Clinical trials of paclitaxel

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
paclitaxel eluting stent vs bare-metal stent			
HAAMU-STENT , 2006 *unpublished* n=70/75 follow-up: 12 months	Taxus Express versus Bare-metal-stent	AMI - STEMI patients undergoing PCI	Parallel groups open Finland
HORIZONS-AMI Stent , 2008 n=2257/749 follow-up: 1 year	paclitaxel-eluting stents (Taxus) versus BMS (Express)	ST-elevation myocardial infarction	Factorial plan open
PASSION , 2006 [ISRCTN65027270] n=310/309 follow-up: 12 months (5y)	Taxus Express2 versus Express2 or Libert	Myocardial Infarction with ST-Segment Elevation	Parallel groups open The Netherlands

More details and results :

- myocardial revascularization for acute myocardial infarction in all type of patients at http://www.trialresultscenter.org/go-Q129
- PCI for acute myocardial infarction in all type of patients at http://www.trialresultscenter.org/go-Q246

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HAAMU-STENT, 2006:

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Tierala I, Syvaenne M, Kupari M Randomised comparison of apaclitaxel-eluting and a bare metal stent in STEMI-PCI. TheHAAMU-STENT-study Annual Scientifi c Meeting of theTranscatheter Cardiovascular Therapeutics; Washington, DC;Oct 2227, 2006. Abstract 178.

HORIZONS-AMI Stent, 2008:

Stone GW, Witzenbichler B, Guagliumi G, Peruga JZ, Brodie BR, Dudek D, Kornowski R, Hartmann F, Gersh BJ, Pocock SJ, Dangas G, Wong SC, Fahy M, Parise H, Mehran R Heparin plus a glycoprotein IIb/IIIa inhibitor versus bivalirudin monotherapy and paclitaxel-eluting stents versus bare-metal stents in acute myocardial infarction (HORIZONS-AMI): final 3-year results from a multicentre, randomised controlled trial. Lancet 2011 Jun 25;377:2193-2204 [21665265] 10.1016/S0140-6736(11)60764-2

PASSION, 2006:

Laarman GJ, Suttorp MJ, Dirksen MT, van Heerebeek L, Kiemeneij F, Slagboom T, van der Wieken LR, Tijssen JG, Rensing BJ, Patterson M Paclitaxel-eluting versus uncoated stents in primary percutaneous coronary intervention. N Engl J Med 2006;355:1105-13 [16971717]

Dirksen MT, Vink MA, Suttorp MJ, Tijssen JG, Patterson MS, Slagboom T, Kiemeneij F, Laarman GJ EuroIntervention 2008 May;4:64-70 [19112781]

2 stable angina

Trial	Treatments	Patients	Trials design and methods
paclitaxel eluting stent vs bare-metal stent			
SCORE , 2004 n=126/140 follow-up: 12 months	QuaDDS stents (paclitaxel) versus uncoated control stents	patients with focal, de novo coronary lesions	Parallel groups open Worldwide
TAXUS I , 2003 n=31/30 follow-up: 12 months	TAXUS NIR versus NIR stent	Stable or unstable AP, silent ischaemia; single de novo or restenotic coronary lesions	Parallel groups double-blind Germany
TAXUS II , 2003 [NCT00299026] n=266/270 follow-up: 12 months	TAXUS versus NIR stent	Stable or unstable AP, silent ischaemia; single de novo target lesion with estimatedstenosis >50% and <99% ,	Parallel groups double-blind Global
TAXUS IV , 2004 [NCT00292474] n=662/652 follow-up: 9 months	TAXUS versus 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 double-blind United States
TAXUS V (all patients) , 2005 [NCT00301522] n=577/579 follow-up: 9 months	TAXUS versus 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 double-blind United States
TAXUS VI , 2005 [NCT00297804] n=219/227 follow-up: 9 months (2y)	TAXUS versus Express2 stent	Stable or unstable AP, silent ischaemia with long, complex coronary artery lesions	Parallel groups double-blind Europe

continued...

