

# Clinical trials of paclitaxel

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unpublished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>

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unpublished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.

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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]

## 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 estimatedstenosis >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

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<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, non-polymeric eluting stent vs bare-metal stent</b>			
<b>ASPECT , 2003</b> [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
<b>DELIVER , 2004</b> 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
<b>ELUTES , 2004</b> 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
<b>PATENCY , 2002</b> <i>unpublished</i> 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
<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 balloon vs paclitaxel eluting stent</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

continued...

Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel eluting stent vs paclitaxel eluting stent</b>			
PERSEUS Workhorse , 2010 <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>			
FRE-RACE <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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ongoing trial NCT00289835

**PEPCAD IV, 0:**

ongoing trial NCT00462631

**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>			
<b>ISAR-DESIRE (PES vs PTCA) , 2005</b> 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
<b>paclitaxel eluting stent vs bare-metal stent</b>			
<b>Erglis , 2007</b> 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
<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

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<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 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, non-polymeric eluting stent vs bare-metal stent</b>			

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>ASPECT , 2003</b> [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
<b>DELIVER , 2004</b> 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
<b>ELUTES , 2004</b> 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
<b>PATENCY , 2002</b> <i>unpublished</i> 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
<b>paclitaxel eluting balloon vs brachytherapy</b>			
<b>TAXUS V ISR , 2006</b> [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
<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 balloon vs paclitaxel eluting stent</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

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Trial	Treatments	Patients	Trials design and methods
<b>paclitaxel eluting stent vs paclitaxel eluting stent</b>			
PERSEUS Workhorse , 2010 <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>			
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 <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 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>
- Drug eluting stent for coronary artery disease in small vessels at <http://www.trialresultscenter.org/go-Q217>

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Erglis A, Narbutė I, Kumsars I, Jegere S, Mintale I, Zakke I, Strazdins U, Saltups A A randomized comparison of paclitaxel-eluting stents versus bare-metal stents for treatment of unprotected left main coronary artery stenosis. *J Am Coll Cardiol* 2007;50:491-7 [[17678730](#)]

### **HAAMU-STENT, 2006:**

unpublished

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