow-up: | PCI with sirolimus-eluting stents<br>versus<br>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 *ongoing* [NCT00299429] n=NA follow-up: | sirolimus-coated stent versus minimally invasive bypass surgery | patients with isolated proximal left anterior descending coronary arteries | |
| Munich Study *ongoing* 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 *ongoing* [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 *ongoing* [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 *unpublished* [NCT00180310] n=223/77 follow-up: 6 months | everolimus eluting stent, XIENCE V versus placitaxel eluting stent, TAXUS EXPRESS2 | De novo lesions (maximim two) | Parallel groups single-blind (patient) |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| SPIRIT III , 2008<br>[NCT00180479]<br>n=669/333<br>follow-up: 12 months | everolimus-eluting stent, XIENCE V<br>versus<br>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<br>single-blind<br>US |
| SPIRIT IV , 2010<br>[NCT00307047]<br>n=2458/1229<br>follow-up: 1 y (2y) | XIENCE V Everolimus Eluting Coronary Stent System<br>versus<br>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<br>270 days (5 years)<br>USA |
| **Genous stent vs paclitaxel eluting stent** | | | |
| TRIAS-HR , 2008<br>*unpublished*<br>[ISRCTN74297220]<br>n=98/95<br>follow-up: 12 months | Genous stent (antibody-coated bare-metal stent) followed by one month of dual antiplatelet therapy<br>versus<br>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<br>single-blind |
| **paclitaxel eluting balloon vs paclitaxel eluting stent** | | | |
| PEPCAD IV *ongoing*<br>[NCT00462631]<br>n=NA<br>follow-up: | Paclitaxel-eluting PTCA-balloon dilation (SeQuentTM Please) followed by cobalt-chromium stent (CoroflexTM Blue) deployment<br>versus<br>Taxus Libert | patients with diabetes mellitus | open |
| **paclitaxel eluting stent vs paclitaxel eluting stent** | | | |
| PERSEUS Workhorse , 2010<br>*ongoing*<br>[NCT00484315]<br>n=NA<br>follow-up: | platinum-chromium alloy, paclitaxel-eluting stent TAXUS Element<br>versus<br>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<br>n=264/281<br>follow-up: 6 months | Cypher<br>versus<br>Taxus | Unselected patients; de-novo lesions | Parallel groups<br>open<br>Switzerland, |
| Cervinka , 2006<br>n=37/33<br>follow-up: 6 months | sirolimus-eluting stent<br>versus<br>paclitaxel-eluting stent | Complex lesionsand patients. Signs and/or symptoms myocardial ischaemia, including AMI | Parallel groups<br>open |
| CORPAL , 2005 *unpublished*<br>n=331/321<br>follow-up: | sirolimus<br>versus<br>paclitaxel | Documented myocardial ischaemia, no AMI | Parallel groups<br>open<br>Spain |
| Di Lorenzo et al. , 2005<br>*unpublished*<br>n=90/90<br>follow-up: | sirolimus<br>versus<br>paclitaxel | ST-segment elevation myocardial infarction | Parallel groups<br>open |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Han , 2006<br>n=210/206<br>follow-up: 19.5 months (mean) | Cypher<br>versus<br>Taxus | Multivessel disease. Stable or unstable AP, no AMI | Parallel groups<br>open<br>China |
| ISAR-DESIRE (SES vs PES) , 2005<br>n=100/100<br>follow-up: 1y | Cypher<br>versus<br>Taxus | In-stent restenosis. AP and/or positive test, previously stented, no AMI | Parallel groups<br>open<br>germany |
| ISAR-DIABETES , 2005<br>n=125/125<br>follow-up: 9 months | Taxus<br>versus<br>Cypher | Diabetic patients. AP or positive stress, no AMI with clinically significant angiographic stenosis in a native coronary vessel | Parallel groups<br>open<br>Germany |
| ISAR-LEFT-MAIN , 2009<br>[NCT00133237]<br>n=302/305<br>follow-up: 1 year | Paclitaxel-eluting stent<br>versus<br>Sirolimus-eluting stent | Unprotected Left Main Coronary Artery Disease | Parallel groups<br>open |
