

# Clinical trials of myocardial revascularization for acute myocardial infarction in facilitated PCI

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## 1 combination facilitated PCI

Trial	Treatments	Patients	Trials design and methods
<b>Abciximab + reteplase vs primary intervention</b>			
<b>BRAVE (Kastrati) , 2004</b> n=125/128 follow-up: 30 days	-	symptom duration <12h	
<b>FINESSE (combination-facilitated PCI) , 2008</b> [NCT00046228] n=828/806 follow-up: 90 days	combination-facilitated PCI with abciximab plus half-dose reteplase versus primary PCI (abciximab administered immediately before the procedure)	patients with acute ST-segment elevation myocardial infarction; symptom duration <6h	Parallel groups open
<b>Eptifibatide + tenecteplase vs primary intervention</b>			
<b>ADVANCE-MI , 2005</b> n=69/77 follow-up: 30 days	-	symptom duration <4h	

## References

### **BRAVE (Kastrati), 2004:**

Kastrati A, Mehilli J, Schlotterbeck K, Dotzer F, Dirschinger J, Schmitt C, Nekolla SG, Seyfarth M, Martinoff S, Markwardt C, Clermont G, Gerbig HW, Leiss J, Schwaiger M, Schmig A Early administration of reteplase plus abciximab vs abciximab alone in patients with acute myocardial infarction referred for percutaneous coronary intervention: a randomized controlled trial. JAMA 2004;291:947-54 [[14982910](#)]

### **FINESSE (combination-facilitated PCI), 2008:**

Ellis SG, Tendera M, de Belder MA, van Boven AJ, Widimsky P, Janssens L, Andersen HR, Betriu A, Savonitto S, Adamus J, Peruga JZ, Kosmider M, Katz O, Neunteufl T, Jorgova J, Dorobantu M, Grinfeld L, Armstrong P, Brodie BR, Herrmann HC, Montalescot G, Neum Facilitated PCI in patients with ST-elevation myocardial infarction. N Engl J Med 2008 May 22;358:2205-17 [[18499565](#)]

### **ADVANCE-MI, 2005:**

Facilitated percutaneous coronary intervention for acute ST-segment elevation myocardial infarction: results from the prematurely terminated Addressing the Value of facilitated ANgioplasty after Combination therapy or Eptifibatide monotherapy in acute Myocardial Infarction (ADVANCE MI) trial. Am Heart J 2005;150:116-22 [[16084157](#)]

## 2 GP IIb/IIIa inhibitor-facilitated PCI

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Abciximab vs primary intervention</b>			
ERAMI (Mesquita Gabriel) , 2003 n=36/38 follow-up: 30-day	facilitated PCI with Abciximab; 025 mg/kg intravenous bolus, 0125 g/kg per min infusion versus primary intervention	symptom duration <12h	
FINESSE (abciximab-facilitated PCI) , 2008 [NCT00046228] n=818/806 follow-up: 90 days	abciximab-facilitated PCI versus primary PCI (abciximab administered immediately before the procedure)	patients with acute ST-segment elevation myocardial infarction; symptom duration <6h	Parallel groups open
REOMOBILE (Arntz) , 2003 n=52/48 follow-up: 30-day	facilitated PCI with Abciximab; 025 mg/kg intravenous bolus, 0125 g/kg per min infusion versus primary intervention	symptom duration <6h	
Zorman , 2002 n=56/56 follow-up: In hospital	facilitated PCI with Abciximab; 025 mg/kg intravenous bolus, 0125 g/kg per min infusion versus primary intervention	symptom duration <12h	
ReoPro-BRIDGING (Gyongyosi) , 2004 n=28/27 follow-up: 30-day	facilitated PCI with Abciximab; 025 mg/kg intravenous bolus, 0125 g/kg per min infusion versus primary intervention	symptom duration <6h	
Bellandi , 2006 n=27/28 follow-up: 30-day	facilitated PCI with Abciximab; 025 mg/kg intravenous bolus, 0125 g/kg per min infusion versus primary intervention	symptom duration <6h	
<b>Eptifibatide vs primary intervention</b>			
INTAMI (Zeymer) , 2005 n=53/49 follow-up: 30-day	facilitated PCI with Eptifibatide; 180 g/kg intravenous double bolus, 20 g/kg per min infusion versus primary intervention	symptom duration <12h	
<b>Tirofiban vs primary intervention</b>			
On-Time (vant Hof) , 2004 n=245/247 follow-up: 65279;30-day	facilitated PCI with Tirofiban; 10 g/kg intravenous bolus, 015 g/kg per min infusion versus primary intervention	symptom duration <6h	
TIGER-PA (Lee) , 2003 n=50/50 follow-up: 30-day	facilitated PCI with Tirofiban; 10 g/kg intravenous bolus, 015 g/kg per min infusion versus primary intervention	symptom duration <12h	
Cutlip , 2003 n=28/30 follow-up: 30-day	facilitated PCI with Tirofiban; 10 g/kg intravenous bolus, 015 g/kg per min infusion versus primary intervention	symptom duration <12h	

