

Clinical trials of myocardial revascularization for coronary artery disease in diabetic patients

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1 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

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BARI 2D, 2009:

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[10.1161/CIRCULATIONAHA.110.978247](#)

2 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
paclitaxel eluting stent vs bare-metal stent			
TAXUS II (diabetics) , 2003 <i>unpublished</i> n=37/41 follow-up: 12 months	TAXUS versus NIR stent	Diabetic patients with stable or unstable AP, silent ischaemia; single de novo target lesion with estimatedstenosis >50% and <99% ,	Parallel groups double-blind Europe

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Trial	Treatments	Patients	Trials design and methods
TAXUS IV (diabetics) , 2005 [NCT00292474] n=155/163 follow-up: 9 months	TAXUS versus EXPRESS	Diabetic patients with stable or unstable AP, provokable ischaemia with a single, previously untreated coronary-artery stenosis (vessel diameter, 2.5 to 3.75 mm; lesion length, 10 to 28 mm)	Parallel groups double-blind United States
TAXUS V (diabetics) , 2005 n=178/171 follow-up: 9 months	TAXUS versus BMS	Diabetic patients with stable or unstable AP, silent ischaemia with complex or previously unstudied lesions (requiring 2.25-mm, 4.0-mm, and/or multiple stents)	Parallel groups double-blind United States
TAXUS VI (diabetics) , 2005 [NCT00297804] n=39/50 follow-up: 9 months	TAXUS versus Express2 stent	Diabetic patients with stable or unstable AP, silent ischaemia with long, complex coronary artery lesions	Parallel groups double-blind Europe
sirolimus eluting stent vs bare-metal stent			
DECODE , 2005 <i>unpublished</i> [NCT00489164] n=54/29 follow-up: 1 year	CYPHER (Up to 3 stents per patient were allowed) versus Bx VELOCITY (Up to 3 stents per patient were allowed)	Stable or unstable angina in diabetic patients with with up to 2 de novo lesions in up to 2 native coronary vessels	Parallel groups open US, Asia/Pacific
DIABETES , 2005 n=80/80 follow-up: 9 months	Cypher versus Bx Velocity/Sonic	de novo lesions in native coronary arteries in 1, 2, or 3 native vessels with symptoms or objective evidence of ischemia; vessel size smaller than 4.0 mm	Parallel groups open Spanish
Ravel (diabetics) , 2004 n=19/25 follow-up: 6 months	coated Bx velocity versus Bx VELOCITY	sub groups of diabetic patients with de novo native coronary artery lesions 2.5 to 3.5 mm in diameter by visual assessment that could be covered by an 18-mm stent	Parallel groups NA Europe
SES-SMART (diabetics) , 2005 n=29/45 follow-up: 8 months	Cypher versus Bx Sonic	Diabetic patients with de novo target lesion <=2.75 mm in diameter in a native coronary artery that could be completely covered by a single stent (maximum length 33 mm)	Parallel groups single-blind Italy
SIRIUS (diabetics) , 2003 n=131/148 follow-up: 12 months	SES versus BMS	sub group of diabetic patients of SIRIUS study	Parallel groups double-blind US
CoStar stent vs paclitaxel eluting stent			
COSTAR II diabetic (sub group) , 2008 n=271/271 follow-up: 8 months	CoStar stent (PES) versus Taxus stent (PES)	patients with de novo single- or multivessel coronary disease	Parallel groups open
paclitaxel eluting balloon vs paclitaxel eluting stent			

