

Clinical trials of myocardial revascularization for stable angina in single vessel disease

TrialResults-center www.trialresultscenter.org

1 PCI

Trial	Treatments	Patients	Trials design and methods
balloon angioplasty vs medical treatment			
ACME , 1992 n=105/107 follow-up: 5y	PTCA within 3 days of randomization versus medical treatment (nitrates, beta-blockers, calcium blockers)	Stable angina, history of angina, MI within 3 months, exercise test with ST depression >3 mm, no previous PTCA; Single or serial stenosis within same artery 70% to 99% proximal two thirds	Parallel groups open US
MASS , 1995 n=72/72 follow-up: 5y	PTCA versus medical treatment (aspirin, nitrates, beta-blockers and calcium channel blocking)	Stable angina, no Q wave MI, no left ventricular dysfunction	Parallel groups open Brazil
Sievers , 1993 n=44/44 follow-up: 2y	PTCA versus medical treatment	Previous non Q wave MI, no angina in daily life, no previous Q wave MI	Parallel groups open Germany
PCI with or without stent vs medical treatment			
ALKK , 2003 n=149/151 follow-up: 4.7y	angioplasty versus medical therapy	patients with single vessel disease of the infarct vessel and no or minor angina pectoris in the subacute phase (1 to 6 weeks) after an acute myocardial infarction	Parallel groups open Germany
balloon angioplasty vs CABG			
MASS , 1995 n=72/70 follow-up: 3.2 y	percutaneous transluminal coronary angioplasty versus mammary bypass surgery	patients with stable angina, normal ventricular function and a proximal stenosis of the left anterior descending coronary artery >80%	open Brazil
Lausanne , 1994 n=68/66 follow-up: 3.2 y	transluminal coronary angioplasty versus Coronary artery bypass grafting	patients with isolated proximal left anterior descending artery stenosis, conserved left ventricular function, and documented ischaemia	open Switzerland
PCI with drug-eluting stents vs CABG			
Hong , 2005 n=119/70 follow-up: 9 months	drug-eluting stents versus invasive direct coronary artery bypass (MIDCAB) surgery	proximal left anterior descending (LAD) coronary artery stenosis	Parallel groups open
stent vs CABG			

continued...

Trial	Treatments	Patients	Trials design and methods
LEMANS , 2002 [NCT00375063] n=52/53 follow-up: 1y	unprotected left main stenting versus coronary artery bypass grafting	patients with unprotected left main coronary artery stenosis	Parallel groups open Poland
stent vs E-ACAB			
Cisowski n=50/50 follow-up: 2 years	Tristar, Tera, Penta (Guidant) (Cordis) versus endoscopic atraumatic coronary artery bypass grafting	single vessel disease ACC/AHA A or B lesion in proximal LAD Angina CCS II or higher Lesion diameter 3 mm or greater/length 20mm or greater	parallel group open Poland
angioplasty vs MIDCAB			
AMIST (Reeves) , 2004 n=50/50 follow-up: 12 months	percutaneous transluminal coronary angioplasty (PTCA) with or without stenting versus minimally invasive direct coronary artery bypass grafting (MIDCAB)	single-vessel disease (at least 50% stenosis) of the left anterior descending coronary artery (LAD).	Parallel groups open England
PCI withsirolimus ES vs MIDCAB			
Thiele , 2009 [NCT00299429] n=65/65 follow-up: 12 months	sirolimus-eluting stent versus MIDCAB surgery	isolated LAD disease	Parallel groups open Germany
stent vs MIDCAB			
Diegeler , 2002 n=110/110 follow-up: 5 years	Various stents versus minimally invasive direct coronary artery bypass (off-pump procedure)	single vessel disease Lesion =75% stenosis in proximal LAD or between origin of left circumflex and 1st septal branch	parallel group open Germany
Drenth , 2002 n=51/51 follow-up: 6 months, 3 years	Stent type not reported versus minimally invasive direct coronary artery bypass (off-pump procedure)	single vessel disease Angina II Lesion (Grade B2 or C) of proximal LAD Suitable for CABG or stenting	parallel group open Netherlands
Grip , 2001 n=28/25 follow-up:	Stent type not reported versus minimally invasive direct coronary artery bypass (off-pump procedure)	single vessel disease engaging LAD Stable or unstable angina	parallel group open Sweden
SIMA , 2000 n=62/59 follow-up: 2.4 years	Any CE marked, but Palmaz-Schatz recommended versus Conventional CABG or minimally invasive direct coronary artery bypass (off-pump procedure) (10% of surgical procedures)	single vessel disease Symptomatic or silent ischaemia 1 LAD lesion Ejection fraction >45% Vessel >3.0mm	parallel group open Europe

