

# Clinical trials of PCI

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

## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>systematic PCI (+stent) vs no systematic PCI</b>			
<b>CAPITAL AMI , 2005</b> n=86/84 follow-up: 6 months	TNK-facilitated angioplasty versus TNK alone	patients with high-risk ST-segment elevation myocardial infarction	Parallel groups
<b>GRACIA-1 , 2004</b> n=248/251 follow-up: 12 months	angiography and intervention if indicated within 24 h of thrombolysis versus ischaemia-guided conservative approach	patients with thrombolysed STEMI (with recombinant tissue plasminogen activator)	Parallel groups
<b>PRAGUE , 2000</b> n=100/99 follow-up: 12 months	thrombolysis during immediate transportation for coronary angioplasty versus thrombolysis in a community hospital	patients with acute ST elevation myocardial infarction presenting to community hospitals	
<b>SIAM III , 2002</b> n=82/81 follow-up: 6 months	immediate stenting after thrombolysis versus conservative treatment	patients receiving thrombolysis in AMI (<12 h)	Parallel groups Germany
<b>WEST , 2006</b> n=104/100 follow-up: 30 days	TNK and mandatory invasive study <= 24 h, including rescue PCI for reperfusion failure versus tenecteplase (TNK) and usual care	STEMI patients (>4 mm ST-elevation/deviation) within 6 h of symptom onset	Parallel groups Canada
<b>primary PCI vs accelerated t-PA</b>			
<b>C-PORT , 2002</b> n=225/226 follow-up: 6 months	primary PCI without on-site cardiac surgery versus accelerated tissue plasminogen activator	thrombolytic-eligible patients with acute MI of less than 12 hours' duration associated with ST-segment elevation	Parallel groups open USA
<b>primary PCI vs Thrombolysis</b>			
<b>senior PAMI , 2005</b> [NCT00136929] n=252/229 follow-up: 30 days	primary percutaneous coronary intervention versus intravenous thrombolytic therapy	elderly (age >= 70 years) patients with acute myocardial infarction	Parallel groups Open

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>
- PCI for acute myocardial infarction in Elderly patients at <http://www.trialresultscenter.org/go-Q316>
- myocardial revascularization for acute myocardial infarction in Elderly patients at <http://www.trialresultscenter.org/go-Q317>

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### **senior PAMI, 2005:**

## 2 stable angina

Trial	Treatments	Patients	Trials design and methods
<b>PCI with or without stent vs medical treatment</b>			
<b>TIME , 2001</b> n=NA follow-up:	coronary angiography and revascularisation versus optimised medical therapy	patients aged 75 years or older with chronic angina of at least Canadian Cardiac Society class II despite at least two antianginal drugs	Parallel groups open
<b>AVERT , 1995</b> n=177/164 follow-up: 1.5y	angioplasty versus atorvastatin at 80 mg per day	Angina or asymptomatic, MI or unstable angina but not within 14 days, no triple vessel disease	Parallel groups open
<b>Dakik , 1998</b> n=19/22 follow-up: 1y	PTCA versus intensive medical therapy	stable survivors of AMI	Parallel groups open
<b>MASS II , 2007</b> n=205/203 follow-up: 5y	PCI versus medical therapy	patients with multivessel coronary artery disease with stable angina and preserved ventricular function	Parallel groups open
<b>COURAGE , 2007</b> [NCT00007657] n=1149/1138 follow-up: median 4.6 y	PCI coupled with optimal medical therapy versus optimal medical therapy alone	patients with stable coronary artery disease	Parallel groups open Canada, US
<b>ALKK , 2003</b> 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
<b>Hambrecht , 2004</b> n=50/51 follow-up: 1y	PCI versus 12 months of exercise training (20 minutes of bicycle ergometry per day)	male patients aged 70 years	Parallel groups open
<b>Bech , 2001</b> n=90/91 follow-up: 2y	PTCA versus deferral of PTCA	patients with planned PTCA and no documented ischemia and with coronary pressure-derived fractional flow reserve >0.75	Parallel groups open
<b>ISCHEMIA ongoing</b> n=NA follow-up:	invasive strategy, consisting of early routine cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) and lifestyle changes versus conservative strategy of optimal medical therapy and lifestyle changes in which invasive procedures will be performed only after failure of OMT	patients with stable ischemic heart disease and moderate to severe ischemia	Parallel groups open-label

continued...