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Trial	Treatments	Patients	Trials design and methods
PEPCAD IV <i>ongoing</i> [NCT00462631] n=NA follow-up:	Paclitaxel-eluting PTCA-balloon dilation (SeQuent™ Please) followed by cobalt-chromium stent (Coroflex™ Blue) deployment versus Taxus Libert	patients with diabetes mellitus	open
sirolimus eluting stent vs paclitaxel eluting stent			
DES-DIABETES , 2008 n=200/200 follow-up: 9 months (1 year)	sirolimus-eluting stent versus paclitaxel-elutingstent	diabetic patients with angina pectoris and/or a positive stress test and a native coronary lesion	Factorial plan open Korea
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
REALITY (diabetics) , 2006 <i>unpublished</i> n=187/192 follow-up: 12 months	SES versus PES	-	Parallel groups open worldwide
SIRTAX diabetics , 2005 [NCT00297661] n=108/93 follow-up: 12 months	Cypher versus Taxus	Sub groups of diabetics patients with either stable angina or an acute coronary syndrome	Parallel groups single-blind Switzerland
TAXi (diabetics) , 3000 <i>unpublished</i> n=33/36 follow-up: 12 months	SES versus PES	-	Parallel groups open Switzerland
Tomai , 2008 n=60/60 follow-up: 8 months	sirolimus-eluting stent versus paclitaxel-eluting stent	diabetic patient with multiple de novo coronary artery lesions	Cross over NA Italy
Lipsia-Yukon-DM <i>ongoing</i> [NCT00368953] n=NA follow-up: 9 months	Yukon Choice stent system versus Taxus Libert stent system	Patients With Diabetes Mellitus	
paclitaxel eluting stent vs sirolimus eluting stent			
ISAR-test (diabetics) , 2006 n=73/58 follow-up: 9 months	Taxus versus rapamycin stent	diabetics patients with de novo lesions in native coronary vessels, excluding the left main trunk	Parallel groups open germany
zotarolimus eluting stent vs sirolimus eluting stent			
DIABEDES IV <i>ongoing</i> [NCT00552994] n=NA follow-up:	Cypher select plus versus Xience V	diabetic patients	
everolimus eluting stent vs sirolimus ES			

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Trial	Treatments	Patients	Trials design and methods
ESSENCE diabetes [NCT00997763] n=149/151 follow-up: 1y for clinical events	everolimus-eluting stent versus sirolimus-eluting stent	diabetic patients with angina or documented ischemia	Parallel groups open South Korea

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SES-SMART (diabetics), 2005:

SIRIUS (diabetics), 2003:

COSTAR II diabetic (sub group), 2008:

PEPCAD IV, 0:

DES-DIABETES, 2008:

ISAR-DIABETES, 2005:

REALITY (diabetics), 2006:

SIRTAX diabetics, 2005:

TAXi (diabetics), 3000:

Tomai, 2008:

Lipsia-Yukon-DM, 0:

ISAR-test (diabetics), 2006:
 DIABEDES IV, 0:
 ESSENCE diabetes, :

3 PCI

Trial	Treatments	Patients	Trials design and methods
PCI with drug-eluting stents vs CABG			
SYNTAX (diabetic) , 2010 [NCT00114972] n=NA follow-up: 1 year	paclitaxel-eluting stents versus surgical revascularization	sub group of diabetic patients with left main and/or 3-vessel disease	Parallel groups
FREEDOM , 2012 [NCT00086450] n=953/947 follow-up: 3.8 yrs (median)	percutaneous coronary stenting versus CABG	patients with diabetes and multivessel coronary artery disease	Parallel groups open international
PCI with drug-eluting stents vs CABG			
VA CARDS ongoing [NCT00326196] n=NA follow-up:	percutaneous coronary stenting with drug eluting stents versus CABG	angiographically significant coronary artery disease in diabetes	Parallel groups open
stent vs CABG			
CARDia (PCI) , 2008 [ISRCTN19872154] n=256/254 follow-up: 1 y	PCI plus stenting (and routine abciximab) versus CABG	Patients with diabetes and symptomatic multivessel coronary artery disease or complex single-vessel disease.	Parallel groups open UK, Ireland

References

SYNTAX (diabetic), 2010:
 FREEDOM, 2012:
 VA CARDS, 0:
 CARDia (PCI), 2008:

4 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.