Trial	Treatments	Patients	Trials design and methods
BASKET-SAVAGE *ongoing* [NCT00595647] n=NA follow-up:	Taxus versus Libert	percutaneous coronary interventions of saphenous vein grafts	open
paclitaxel, non-polymeric eluting stent vs bare-metal stent			
ASPECT , 2003 [NCT00196079] n=117/58 follow-up: 6 months	coated Supra-G stent versus Supra-G stent	patientswith discrete coronary lesions (<15 mm in length, 2.25 to 3.5 mm in diameter)	Parallel groups double-blind
DELIVER , 2004 n=524/519 follow-up: 9 months	non-polymer-based paclitaxel-coated ACHIEVE stent versus 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 single-blind US
ELUTES , 2004 n=152/38 follow-up: 12 months	coated V-Flex Plus versus V-Flex Plus	single de novo type A or type B1 lesions 15 mm length in a nativecoronary artery	Parallel groups open Europe
PATENCY , 2002 *unpublished* n=24/26 follow-up: 9 months	Logic PTX paclitaxel Eluting CoronaryStents versus 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 double blind
paclitaxel eluting stent vs CABG			
SYNTAX , 2009 [NCT00114972] n=903/897 follow-up: 1 year	paclitaxel (taxus Express SR) versus 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 open
paclitaxel eluting stent vs medical treatment			
VELETI *ongoing* [NCT00289835] n=NA follow-up:	TAXUS versus standard medical treatment	Moderate Vein Graft Lesions	
paclitaxel eluting balloon vs paclitaxel eluting stent			
PEPCAD IV *ongoing* [NCT00462631] n=NA follow-up:	Paclitaxel-eluting PTCA-balloon dilation (SeQuentTM Please) followed by cobalt-chromium stent (CoroflexTM Blue) deployment versus Taxus Libert	patients with diabetes mellitus	open

continued...

Trial	Treatments	Patients	Trials design and methods
paclitaxel eluting stent vs paclitaxel eluting stent			
PERSEUS Workhorse , 2010 *ongoing* [NCT00484315] n=NA follow-up:	platinum-chromium alloy, paclitaxel-eluting stent TAXUS Element versus 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	
paclitaxel eluting stent vs sirolimus eluting stent			
FRE-RACE *ongoing* [NCT00130546] n=NA follow-up:	Cypher select versus Taxus	de novo native coronary lesions with two or more coronary artery stenoses	Cross over

More details and results :

- myocardial revascularization for stable angina in all type of patient at http://www.trialresultscenter.org/go-Q25

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FRE-RACE, 0:

ongoing trial NCT00130546

3 coronary artery disease

Trial	Treatments	Patients	Trials design and methods
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

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Trial	Treatments	Patients	Trials design and methods
paclitaxel eluting stent vs bare-metal stent			
Erglis , 2007 n=53/50 follow-up: 6 months	IVUS-guided paclitaxel-eluting stent (Taxus Express) after lesion pre-treatment with cutting balloon versus IVUS-guided bare-metal (Express or Liberte) after lesion pre-treatment with cutting balloon	percutaneous coronary intervention for unprotected left main artery stenosis	Parallel groups open
HAAMU-STENT , 2006 *unpublished* n=70/75 follow-up: 12 months	Taxus Express versus Bare-metal-stent	AMI - STEMI patients undergoing PCI	Parallel groups open Finland
HORIZONS-AMI Stent , 2008 n=2257/749 follow-up: 1 year	paclitaxel-eluting stents (Taxus) versus BMS (Express)	ST-elevation myocardial infarction	Factorial plan open
PASSION , 2006 [ISRCTN65027270] n=310/309 follow-up: 12 months (5y)	Taxus Express2 versus Express2 or Libert	Myocardial Infarction with ST-Segment Elevation	Parallel groups open The Netherlands
SCORE , 2004 n=126/140 follow-up: 12 months	QuaDDS stents (paclitaxel) versus uncoated control stents	patients with focal, de novo coronary lesions	Parallel groups open Worldwide
SOS , 2008 [NCT00247208] n=41/39 follow-up: 1.5y median	Paclitaxel-Eluting Stent (Taxus) versus bare metal stent (Express-2)	patients undergoing percutaneous coronary intervention of saphenous vein bypass grafts	Parallel groups open USA, Greece
TAXUS I , 2003 n=31/30 follow-up: 12 months	TAXUS NIR versus NIR stent	Stable or unstable AP, silent ischaemia; single de novo or restenotic coronary lesions	Parallel groups double-blind Germany
TAXUS II , 2003 [NCT00299026] n=266/270 follow-up: 12 months	TAXUS versus NIR stent	Stable or unstable AP, silent ischaemia; single de novo target lesion with estimatedstenosis >50% and <99% ,	Parallel groups double-blind Global
TAXUS II (diabetics) , 2003 *unpublished* 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

continued...

Trial	Treatments	Patients	Trials design and methods
TAXUS IV , 2004 [NCT00292474] n=662/652 follow-up: 9 months	TAXUS versus 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 double-blind United States
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 (all patients) , 2005 [NCT00301522] n=577/579 follow-up: 9 months	TAXUS versus 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 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 V small vessels sub groups n=NA follow-up:	paclitaxel-eluting stents versus bare metal stents	patients who underwent stent implantation in a single coronary artery stenosis (vessel diameter, 2.25-4.0 mm; lesion length, 10-46 mm), subgroup of small vessel patients	
TAXUS VI , 2005 [NCT00297804] n=219/227 follow-up: 9 months (2y)	TAXUS versus Express2 stent	Stable or unstable AP, silent ischaemia with long, complex coronary artery lesions	Parallel groups double-blind Europe
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
BASKET-SAVAGE *ongoing* [NCT00595647] n=NA follow-up:	Taxus versus Libert	percutaneous coronary interventions of saphenous vein grafts	open
paclitaxel, non-polymeric eluting stent vs bare-metal stent			

continued...

