

# Clinical trials of paclitaxel eluting stent

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel eluting stent vs bare-metal stent</b>			
<b>HAAMU-STENT , 2006</b> <i>unpublished</i> n=70/75 follow-up: 12 months	Taxus Express versus Bare-metal-stent	AMI - STEMI patients undergoing PCI	Parallel groups open Finland
<b>HORIZONS-AMI Stent , 2008</b> n=2257/749 follow-up: 1 year	paclitaxel-eluting stents (Taxus) versus BMS (Express)	ST-elevation myocardial infarction	Factorial plan open
<b>PASSION , 2006</b> [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>

## References

### HAAMU-STENT, 2006:

unpublished

Tierala I, Syvaenne M, Kupari M Randomised comparison of apaclitaxel-eluting and a bare metal stent in STEMI-PCI. TheHAAMU-STENT-study Annual Scientific 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](https://doi.org/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
<b>paclitaxel eluting stent vs bare-metal stent</b>			
<b>SCORE , 2004</b> 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
<b>TAXUS I , 2003</b> 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
<b>TAXUS II , 2003</b> [NCT00299026] n=266/270 follow-up: 12 months	TAXUS versus NIR stent	Stable or unstable AP, silent ischaemia; single de novo target lesion with estimated stenosis >50% and <99% ,	Parallel groups double-blind Global
<b>TAXUS IV , 2004</b> [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
<b>TAXUS V (all patients) , 2005</b> [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
<b>TAXUS VI , 2005</b> [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
<b>BASKET-SAVAGE</b> <i>ongoing</i> [NCT00595647] n=NA follow-up:	Taxus versus Libert	percutaneous coronary interventions of saphenous vein grafts	open
<b>paclitaxel eluting stent vs CABG</b>			
<b>SYNTAX , 2009</b> [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
<b>paclitaxel eluting stent vs medical treatment</b>			
<b>VELETI</b> <i>ongoing</i> [NCT00289835] n=NA follow-up:	TAXUS versus standard medical treatment	Moderate Vein Graft Lesions	
<b>paclitaxel eluting stent vs paclitaxel eluting stent</b>			
<b>PERSEUS Workhorse , 2010</b> <i>ongoing</i> [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	
<b>paclitaxel eluting stent vs sirolimus eluting stent</b>			
<b>FRE-RACE</b> <i>ongoing</i> [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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### SCORE, 2004:

Stone GW. Adverse outcomes from a taxane-loaded polymeric-sleeved stent: final results from the SCORE Trial. American College of Cardiology Scientific Session, March, 2002

Grube E, Lansky A, Hauptmann KE, Di Mario C, Di Sciascio G, Colombo A, Silber S, Stumpf J, Reifart N, Fajadet J, Marzocchi A, Schofer J, Dumas P, Hoffmann R, Guagliumi G, Pitney M, Russell ME High-dose 7-hexanoyltaxol-eluting stent with polymer sleeves for coronary revascularization: one-year results from the SCORE randomized trial. J Am Coll Cardiol 2004 Oct 6;44:1368-72 [15464315]

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### **BASKET-SAVAGE, 0:**

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### VELETI, 0:

ongoing trial NCT00289835

### PERSEUS Workhorse, 2010:

ongoing trial NCT00484315

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### FRE-RACE, 0:

ongoing trial NCT00130546

## 3 coronary artery disease

Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel eluting stent vs balloon angioplasty</b>			
<a href="#">ISAR-DESIRE (PES vs PTCA) , 2005</a> 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
<b>paclitaxel eluting stent vs bare-metal stent</b>			
<a href="#">Erglis , 2007</a> 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

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>HAAMU-STENT , 2006</b> <i>unpublished</i> n=70/75 follow-up: 12 months	Taxus Express versus Bare-metal-stent	AMI - STEMI patients undergoing PCI	Parallel groups open Finland
<b>HORIZONS-AMI Stent , 2008</b> n=2257/749 follow-up: 1 year	paclitaxel-eluting stents (Taxus) versus BMS (Express)	ST-elevation myocardial infarction	Factorial plan open
<b>PASSION , 2006</b> [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
<b>SCORE , 2004</b> 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
<b>SOS , 2008</b> [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
<b>TAXUS I , 2003</b> 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
<b>TAXUS II , 2003</b> [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
<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
<b>TAXUS IV , 2004</b> [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

continued...

<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 (all patients) , 2005</b> [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
<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 V small vessels sub groups</b> 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	
<b>TAXUS VI , 2005</b> [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
<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>BASKET-SAVAGE ongoing</b> [NCT00595647] n=NA follow-up:	Taxus versus Libert	percutaneous coronary interventions of saphenous vein grafts	open
<b>paclitaxel eluting stent vs CABG</b>			
<b>SYNTAX , 2009</b> [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
<b>paclitaxel eluting stent vs medical treatment</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>VELETI</b> <i>ongoing</i> [NCT00289835] n=NA follow-up:	TAXUS versus standard medical treatment	Moderate Vein Graft Lesions	
<b>paclitaxel eluting stent vs paclitaxel eluting stent</b>			
<b>PERSEUS Workhorse</b> , <b>2010</b> <i>ongoing</i> [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	
<b>paclitaxel eluting stent vs sirolimus eluting stent</b>			
<b>ISAR-test (diabetics)</b> , <b>2006</b>  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>FRE-RACE</b> <i>ongoing</i> [NCT00130546] n=NA follow-up:	Cypher select versus Taxus	de novo native coronary lesions with two or more coronary artery stenoses	Cross over

8

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 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>
- Drug eluting stent for coronary artery disease in small vessels at <http://www.trialresultscenter.org/go-Q217>



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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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