2

References

ACME, 1992:

Parisi AF, Folland ED, Hartigan P A comparison of angioplasty with medical therapy in the treatment of single-vessel coronary artery disease. Veterans Affairs ACME Investigators N Engl J Med 1992;326:10-6 [1345754]

Hartigan PM, Giacomini JC, Folland ED, Parisi AF Two- to three-year follow-up of patients with single-vessel coronary artery disease randomized to PTCA or medical therapy

(results of a VA cooperative study). Veterans Affairs Cooperative Studies Program ACME Investigators. Angioplasty Compared to Medicine Am J Cardiol 1998;82:1445-50 [9874045]

MASS, 1995:

Hueb WA, Bellotti G, de Oliveira SA, Arie S, de Albuquerque CP, Jatene AD, Pileggi F The Medicine, Angioplasty or Surgery Study (MASS): a prospective, randomized trial of medical therapy, balloon angioplasty or bypass surgery for single proximal left anterior descending artery stenoses J Am Coll Cardiol 1995;26:1600-5 [7594092] 10.1016/0735-1097(95)00384-3

Sievers, 1993:

Sievers N, Hamm CW, Herzner A, Kuck KH Medical therapy versus PTCA: a prospective, randomized trial in patients with asymptomatic coronary single-vessel disease. Abstract. Circulation. 1993;88(suppl I):I-297 [0]

ALKK, 2003:

Zeymer U, Uebis R, Vogt A, Glunz HG, Vhringer HF, Harmjanz D, Neuhaus KL Randomized comparison of percutaneous transluminal coronary angioplasty and medical therapy in stable survivors of acute myocardial infarction with single vessel disease: a study of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte Circulation 2003;108:1324-8 [12939210] 10.1161/01.CIR.0000087605.09362.0E

MASS, 1995:

Hueb WA, Bellotti G, de Oliveira SA, Arie S, de Albuquerque CP, Jatene AD, Pileggi F The Medicine, Angioplasty or Surgery Study (MASS): a prospective, randomized trial of medical therapy, balloon angioplasty or bypass surgery for single proximal left anterior descending artery stenoses. J Am Coll Cardiol 1995 Dec;26:1600-5 [7594092]

Lausanne, 1994:

Goy JJ, Eeckhout E, Burnand B, Vogt P, Stauffer JC, Hurni M, Stumpe F, Ruchat P, Sadeghi H, Kappenberger L Coronary angioplasty versus left internal mammary artery grafting for isolated proximal left anterior descending artery stenosis. Lancet 1994 Jun 11;343:1449-53 [7911175]

Hong, 2005:

Hong SJ, Lim DS, Seo HS, Kim YH, Shim WJ, Park CG, Oh DJ, Ro YM Percutaneous coronary intervention with drug-eluting stent implantation vs. minimally invasive direct coronary artery bypass (MIDCAB) in patients with left anterior descending coronary artery stenosis. Catheter Cardiovasc Interv 2005;64:75-81 [15619278]

LEMANS, 2002:

Buszman PE, Kiesz SR, Bochenek A, Peszek-Przybyla E, Szkrobka I, Debinski M, Bialkowska B, Dudek D, Gruszka A, Zurakowski A, Milewski K, Wilczynski M, Rzeszutko L, Buszman P, Szymaszal J, Martin JL, Tendera M Acute and late outcomes of unprotected left main stenting in comparison with surgical revascularization. J Am Coll Cardiol 2008;51:538-45 [18237682]

Cisowski, 0:

AMIST (Reeves), 2004:

Reeves BC, Angelini GD, Bryan AJ, Taylor FC, Cripps T, Spyt TJ, Samani NJ, Roberts JA, Jacklin P, Seehra HK, Culliford LA, Keenan DJ, Rowlands DJ, Clarke B, Stanbridge R, Foale R A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery. Health Technol Assess 2004;8:1-43 [15080865]

Thiele, 2009:

Thiele H, Neumann-Schriedewind P, Jacobs S, Boudriot E, Walther T, Mohr FW, Schuler G, Falk V Randomized comparison of minimally invasive direct coronary artery bypass surgery versus sirolimus-eluting stenting in isolated proximal left anterior descending coronary artery stenosis. J Am Coll Cardiol 2009 Jun 23;53:2324-31 [19539141]

Diegeler, 2002:

Diegeler A, Thiele H, Falk V, Hambrecht R, Spyrtantis N, Sick P, Diederich KW, Mohr FW, Schuler G Comparison of stenting with minimally invasive bypass surgery for stenosis of the left anterior descending coronary artery. N Engl J Med 2002;347:561-6 [12192015]

Diegeler A, Spyrtantis N, Matin M, Falk V, Hambrecht R, Autschbach R, Mohr FW, Schuler G The revival of surgical treatment for isolated proximal high grade LAD lesions by minimally invasive coronary artery bypass grafting. Eur J Cardiothorac Surg 2000;17:501-4 [10814909]

Drenth, 2002:

Drenth DJ, Veeger NJ, Grandjean JG, Mariani MA, van Boven AJ, Boonstra PW Isolated high-grade lesion of the proximal LAD: a stent or off-pump LIMA? Eur J Cardiothorac Surg 2004;25:567-71 [15037273]

Drenth DJ, Veeger NJ, Winter JB, Grandjean JG, Mariani MA, Boven van AJ, Boonstra PW A prospective randomized trial comparing stenting with off-pump coronary surgery for high-grade stenosis in the proximal left anterior descending coronary artery: three-year follow-up. *J Am Coll Cardiol* 2002;40:1955-60 [[12475455](#)]

Drenth DJ, Winter JB, Veeger NJ, Monnick SH, van Boven AJ, Grandjean JG, Mariani MA, Boonstra PW Minimally invasive coronary artery bypass grafting versus percutaneous transluminal coronary angioplasty with stenting in isolated high-grade stenosis of the proximal left anterior descending coronary artery: six months' angiographic and clinical follow-up of a prospective randomized study. *J Thorac Cardiovasc Surg* 2002;124:130-5 [[12091818](#)]

Grip, 2001:

Grip L, Wahrborg P, Odell A, Albertsson P, Berglin E, Brandrup- Coronary artery bypass beating heart surgery with LIMA graft, versus coronary angioplasty with stent for patients with single left anterior descending artery - a pilot study *European Heart Journal* 2001;22 (Suppl):597

SIMA, 2000:

Goy JJ, Kaufmann U, Goy-Eggenberger D, Garachemani A, Hurni M, Carrel T, Gaspardone A, Burnand B, Meier B, Versaci F, Tomai F, Bertel O, Pieper M, de Benedictis M, Eeckhout E A prospective randomized trial comparing stenting to internal mammary artery grafting for proximal, isolated de novo left anterior coronary artery stenosis: the SIMA trial. *Stenting vs Internal Mammary Artery*. *Mayo Clin Proc* 2000;75:1116-23 [[11075740](#)]

2 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.