| ISAR-SMART 3 , 2006<br>[NCT00146575]<br>n=180/180<br>follow-up: | Taxus<br>versus<br>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<br>NA<br>Germany |
| ISAR-TEST-1 , 2006<br>[NCT00140530]<br>n=225/225<br>follow-up: 9 months | rapamycin-eluting stent Yukon<br>versus<br>Taxus | stable or unstable anginaor a positive stress test, stable or unstable anginaor a positive stress test | Parallel groups<br>open<br>Germany |
| LONG DES II , 2006<br>n=250/250<br>follow-up: 9 months | SES<br>versus<br>PES | Long lesions. AP or positive stress, no AMI | Parallel groups<br>single-blind<br>Korea |
| Pan , 2007<br>n=103/102<br>follow-up: 24 months (mean) | SES for provisional T-stenting<br>versus<br>PES for provisional T-stenting | patients with bifurcation lesions | Parallel groups<br>open<br>Spain |
| Petronio et al , 2007<br>n=50/50<br>follow-up: 9 months | Cypher<br>versus<br>Taxus | Complex lesions. Stable AP or documented ischaemia, no AMI | Parallel groups<br>open<br>Italy |
| PROSIT , 2006<br>n=154/154<br>follow-up: 1 year | SES Cordis<br>versus<br>PES Boston Scientific | AMI or persistent ischaemia 12-24h | Parallel groups<br>open<br>Korea |
| REALITY , 2006<br>[NCT00235092]<br>n=701/685<br>follow-up: 12 months | Cypher<br>versus<br>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<br>open<br>Europe, Latin America, and Asiam |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| SIRTAX (Windecker) , 2005<br>n=503/509<br>follow-up: 9 mo (5y) | sirolimus-eluting stents (Cypher)<br>versus<br>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<br>single-blind<br>Switzerland |
| SORT OUT II , 2008<br>[NCT00388934]<br>n=1065/1033<br>follow-up: | Cypher stent<br>versus<br>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<br>open<br>Denmark. |
| TAXi , 2005<br>n=102/100<br>follow-up: 6 months | Cypher<br>versus<br>Taxus | Unselected patients | Parallel groups<br>open<br>Switzerland. |
| Tomai , 2008<br>n=60/60<br>follow-up: 8 months | sirolimus-eluting stent<br>versus<br>paclitaxel-eluting stent | diabetic patient with multiple de novo coronary artery lesions | Cross over<br>NA<br>Italy |
| Zhang (SES vs PES) , 2006<br>n=246/203<br>follow-up: 1y | Cypher<br>versus<br>Taxus | Unselected patients. Stable or unstable AP, ACS with de novo coronary lesions | Parallel groups<br>open<br>China |
| DES-ISR *ongoing*<br>[NCT00485030]<br>n=NA<br>follow-up: | Cypher<br>versus<br>Taxus | patients Diffuse Type In-Stent Restenosis After Drug-Eluting Stents Implantation | |
| Lipsia-Yukon-DM *ongoing*<br>[NCT00368953]<br>n=NA<br>follow-up: 9 months | Yukon Choice stent system<br>versus<br>Taxus Libert stent system | Patients With Diabetes Mellitus | |
| **zotarolimus eluting stent vs paclitaxel eluting stent** | | | |
| ENDEAVOR IV , 2009<br>*unpublished*<br>[NCT00217269]<br>n=773/775<br>follow-up: mean 36 mo | zotarolimus-eluting stent (Endeavor)<br>versus<br>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<br>open<br>US |
| ZEST (vs PES) , 2009<br>[NCT00418067]<br>n=883/884<br>follow-up: 1 year | zotarolimus-eluting stents<br>versus<br>paclitaxel-eluting stents | Patients with coronary artery disease | NA |
| ZEST AMI (vs PES) , 2009<br>[NCT00422565]<br>n=108/110<br>follow-up: 1 year (mean) | zotarolimus-eluting stent (Endeavor)<br>versus<br>paclitaxel-eluting stent (Taxus Libert) | Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours | open<br>Korea |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| ZoMaxx I , 2008<br>n=199/197<br>follow-up: 9 months | ZoMaxx zotarolimus-eluting stent<br>versus<br>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<br>open |