Trial	Treatments	Patients	Trials design and methods
<b>FFR-guided PCI vs no PCI</b>			
<b>FAME II , 2012</b> [NCT01132495] n=447/441 follow-up:	fractional-flow-reserve (FFR)-guided stenting versus optimal medical therapy alone	patients with stable CAD found on FFR to have hemodynamically relevant disease	Parallel groups Europe, US, and Canada
<b>FAME , 2008</b> [NCT00267774] n=509/496 follow-up: 1 year	FFR-guided PCI (PCI with implantation of drug-eluting stents guided by FFR measurements in addition to angiography) versus angiography-PCI (PCI with implantation of drug-eluting stents guided by angiography alone)	patients with multivessel coronary artery disease	Parallel groups open USA, Europe
<b>DEFER , 2001</b> n=90/91 follow-up: 24 months	PCI versus deferral (no PCI)	patients for whom PTCA was planned and who did not have documented ischemia and with fractional flow reserve >0.75	Parallel groups open
<b>PCI vs CABG</b>			
<b>AWESOME , 2001</b> n=222/232 follow-up: 5 years	percutaneous coronary intervention versus coronary artery bypass graft	high-risk patients with medically refractory ischemia	Parallel groups open US (Veterans Affairs Medical Centers)
<b>PCI with drug-eluting stents vs CABG</b>			
<b>SYNTAX (diabetic) , 2010</b> [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
<b>FREEDOM , 2012</b> [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
<b>PCI with drug-eluting stents vs CABG</b>			
<b>Hong , 2005</b> 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
<b>VA CARDS ongoing</b> [NCT00326196] n=NA follow-up:	percutaneous coronary stenting with drug eluting stents versus CABG	angiographically significant coronary artery disease in diabetes	Parallel groups open

continued...

Trial	Treatments	Patients	Trials design and methods
<b>CABG or PCI vs medical treatment</b>			
<b>BARI 2D , 2009</b> [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
<b>PCI withsirolimus ES vs MIDCAB</b>			
<b>Thiele , 2009</b> [NCT00299429] n=65/65 follow-up: 12 months	sirolimus-eluting stent versus MIDCAB surgery	isolated LAD disease	Parallel groups open Germany

More details and results :

- myocardial revascularization for stable angina in all type of patient at <http://www.trialresultscenter.org/go-Q25>
- myocardial revascularization for stable angina in single vessel disease at <http://www.trialresultscenter.org/go-Q27>
- myocardial revascularization for stable angina in multivessels disease at <http://www.trialresultscenter.org/go-Q28>
- myocardial revascularization for stable angina in diabetic patients at <http://www.trialresultscenter.org/go-Q29>

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ongoing trial

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ongoing trial NCT00326196

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### 3 coronary artery disease

Trial	Treatments	Patients	Trials design and methods
<b>PCI with or without stent vs medical treatment</b>			
TIME , 2001 n=NA follow-up:	coronary angiography and revascularisation versus optimised medical therapy	patients aged 75 years or older with chronic angina of at least Canadian Cardiac Society class II despite at least two antianginal drugs	Parallel groups open