Trial	Treatments	Patients	Trials design and methods
ASPECT , 2003 [NCT00196079] n=117/58 follow-up: 6 months	coated Supra-G stent versus Supra-G stent	patientswith discrete coronary lesions (<15 mm in length, 2.25 to 3.5 mm in diameter)	Parallel groups double-blind
DELIVER , 2004 n=524/519 follow-up: 9 months	non-polymer-based paclitaxel-coated ACHIEVE stent versus 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 single-blind US
ELUTES , 2004 n=152/38 follow-up: 12 months	coated V-Flex Plus versus V-Flex Plus	single de novo type A or type B1 lesions 15 mm length in a nativecoronary artery	Parallel groups open Europe
PATENCY , 2002 *unpublished* n=24/26 follow-up: 9 months	Logic PTX paclitaxel Eluting CoronaryStents versus 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 double blind
paclitaxel eluting balloon vs brachytherapy			
TAXUS V ISR , 2006 [NCT00287573] n=195/201 follow-up:	TAXUS Express2 versus angioplasty followed by vascular brachytherapy with a beta source	patients with restenotic lesions after prior stent implantation in native coronary arteries	Parallel groups open North America
paclitaxel eluting stent vs CABG			
SYNTAX , 2009 [NCT00114972] n=903/897 follow-up: 1 year	paclitaxel (taxus Express SR) versus 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 open
paclitaxel eluting stent vs medical treatment			
VELETI *ongoing* [NCT00289835] n=NA follow-up:	TAXUS versus standard medical treatment	Moderate Vein Graft Lesions	
paclitaxel eluting balloon vs paclitaxel eluting stent			
PEPCAD IV *ongoing* [NCT00462631] n=NA follow-up:	Paclitaxel-eluting PTCA-balloon dilation (SeQuentTM Please) followed by cobalt-chromium stent (CoroflexTM Blue) deployment versus Taxus Libert	patients with diabetes mellitus	open

continued...

Trial	Treatments	Patients	Trials design and methods
paclitaxel eluting stent vs paclitaxel eluting stent			
PERSEUS Workhorse , 2010 *ongoing* [NCT00484315] n=NA follow-up:	platinum-chromium alloy, paclitaxel-eluting stent TAXUS Element versus 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	
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
FRE-RACE *ongoing* [NCT00130546] n=NA follow-up:	Cypher select versus Taxus	de novo native coronary lesions with two or more coronary artery stenoses	Cross over

More details and results :

- myocardial revascularization for coronary artery disease in all type of patient at http://www.trialresultscenter.org/go-Q26
- myocardial revascularization for coronary artery disease in diabetic patients at http://www.trialresultscenter.org/go-Q30
- Drug eluting stent for coronary artery disease in all type of patients at http://www.trialresultscenter.org/go-Q206
- Drug eluting stent for coronary artery disease in diabetic patients at http://www.trialresultscenter.org/go-Q207
- Drug eluting stent for coronary artery disease in acute myocardial infarction at http://www.trialresultscenter.org/go-Q208
- Drug eluting stent for coronary artery disease in long or complex lesion at http://www.trialresultscenter.org/go-Q209
- Drug eluting stent for coronary artery disease in bypass graft lesion at http://www.trialresultscenter.org/go-Q210
- Drug eluting stent for coronary artery disease in in stent restenosis at http://www.trialresultscenter.org/go-Q211
- Drug eluting stent for coronary artery disease in unprotected left main artery stenosis at http://www.trialresultscenter.org/go-Q212
- Drug eluting stent for coronary artery disease in unparticular patients at http://www.trialresultscenter.org/go-Q215
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Laarman GJ, Suttorp MJ, Dirksen MT, van Heerebeek L, Kiemeneij F, Slagboom T, van der Wieken LR, Tijssen JG, Rensing BJ, Patterson M Paclitaxel-eluting versus uncoated stents in primary percutaneous coronary intervention. N Engl J Med 2006;355:1105-13 [16971717]

Dirksen MT, Vink MA, Suttorp MJ, Tijssen JG, Patterson MS, Slagboom T, Kiemeneij F, Laarman GJ EuroIntervention 2008 May;4:64-70 [19112781]

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