| ZoMaxx phase 2 *ongoing*<br>[NCT00140101]<br>n=NA<br>follow-up: | ZoMaxx drug-eluting stent<br>versus<br>TAXUS Express2 | de Novo Coronary Artery Lesions | |
| **pimecrolimus eluting stent vs pimecrolimus paclitaxel** | | | |
| GENESIS Trial CP-01<br>*ongoing*<br>[NCT00322569]<br>n=NA<br>follow-up: 6 months | Corio Pimecrolimus<br>versus<br>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<br>[NCT00332397]<br>n=333/335<br>follow-up: 12 months | dual DES (polymer-free stent consisting of probucol and rapamycin)<br>versus<br>SES | patients with De novo lesions in native coronary arteries | Parallel groups<br>open<br>Germany |
| **everolimus eluting stent vs sirolimus eluting stent** | | | |
| ISAR-TEST 4 (EES vs SES)<br>n=652/652<br>follow-up: 2 years | everolimus-eluting stent<br>versus<br>sirolimus-eluting stent | patients with de novo coronary artery stenosis >50% and symptoms or objective evidence of ischemia | Parallel groups |
| RESET , 2011<br>[NCT01035450]<br>n=NA | - | - | |
| SORT OUT IV , 2012<br>[NCT00552877]<br>n=1390/1384<br>follow-up: 9 months (3 years) | everolimus-eluting stents<br>versus<br>sirolimus-eluting stents | unselected patients with coronary artery disease | Parallel groups<br>open<br>Denmark |
| **paclitaxel eluting stent vs sirolimus eluting stent** | | | |
| FRE-RACE *ongoing*<br>[NCT00130546]<br>n=NA<br>follow-up: | Cypher select<br>versus<br>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<br>[NCT00217256]<br>n=327/109<br>follow-up: 12 months (and 24 months) | ABT-578 coated Endeavor<br>versus<br>Cypher | single de novo lesions in native coronary arteries 2.5-3.5 mm in diameter | Parallel groups<br>open<br>US |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| PROTECT , 2012<br>[NCT00476957]<br>n=4357/4352<br>follow-up: | Medtronic Endeavor Zotarolimus Eluting Coronary Stent System<br>versus<br>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<br>open-label |
| ZEST (vs SES) , 2009<br>[NCT00418067]<br>n=883/878<br>follow-up: 1 year | zotarolimus-eluting stents<br>versus<br>sirolimus-eluting stents | Patients with coronary artery disease | Parallel groups<br>Open<br>Korea |
| ZEST AMI (vs SES) , 2009<br>[NCT00422565]<br>n=108/110<br>follow-up: 1 year (mean) | zotarolimus-eluting stent (Endeavor)<br>versus<br>sirolimus-eluting stents (Cypher) | Acute Myocardial Infarction Patients (STEMI)requiring primary angioplasty with symptom onset <= 12 hours | Parallel groups<br>open<br>Korea |
| DIABEDES IV *ongoing*<br>[NCT00552994]<br>n=NA<br>follow-up: | Cypher select plus<br>versus<br>Xience V | diabetic patients | |
| PRISON III , 2007 *ongoing*<br>[NCT00428454]<br>n=NA<br>follow-up: 8 months | Endeavor<br>versus<br>Cypher | patients with total coronary occlusions for at least 2 weeks with evidence of ischemia related to the occluded coronary artery | Parallel groups<br>open |
| **dual sirolimus, probucol eluting stent vs zotarolimus eluting stent** | | | |
| ISAR TEST 2 (vs ZES) , 2009<br>[NCT00332397]<br>n=333/339<br>follow-up: 12 months | dual DES (polymer-free stent consisting of probucol and rapamycin)<br>versus<br>permanent polymer zotarolimus-eluting stent (Endeavor) | patients with De novo lesions in native coronary arteries | Parallel groups<br>open<br>Germany |
| ISAR TEST 5<br>[NCT00598533]<br>n=2002/1000<br>follow-up: 1 year | polymer-free, rapamycin/probucol-eluting Dual-DES stent<br>versus<br>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 *ongoing*<br>[NCT00598637]<br>n=NA<br>follow-up: | Xience<br>versus<br>Endeavor Resolute | unprotected left main coronary artery disease | open |