## References

### **ERAMI (Mesquita Gabriel), 2003:**

Mesquita Gabriel H, Oliveira J, et al. Early administration of abciximab bolus in the emergency room improves microperfusion after primary percutaneous coronary intervention, as assessed by TIMI frame count: results of the ERAMI trial. *N Engl J Med* 2003; 24 (suppl): 543 (abstr& txtPag

### **FINESSE (abciximab-facilitated PCI), 2008:**

Ellis SG, Tendera M, de Belder MA, van Boven AJ, Widimsky P, Janssens L, Andersen HR, Betriu A, Savonitto S, Adamus J, Peruga JZ, Kosmider M, Katz O, Neunteufl T, Jorgova J, Dorobantu M, Grinfeld L, Armstrong P, Brodie BR, Herrmann HC, Montalescot G, Neum Facilitated PCI in patients with ST-elevation myocardial infarction. *N Engl J Med* 2008 May 22;358:2205-17 [[18499565](#)]

### **REOMOBILE (Arntz), 2003:**

Arntz HR, Schroeder J, Pels K, Schwimmbeck P, Witzenbichler B, Prehospital versus periprocedural administration of abciximab in STEMI: early and late results from the randomised REOMOBILE study. *Eur Heart J* 2003; 24 (suppl): 268 (abstr).xtPag

### **Zorman, 2002:**

Zorman S, Zorman D, Noc M Effects of abciximab pretreatment in patients with acute myocardial infarction undergoing primary angioplasty. *Am J Cardiol* 2002;90:533-6 [[12208418](#)]

### **ReoPro-BRIDGING (Gyongyosi), 2004:**

Gyngysi M, Domanovits H, Benzer W, Haugk M, Heinisch B, Sodeck G, Hdl R, Gaul G, Bonner G, Wojta J, Laggner A, Glogar D, Huber K Use of abciximab prior to primary angioplasty in STEMI results in early recanalization of the infarct-related artery and improved myocardial tissue reperfusion - results of the Austrian multi-centre randomized ReoPro-BRIDGING Study. *Eur Heart J* 2004;25:2125-33 [[15571828](#)]

### **Bellandi, 2006:**

Bellandi F, Maioli M, Leoncini M, Toso A, Dabizzi RP Early abciximab administration in acute myocardial infarction treated with primary coronary intervention. *Int J Cardiol* 2006;108:36-42 [[15927285](#)]

### **INTAMI (Zeymer), 2005:**

Zeymer U, Zahn R, Schiele R, Jansen W, Girth E, Gitt A, Seidl K, Schrder R, Schneider S, Senges J Early eptifibatid improves TIMI 3 patency before primary percutaneous coronary intervention for acute ST elevation myocardial infarction: results of the randomized integrilin in acute myocardial infarction (INTAMI) pilot trial. *Eur Heart J* 2005;26:1971-7 [[15857851](#)]

### **On-Time (vant Hof), 2004:**

van 't Hof AW, Ernst N, de Boer MJ, de Winter R, Boersma E, Bunt T, Petronio S, Marcel Gosselink AT, Jap W, Hollak F, Hoorntje JC, Suryapranata H, Dambrink JH, Zijlstra F Facilitation of primary coronary angioplasty by early start of a glycoprotein 2b/3a inhibitor: results of the ongoing tirofiban in myocardial infarction evaluation (On-TIME) trial. *Eur Heart J* 2004;25:837-46 [[15140531](#)]

### **TIGER-PA (Lee), 2003:**

Lee DP, Herity NA, Hiatt BL, Fearon WF, Rezaee M, Carter AJ, Huston M, Schreiber D, DiBattiste PM, Yeung AC Adjunctive platelet glycoprotein IIb/IIIa receptor inhibition with tirofiban before primary angioplasty improves angiographic outcomes: results of the Tirofiban Given in the Emergency Room before Primary Angioplasty (TIGER-PA) pilot trial. *Circulation* 2003;107:1497-501 [[12654606](#)]

