

Clinical trials of myocardial revascularization for stable angina 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 |

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 |
|--|---|---|--|
| sirolimus eluting stent vs bare-metal stent | | | |
| DESSERT , 2008 n=75/75 follow-up: 12 months | Cypher andCypher Select versus Sonic (Cordis) | de novo lesions of diabetic patients treated with insulin and/or oral antidiabetics for >3 months | Parallel groups single-blind Italy |
| sirolimus eluting stent vs paclitaxel eluting stent | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|---------------------------|---|----------------------------------|
| Kim , 2008 n=85/84 follow-up: 6 months | Cypher versus Taxus | Korean diabetic patients with high-grade de novo coronary lesions (stenosis of >70 percent of the luminal diameter) requiring <3 stents | Parallel groups open Korea |

References

DESSERT, 2008:

Maresta A, Varani E, Balducelli M, Varbella F, Lettieri C, Uguccioni L, Sangiorgio P, Zoccai GB Comparison of effectiveness and safety of sirolimus-eluting stents versus bare-metal stents in patients with diabetes mellitus (from the Italian Multicenter Randomized DESSERT Study). *Am J Cardiol* 2008;101:1560-6 [18489933]

Kim, 2008:

Kim MH, Hong SJ, Cha KS, Park HS, Chae SC, Hur SH, Gwon HC, Bae JH, Lim DS Effect of Paclitaxel-eluting versus sirolimus-eluting stents on coronary restenosis in Korean diabetic patients. *J Interv Cardiol* 2008 Jun;21:225-31 [18341520]

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:

Banning AP, Westaby S, Morice MC, Kappetein AP, Mohr FW, Berti S, Glauber M, Kellett MA, Kramer RS, Leadley K, Dawkins KD, Serruys PW Diabetic and nondiabetic patients with left main and/or 3-vessel coronary artery disease: comparison of outcomes with cardiac surgery and paclitaxel-eluting stents. *J Am Coll Cardiol* 2010;55:1067-75 [20079596]

FREEDOM, 2012:

Farkouh ME, Domanski M, Sleeper LA, Siami FS, Dangas G, Mack M, Yang M, Cohen DJ, Rosenberg Y, Solomon SD, Desai AS, Gersh BJ, Magnuson EA, Lansky A, Boineau R, Weinberger J, Ramanathan K, Sousa JE, Rankin J, Bhargava B, Buse J, Hueb W, Smith CR, Muratov Strategies for Multivessel Revascularization in Patients with Diabetes. *N Engl J Med* 2012 Nov 4; [23121323] [10.1056/NEJMoa1211585](https://doi.org/10.1056/NEJMoa1211585)

VA CARDS, 0:**CARDia (PCI), 2008:**

Kapur A, Hall RJ, Malik IS, Qureshi AC, Butts J, de Belder M, Baumbach A, Angelini G, de Belder A, Oldroyd KG, Flather M, Roughton M, Nihoyannopoulos P, Bagger JP, Morgan K, Beatt KJ Randomized comparison of percutaneous coronary intervention with coronary artery bypass grafting in diabetic patients. 1-year results of the CARDia (Coronary Artery Revascularization in Diabetes) trial. *J Am Coll Cardiol* 2010 Feb 2;55:432-40 [20117456] [10.1016/j.jacc.2009.10.014](https://doi.org/10.1016/j.jacc.2009.10.014)

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.