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**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<br>[NCT01132495]<br>n=447/441<br>follow-up: | fractional-flow-reserve (FFR)-guided stenting<br>versus<br>optimal medical therapy alone | patients patients with stable CAD found on FFR to have hemodynamically relevant disease | Parallel groups<br>Europe, US, and Canada |
| FAME , 2008<br>[NCT00267774]<br>n=509/496<br>follow-up: 1 year | FFR-guided PCI (PCI with implantation of drug-eluting stents guided by FFR measurements in addition to angiography<br>versus<br>angiography-PCI (PCI with implantation of drug-eluting stents guided by angiography alone) | patients with multivessel coronary artery disease | Parallel groups<br>open<br>USA, Europe |
| DEFER , 2001<br>n=90/91<br>follow-up: 24 months | PCI<br>versus<br>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<br>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<br>[NCT00196079]<br>n=117/58<br>follow-up: 6 months | coated Supra-G stent<br>versus<br>Supra-G stent | patientswith discrete coronary lesions (<15 mm in length, 2.25 to 3.5 mm in diameter) | Parallel groups<br>double-blind |
| DELIVER , 2004<br>n=524/519<br>follow-up: 9 months | non-polymer-based paclitaxel-coated ACHIEVE stent<br>versus<br>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<br>single-blind<br>US |
| ELUTES , 2004<br>n=152/38<br>follow-up: 12 months | coated V-Flex Plus<br>versus<br>V-Flex Plus | single de novo type A or type B1 lesions 15 mm length in a nativecoronary artery | Parallel groups<br>open<br>Europe |
| PATENCY , 2002<br>*unpublished*<br>n=24/26<br>follow-up: 9 months | Logic PTX paclitaxel Eluting CoronaryStents<br>versus<br>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<br>double blind |
| **polymer-free biolimus a9-eluting stents vs paclitaxel eluting stent** | | | |
| BIOFREEDOM<br>[NCT01172119]<br>n=NA<br>follow-up: | polymer-free biolimus A9-eluting stent<br>versus<br>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<br>n=201/202<br>follow-up: 12 months | polymer free 2% rapamycin (479 mg rapamycin/cm2) stent<br>versus<br>permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2) | Patients with de novo coronary lesions in native vessels | open<br>Germany |

