

# 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
<b>CABG or PCI vs medical treatment</b>			
<b>BARI 2D , 2009</b> [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:

Baseline characteristics of patients with diabetes and coronary artery disease enrolled in the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) trial. Am Heart J 2008;156:528-536, 536.e1-5 [[18760137](#)]

A Randomized Trial of Therapies for Type 2 Diabetes and Coronary Artery Disease. N Engl J Med 2009;: [[19502645](#)]

Chaitman BR, Hardison RM, Adler D, Gebhart S, Grogan M, Ocampo S, Sopko G, Ramires JA, Schneider D, Frye RL The Bypass Angioplasty Revascularization Investigation 2 Diabetes Randomized Trial of Different Treatment Strategies in Type 2 Diabetes Mellitus With Stable Ischemic Heart Disease. Impact of Treatment Strategy on Cardiac Mortality and Myocardial Infarction. Circulation 2009;: [[19920001](#)]

Dagenais GR, Lu J, Faxon DP, Kent K, Lago RM, Lezama C, Hueb W, Weiss M, Slater J, Frye RL Effects of Optimal Medical Treatment With or Without Coronary Revascularization on Angina and Subsequent Revascularizations in Patients With Type 2 Diabetes Mellitus and Stable Ischemic Heart Disease. Circulation 2011;123:1492-1500 [[21444887](#)]  
[10.1161/CIRCULATIONAHA.110.978247](#)

## 2 drug-eluting stents

Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel eluting stent vs bare-metal stent</b>			
<b>TAXUS II (diabetics) , 2003</b> <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unpublished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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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>TAXUS IV (diabetics) , 2005</b> [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
<b>TAXUS V (diabetics) , 2005</b> 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
<b>TAXUS VI (diabetics) , 2005</b> [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
<b>sirolimus eluting stent vs bare-metal stent</b>			
<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 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>Ravel (diabetics) , 2004</b> 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
<b>SES-SMART (diabetics) , 2005</b> 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
<b>SIRIUS (diabetics) , 2003</b> n=131/148 follow-up: 12 months	SES versus BMS	sub group of diabetic patients of SIRIUS study	Parallel groups double-blind US
<b>CoStar stent vs paclitaxel eluting stent</b>			
<b>COSTAR II diabetic (sub group) , 2008</b> 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
<b>paclitaxel eluting balloon vs paclitaxel eluting stent</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>PEPCAD IV</b> <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
<b>sirolimus eluting stent vs paclitaxel eluting stent</b>			
<b>DES-DIABETES</b> , 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
<b>ISAR-DIABETES</b> , 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
<b>REALITY (diabetics)</b> , 2006 <i>unpublished</i> n=187/192 follow-up: 12 months	SES versus PES	-	Parallel groups open worldwide
<b>SIRTAX diabetics</b> , 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
<b>TAXi (diabetics)</b> , 3000 <i>unpublished</i> n=33/36 follow-up: 12 months	SES versus PES	-	Parallel groups open Switzerland
<b>Tomai</b> , 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
<b>Lipsia-Yukon-DM</b> <i>ongoing</i> [NCT00368953] n=NA follow-up: 9 months	Yukon Choice stent system versus Taxus Libert stent system	Patients With Diabetes Mellitus	
<b>paclitaxel eluting stent vs sirolimus eluting stent</b>			
<b>ISAR-test (diabetics)</b> , 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
<b>zotarolimus eluting stent vs sirolimus eluting stent</b>			
<b>DIABEDES IV</b> <i>ongoing</i> [NCT00552994] n=NA follow-up:	Cypher select plus versus Xience V	diabetic patients	
<b>everolimus eluting stent vs sirolimus ES</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>ESSENCE diabetes</b> [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

## References

### **TAXUS II (diabetics), 2003:**

Hermiller J. Diabetic results: Taxus II, IV and VI TCT [0]

### **TAXUS IV (diabetics), 2005:**

Hermiller JB, Raizner A, Cannon L, Gurbel PA, Kutcher MA, Wong SC, Russell ME, Ellis SG, Mehran R, Stone GW Outcomes with the polymer-based paclitaxel-eluting TAXUS stent in patients with diabetes mellitus: the TAXUS-IV trial. J Am Coll Cardiol 2005;45:1172-9 [15837245]

### **TAXUS V (diabetics), 2005:**

Ellis SG TAXUS V trial global results: expanding the randomizeddata 2005 American College of CardiologyAnnual Scientific Session

### **TAXUS VI (diabetics), 2005:**

Dawkins KD, Grube E, Guagliumi G, Banning AP, Zmudka K, Colombo A, Thuesen L, Hauptman K, Marco J, Wijns W, Popma JJ, Koglin J, Russell ME Clinical efficacy of polymer-based paclitaxel-eluting stents in the treatment of complex, long coronary artery lesions from a multicenter, randomized trial: support for the use of drug-eluting stents in contemporary clinical practice. Circulation 2005;112:3306-13 [16286586]

### **DECODE, 2005:**

Chan C, Zambahari R, Kaul U, Cohen SA, Buchbinder M. Outcomesin diabetic patients with multivessel disease and long lesions: resultsfrom the DECODE study Am J Cardiol 2005; 96 (suppl 7A): 31H

### **DIABETES, 2005:**

Sabat M, Jimnez-Quevedo P, Angiolillo DJ, Gmez-Hospital JA, Alfonso F, Hernndez-Antoln R, Goicolea J, Baelos C, Escaned J, Moreno R, Fernndez C, Fernndez-Avils F, Macaya C Randomized comparison of sirolimus-eluting stent versus standard stent for percutaneous coronary revascularization in diabetic patients: the diabetes and sirolimus-eluting stent (DIABETES) trial. Circulation 2005;112:2175-83 [16203930]

Jimnez-Quevedo P, Sabat M, Angiolillo DJ, Alfonso F, Hernndez-Antoln R, SanMartn M, Gmez-Hospital JA, Baelos C, Escaned J, Moreno R, Fernndez C, Fernndez-Avils F, Macaya C Long-term clinical benefit of sirolimus-eluting stent implantation in diabetic patients with de novo coronary stenoses: long-term results of the DIABETES trial. Eur Heart J 2007;28:1946-52 [17562666]

### **Ravel (diabetics), 2004:**

### **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 diabetes, 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
<b>PCI with drug-eluting stents vs CABG</b>			
<b>SYNTAX (diabetic) , 2010</b> [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
<b>FREEDOM , 2012</b> [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
<b>PCI with drug-eluting stents vs CABG</b>			
<b>VA CARDS ongoing</b> [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>stent vs CABG</b>			
<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

### 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.