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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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<b>ALKK , 2003</b> 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
<b>Hambrecht , 2004</b> n=50/51 follow-up: 1y	PCI versus 12 months of exercise training (20 minutes of bicycle ergometry per day)	male patients aged 70 years	Parallel groups open
<b>Bech , 2001</b> n=90/91 follow-up: 2y	PTCA versus deferral of PTCA	patients with planned PTCA and no documented ischemia and with coronary pressure-derived fractional flow reserve >0.75	Parallel groups open
<b>ISCHEMIA</b> <i>ongoing</i> n=NA follow-up:	invasive strategy, consisting of early routine cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) and lifestyle changes versus conservative strategy of optimal medical therapy and lifestyle changes in which invasive procedures will be performed only after failure of OMT	patients with stable ischemic heart disease and moderate to severe ischemia	Parallel groups open-label
<b>FFR-guided PCI vs no PCI</b>			
<b>FAME II , 2012</b> [NCT01132495] n=447/441 follow-up:	fractional-flow-reserve (FFR)-guided stenting versus optimal medical therapy alone	patients with stable CAD found on FFR to have hemodynamically relevant disease	Parallel groups Europe, US, and Canada

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>FAME , 2008</b> [NCT00267774] n=509/496 follow-up: 1 year	FFR-guided PCI (PCI with implantation of drug-eluting stents guided by FFR measurements in addition to angiography versus angiography-PCI (PCI with implantation of drug-eluting stents guided by angiography alone)	patients with multivessel coronary artery disease	Parallel groups open USA, Europe
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<b>PCI with drug-eluting stents vs CABG</b>			
<b>Hong , 2005</b> 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
<b>VA CARDS ongoing</b> [NCT00326196] n=NA follow-up:	percutaneous coronary stenting with drug eluting stents versus CABG	angiographically significant coronary artery disease in diabetes	Parallel groups open
<b>CABG or PCI vs medical treatment</b>			
<b>BARI 2D , 2009</b> [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
<b>PCI with sirolimus ES vs MIDCAB</b>			
<b>Thiele , 2009</b> [NCT00299429] n=65/65 follow-up: 12 months	sirolimus-eluting stent versus MIDCAB surgery	isolated LAD disease	Parallel groups open Germany

continued...

Trial	Treatments	Patients	Trials design and methods
<b>PCI vs CABG</b>			
<b>AWESOME , 2001</b> n=222/232 follow-up: 5 years	percutaneous coronary intervention versus coronary artery bypass graft	high-risk patients with medically refractory ischemia	Parallel groups open US (Veterans Affairs Medical Centers)
<b>COMBAT</b> <i>ongoing</i> n=NA	PCI versus CABG	-	
<b>Korean Randomized Study</b> <i>ongoing</i> n=NA	PCI versus CABG	-	
<b>REVASCULARIZE</b> <i>ongoing</i> n=NA	PCI versus CABG	-	

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>
- myocardial revascularization for coronary artery disease in multivessels disease at <http://www.trialresultscenter.org/go-Q31>
- myocardial revascularization for coronary artery disease in single vessel disease at <http://www.trialresultscenter.org/go-Q32>
- 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 unparticular patients at <http://www.trialresultscenter.org/go-Q215>
- fractional-flow-reserve-guided PCI for coronary artery disease in all type of patients at <http://www.trialresultscenter.org/go-Q563>

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#### **COMBAT, 0:**

ongoing trial

#### **Korean Randomized Study, 0:**

ongoing trial

**REVASCULARIZE, 0:**

ongoing trial

Entry terms: drug-eluting stents, CYPHER, TAXUS, Promus, Xience, Biomatrix, Nobori, Endeavor, Drug-Eluting Stents, Drug Eluting Stents, Drug-Eluting Stent, Drug-Coated Stents, Drug Coated Stents, Drug-Coated Stent, , sirolimus eluting stent, CYPHER, , Coronary Artery Bypass Surgery, Coronary Artery Bypass, Coronary Artery Bypasses, Coronary Artery Bypass Surgery, Aortocoronary Bypass, Aortocoronary Bypasses, Coronary Artery Bypass Grafting, CABG