## References

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

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

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Weaver , 2000<br>n=229/248<br>follow-up: 6 months | routine stent implantation (Palmaz-Schatz)<br>versus<br>balloon angioplasty and provisional stenting | patients undergoing single-vessel coronary angioplasty | Parallel groups<br>open |
| Lotan , 2000<br>n=48/48<br>follow-up: 6 months | stent implantation (AVE Micro Stent)<br>versus<br>no further treatment | with total coronary artery occlusions who had an optimal PTCA result | Parallel groups<br>open |
| Park , 2000<br>n=60/60<br>follow-up: 6 months (16 m) | elective stent placement (7-cell NIR stent)<br>versus<br>balloon angioplasty | patients with lesions in small coronary arteries (de novo, non-ostial lesion and reference diameter <3 mm) | Parallel groups<br>open |
| Koning , 2001<br>n=192/189<br>follow-up: 6 months | stent implantation (beStent Small)<br>versus<br>standard balloon angioplasty | symptomatic patients with de novo focal lesion located on a small coronary segment vessel (<3 mm) | Parallel groups<br>open |
| Doucet , 2001<br>n=169/182<br>follow-up: 6 months | stent implantation (beStent-Artist)<br>versus<br>angioplasty alone | symptomatic patients needing dilatation of 1 native coronary vessel between 2.3 and 2.9 mm in size | Parallel groups<br>open |
| Moer , 2001<br>n=74/71<br>follow-up: 6 months | elective stenting treatment with the heparin (Hepamed)-coated beStent<br>versus<br>PTCA | patients with stable or unstable angina | Parallel groups<br>open |
| **balloon angioplasty vs medical treatment** | | | |
| RITA 2 , 1997<br>n=504/514<br>follow-up: 7y | PTCA within 3 mo of the randomisation<br>versus<br>medical treatment | Angina leading to admission within 90days, previous Q wave MI, no previousPTCA, no left main stem disease | Parallel groups<br>open<br>UK |
| ACME , 1992<br>n=105/107<br>follow-up: 5y | PTCA within 3 days of randomization<br>versus<br>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<br>open<br>US |
| ACIP , 1997<br>n=192/366<br>follow-up: 24 months | revascularization by angioplasty or bypass surgery<br>versus<br>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<br>open |
| INSPIRE , 2006<br>n=104/101<br>follow-up: 60 months | coronary revascularization for suppressing scintigraphic ischemia<br>versus<br>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<br>open |
| SWISSI II , 2007<br>[NCT00387231]<br>n=96/105<br>follow-up: 10.2y | Percutaneous coronary intervention aimed at full revascularization<br>versus<br>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<br>open<br>Switzerland |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| ACME 2 (Folland) , 1997<br>n=51/50<br>follow-up: 5y | PTCA<br>versus<br>medical therapy | Stable angina, history of angina, MIwithin 3 months, exercise test with STdepression >3 mm, no previous PTCA; Stenosis >70% proximal two thirds,no main artery stenosis >50% , no 3vessel disease | Parallel groups<br>open |
| MASS , 1995<br>n=72/72<br>follow-up: 5y | PTCA<br>versus<br>medical treatment (aspirin, nitrates, beta-blockers and calcium channel blocking | Stable angina, no Q wave MI, no leftventricular dysfunction | Parallel groups<br>open<br>Brazil |
| Sievers , 1993<br>n=44/44<br>follow-up: 2y | PTCA<br>versus<br>medical treatment | Previous nonQ wave MI, no angina indaily life, no previous Q wave MI | Parallel groups<br>open<br>Germany |
| **PCI with or without stent vs medical treatment** | | | |
| TIME , 2001<br>n=NA<br>follow-up: | coronary angiography and revascularisation<br>versus<br>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<br>open |
| AVERT , 1995<br>n=177/164<br>follow-up: 1.5y | angioplasty<br>versus<br>atorvastatin at 80 mg per day | Angina or asymptomatic, MI orunstable angina but not within 14 days,no triple vessel disease | Parallel groups<br>open |
| Dakik , 1998<br>n=19/22<br>follow-up: 1y | PTCA<br>versus<br>intensive medical therapy | stable survivors of AMI | Parallel groups<br>open |
| MASS II , 2007<br>n=205/203<br>follow-up: 5y | PCI<br>versus<br>medical therapy | patients with multivessel coronary artery disease with stable angina and preserved ventricular function | Parallel groups<br>open |
| COURAGE , 2007<br>[NCT00007657]<br>n=1149/1138<br>follow-up: median 4.6 y | PCI coupled with optimal medical therapy<br>versus<br>optimal medical therapy aloneitm | patients with stable coronary artery disease | Parallel groups<br>open<br>Canada, US |
| ALKK , 2003<br>n=149/151<br>follow-up: 4.7y | angioplasty<br>versus<br>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<br>open<br>Germany |
| Hambrecht , 2004<br>n=50/51<br>follow-up: 1y | PCI<br>versus<br>12 months of exercise training (20 minutes of bicycle ergometry per day) | male patients aged 70 years | Parallel groups<br>open |
| Bech , 2001<br>n=90/91<br>follow-up: 2y | PTCA<br>versus<br>deferral of PTCA | patients with planned PTCA and no documented ischemia and with coronary pressurederived fractional flow reserve >0.75 | Parallel groups<br>open |

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

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| AWESOME , 2001<br>n=222/232<br>follow-up: 5 years | percutaneous coronary intervention<br>versus<br>coronary artery bypass graft | high-risk patients with medically refractory ischemia | Parallel groups<br>open<br>US (Veterans Affairs Medical Centers) |
| COMBAT *ongoing*<br>n=NA | PCI<br>versus<br>CABG | - | |
| Korean Randomized Study<br>*ongoing*<br>n=NA | PCI<br>versus<br>CABG | - | |
| REVASCULARIZE *ongoing*<br>n=NA | PCI<br>versus<br>CABG | - | |
| **PCI with drug-eluting stents vs CABG** | | | |
| FREEDOM , 2012<br>[NCT00086450]<br>n=953/947<br>follow-up: 3.8 yrs (median) | percutaneous coronary stenting<br>versus<br>CABG | patients with diabetes and multivessel coronary artery disease | Parallel groups<br>open<br>international |
| **PCI withdrug-eluting stents vs CABG** | | | |
| Hong , 2005<br>n=119/70<br>follow-up: 9 months | drug-eluting stents<br>versus<br>invasive direct coronary artery bypass (MIDCAB) surgery | proximal left anterior descending (LAD) coronary artery stenosis | Parallel groups<br>open |
| VA CARDS *ongoing*<br>[NCT00326196]<br>n=NA<br>follow-up: | percutaneous coronary stenting with drug eluding stents<br>versus<br>CABG | angiographically significant coronary artery disease in diabetes | Parallel groups<br>open |
| **stent vs CABG** | | | |
| ARTS , 2001<br>n=600/605<br>follow-up: 1 year | Palmaz-Schatz Crown/Cross flex (Cordis)<br>versus<br>Conventional CABG | Multi vessel disease with 2 or more de novo lesion in different major arteries Total occlusion <1month | parallel group<br>open<br>International |
| CARDia (PCI) , 2008<br>[ISRCTN19872154]<br>n=256/254<br>follow-up: 1 y | PCI plus stenting (and routine abciximab)<br>versus<br>CABG | Patients with diabetes and symptomatic multivessel coronary artery disease or complex single-vessel disease. | Parallel groups<br>open<br>UK, Ireland |
| ERACI II , 2003<br>n=225/225<br>follow-up: 30d, 1year | Gianturco Robin II (Cook) Primary device<br>versus<br>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<br>open<br>Argentinad |
| LEMANS , 2002<br>[NCT00375063]<br>n=52/53<br>follow-up: 1y | unprotected left main stenting<br>versus<br>coronary artery bypass grafting | patients with unprotected left main coronary artery stenosis | Parallel groups<br>open<br>Poland |

continued...

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

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| SIMA , 2000<br>n=62/59<br>follow-up: 2.4 years | Any CE marked, but Palmaz-Schatz recommended<br>versus<br>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<br>open<br>Europe |
| **stent vs OPCAB** | | | |
| OCTOSTENT , 2003<br>[NCT00975858]<br>n=138/142<br>follow-up: 1 year | Stent type not reported<br>versus<br>off-pump coronary artery bypass | multi or single vessel disease Moderate LV function CABG or stenting to be considered feasible | Parallel groups<br>open<br>Europe |

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# 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<br>n=264/281<br>follow-up: 6 months | Cypher<br>versus<br>Taxus | Unselected patients; de-novo lesions | Parallel groups<br>open<br>Switzerland, |
| Cervinka , 2006<br>n=37/33<br>follow-up: 6 months | sirolimus-eluting stent<br>versus<br>paclitaxel-eluting stent | Complex lesionsand patients. Signs and/or symptoms myocardial ischaemia, including AMI | Parallel groups<br>open |
| CORPAL , 2005 *unpublished*<br>n=331/321<br>follow-up: | sirolimus<br>versus<br>paclitaxel | Documented myocardial ischaemia, no AMI | Parallel groups<br>open<br>Spain |
| Di Lorenzo et al. , 2005 *unpublished*<br>n=90/90<br>follow-up: | sirolimus<br>versus<br>paclitaxel | ST-segment elevation myocardial infarction | Parallel groups<br>open |
| Han , 2006<br>n=210/206<br>follow-up: 19.5 months (mean) | Cypher<br>versus<br>Taxus | Multivessel disease. Stable or unstable AP, no AMI | Parallel groups<br>open<br>China |
| ISAR-DESIRE (SES vs PES) , 2005<br>n=100/100<br>follow-up: 1y | Cypher<br>versus<br>Taxus | In-stent restenosis. AP and/or positive test, previously stented, no AMI | Parallel groups<br>open<br>germany |
| ISAR-DIABETES , 2005<br>n=125/125<br>follow-up: 9 months | Taxus<br>versus<br>Cypher | Diabetic patients. AP or positive stress, no AMI with clinically significant angiographic stenosis in a native coronary vessel | Parallel groups<br>open<br>Germany |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| ISAR-LEFT-MAIN , 2009<br>[NCT00133237]<br>n=302/305<br>follow-up: 1 year | Paclitaxel-eluting stent<br>versus<br>Sirolimus-eluting stent | Unprotected Left Main Coronary Artery Disease | Parallel groups<br>open |
| ISAR-SMART 3 , 2006<br>[NCT00146575]<br>n=180/180<br>follow-up: | Taxus<br>versus<br>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<br>NA<br>Germany |
| ISAR-TEST-1 , 2006<br>[NCT00140530]<br>n=225/225<br>follow-up: 9 months | rapamycin-eluting stent Yukon<br>versus<br>Taxus | stable or unstable anginaor a positive stress test, stable or unstable anginaor a positive stress test | Parallel groups<br>open<br>Germany |
| LONG DES II , 2006<br>n=250/250<br>follow-up: 9 months | SES<br>versus<br>PES | Long lesions. AP or positive stress, no AMI | Parallel groups<br>single-blind<br>Korea |
| Pan , 2007<br>n=103/102<br>follow-up: 24 months (mean) | SES for provisional T-stenting<br>versus<br>PES for provisional T-stenting | patients with bifurcation lesions | Parallel groups<br>open<br>Spain |
| Petronio et al , 2007<br>n=50/50<br>follow-up: 9 months | Cypher<br>versus<br>Taxus | Complex lesions. Stable AP or documented ischaemia, no AMI | Parallel groups<br>open<br>Italy |
| PROSIT , 2006<br>n=154/154<br>follow-up: 1 year | SES Cordis<br>versus<br>PES Boston Scientific | AMI or persistent ischaemia 12-24h | Parallel groups<br>open<br>Korea |
| REALITY , 2006<br>[NCT00235092]<br>n=701/685<br>follow-up: 12 months | Cypher<br>versus<br>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<br>open<br>Europe, Latin America, and Asiam |
| SIRTAX (Windecker) , 2005<br>n=503/509<br>follow-up: 9 mo (5y) | sirolimus-eluting stents (Cypher)<br>versus<br>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<br>single-blind<br>Switzerland |
| SORT OUT II , 2008<br>[NCT00388934]<br>n=1065/1033<br>follow-up: | Cypher stent<br>versus<br>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<br>open<br>Denmark. |
| TAXi , 2005<br>n=102/100<br>follow-up: 6 months | Cypher<br>versus<br>Taxus | Unselected patients | Parallel groups<br>open<br>Switzerland. |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Tomai , 2008<br>n=60/60<br>follow-up: 8 months | sirolimus-eluting stent<br>versus<br>paclitaxel-eluting stent | diabetic patient with multiple de novo<br>coronary artery lesions | Cross over<br>NA<br>Italy |
| Zhang (SES vs PES) , 2006<br>n=246/203<br>follow-up: 1y | Cypher<br>versus<br>Taxus | Unselected patients. Stable or unstable AP,<br>ACS with de novo coronary lesions | Parallel groups<br>open<br>China |
| DES-ISR *ongoing*<br>[NCT00485030]<br>n=NA<br>follow-up: | Cypher<br>versus<br>Taxus | patients Diffuse Type In-Stent Restenosis<br>After Drug-Eluting Stents Implantation | |
| Lipsia-Yukon-DM *ongoing*<br>[NCT00368953]<br>n=NA<br>follow-up: 9 months | Yukon Choice stent system<br>versus<br>Taxus Libert stent system | Patients With Diabetes Mellitus | |

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# 9 resordable

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **sirolimus biodegradable polymer vs sirolimus eluting stent** | | | |
| ISAR TEST 3 (BP) , 2009<br>n=202/202<br>follow-up: 12 months | biodegradable-polymer 0.4% rapamycin stent (180 mg rapamycin/cm2)<br>versus<br>permanent-polymer rapamycin-eluting stent (Cypher) (140 mg rapamycin/cm2) | Patients with de novo coronary lesions in native vessels | Parallel groups<br>open<br>Germany |
| ISAR-TEST-4 (biodegradable polymer) , 2009<br>[NCT00598676).]<br>n=1299/1304<br>follow-up: 12 mo | biodegradable polymer rapamycin-eluting stent<br>versus<br>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<br>open<br>Germany |

## References


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**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<br>[NCT00023595]<br>n=501/499<br>follow-up: 48 months | CABG with surgical ventricular reconstruction<br>versus<br>CABG | patients with anterior-apical regional left ventricular dysfunction | Parallel groups<br>open |
| **CABG vs medical treatment** | | | |
| STICH (vs med) , 2011<br>[NCT00023595]<br>n=602/610<br>follow-up: 56 months | CABG<br>versus<br>medical therapy | patients with congestive heart failure and severe LV dysfunction | Parallel groups<br>open<br>26 countries |
| ECSS (European) , 1988<br>n=394/373<br>follow-up: 12 y | early coronary bypass surgery<br>versus<br>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<br>open<br>Europe (6 countries) |
| CASS , 1983<br>[NCT00000489]<br>n=390/390<br>follow-up: 5y | surgical<br>versus<br>nonsurgical | patients with stable ischemic heart disease | Parallel groups<br>open<br>USA, Canada |

continued...

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

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**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<br>n=45/47<br>follow-up: 6 mo | titanium-nitride-oxide coated stents<br>versus<br>stainless steel stents of similar design | - | Parallel groups<br>open<br>Switzerlanf, Germany |

## References


**TINOX, 2005:**

# 12 transmyocardial revascularization

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

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Frazier , 1999<br>n=91/101<br>follow-up: 12 months (4y) | transmyocardial revascularization<br>versus<br>continued medical treatment | patients with end-stage coronary artery disease | Parallel groups<br>open<br>US |
| Gray , 2003<br>n=36/37<br>follow-up: 12 months | percutaneous myocardial laser revascularization<br>versus<br>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<br>open |
| Huikeshoven , 2003<br>n=30<br>follow-up: 1y | XeCl excimer transmyocardial laser revascularization<br>versus<br>optimal cardiac medication | - | Parallel groups<br>open |
| March , 1999<br>n=198<br>follow-up: 12 months | Transmyocardial laser revascularization<br>versus<br>continued medical management | patients with symptomatic end-stage coronary artery disease | Parallel groups<br>open |
| PACIFIC , 2000<br>n=110/111<br>follow-up: 12 months | Percutaneous transmyocardial laser revascularisation<br>versus<br>medical treatment only | patients with reversible ischaemia of Canadian Cardiovascular Society angina class III or IV and incomplete response to other therapies | Parallel groups<br>open<br>US, UK |
| Salem , 2004<br>n=40/42<br>follow-up: 12 months | percutaneous myocardial laser revascularization<br>versus<br>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<br>double blind<br>Norway |
| Schofield , 1999<br>n=94/94<br>follow-up: 1 y | Transmyocardial laser revascularisation<br>versus<br>medical management alone | patients with refractory angina | Parallel groups<br>open |
| Stone , 2002<br>n=71/70<br>follow-up: 6 months | percutaneous transmyocardial revascularization<br>versus<br>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<br>single blind (patient)<br>US |
| van der Sloot , 2004<br>n=15/15<br>follow-up: 12 months | XeCl excimer transmyocardial laser revascularization<br>versus<br>maximal medication | patients with refractory angina | Parallel groups<br>open<br>the Netherlands |
| **TMR vs thoracic sympathectomy** | | | |
| Galianes , 2004<br>n=10/10<br>follow-up: 42 months | Transmyocardial laser revascularization by holmium: yttrium aluminum garnet laser<br>versus<br>thoracic sympathectomy | patients with nonrevascularizable coronary arteries and intractable angina | Parallel groups<br>open |



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# 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.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.