### **Cutlip, 2003:**

Cutlip DE, Ricciardi MJ, Ling FS, Carrozza JP Jr, Dua V, Garringer J, Giri S, Caputo RP Effect of tirofiban before primary angioplasty on initial coronary flow and early ST-segment resolution in patients with acute myocardial infarction. *Am J Cardiol* 2003;92:977-80 [[14556878](#)]

## 3 thrombolysis-facilitated PCI

Trial	Treatments	Patients	Trials design and methods
<b>vs primary intervention</b>			
ASSENT-4 PCI (Van de Werf) , 2006 [NCT00168792] n=829/838 follow-up: 30-day	facilitated PCI with tenecteplase bodyweight-adjusted intravenous bolus: 30 mg of drug if bodyweight <60 kg, 35 mg if 60-69 kg, 40 mg if 70-79 kg, 45 mg if 80-89 kg, and 50 mg if ≥90 kg versus primary intervention	symptom duration <6 h	
<b>alteplase vs primary intervention</b>			
LIMI (Vermeer) , 1999 n=74/75 follow-up: 42-day	facilitated PCI with Alteplase 50 mg(intravenous bolus) mag versus primary intervention	symptom duration <6h	
PACT (Ross.) , 1999 n=302/304 follow-up: 30-day	facilitated PCI with alteplase 50 mg (intravenous bolus) versus primary intervention	symptom duration <6h	
<b>streptokinase vs primary intervention</b>			
SAMI (O'Neill) , 1992 n=59/63 follow-up: In hospital	facilitated PCI with streptokinase 15 million units(intravenous) versus primary intervention	symptom duration <4h	
PRAGUE (Widimisky) , 2000 n=100/101 follow-up: 30-day	facilitated PCI with Streptokinase 15 million units (intravenous) versus primary intervention	symptom duration <6h	
<b>tenecteplase vs primary intervention</b>			
GRACIA (Fernandez-Aviles) , 2004 n=104/108 follow-up: 30-day	facilitated PCI with bodyweight-adjusted intravenous tenecteplase bolus: 30 mg of drug if bodyweight <60 kg, 35 mg if 60-69 kg, 40 mg if 70-79 kg, 45 mg if 80-89 kg, and 50 mg if ≥90 kg and Abciximab; 0.25 mg/kg intravenous bolus, 0.125 g/kg per min infusi versus primary intervention	symptom duration <12h	

## References

### ASSENT-4 PCI (Van de Werf), 2006:

Primary versus tenecteplase-facilitated percutaneous coronary intervention in patients with ST-segment elevation acute myocardial infarction (ASSENT-4 PCI): randomised trial. *Lancet* 2006;367:569-78 [[16488800](#)]

### LIMI (Vermeer), 1999:

Vermeer F, Oude Ophuis AJ, vd Berg EJ, Brunninkhuis LG, Werter CJ, Boehmer AG, Lousberg AH, Dassen WR, Br FW Prospective randomised comparison between thrombolysis, rescue PTCA, and primary PTCA in patients with extensive myocardial infarction admitted to a hospital without PTCA facilities: a safety and feasibility study. *Heart* 1999;82:426-31 [[10490554](#)]

**PACT (Ross,), 1999:**

Ross AM, Coyne KS, Reiner JS, Greenhouse SW, Fink C, Frey A, Moreyra E, Traboulsi M, Racine N, Riba AL, Thompson MA, Rohrbeck S, Lundergan CF A randomized trial comparing primary angioplasty with a strategy of short-acting thrombolysis and immediate planned rescue angioplasty in acute myocardial infarction: the PACT trial. PACT investigators. Plasminogen-activator Angioplasty Compatibility Trial. J Am Coll Cardiol 1999;34:1954-62 [[10588209](#)]

**SAMI (O'Neill), 1992:**

O'Neill WW, Weintraub R, Grines CL, Meany TB, Brodie BR, Friedman HZ, Ramos RG, Gangadharan V, Levin RN, Choksi N A prospective, placebo-controlled, randomized trial of intravenous streptokinase and angioplasty versus lone angioplasty therapy of acute myocardial infarction. Circulation 1992;86:1710-7 [[1451242](#)]

**PRAGUE (Widimisky), 2000:**

Widimsk P, Groch L, Zelzko M, Aschermann M, Bednr F, Suryapranata H Multicentre randomized trial comparing transport to primary angioplasty vs immediate thrombolysis vs combined strategy for patients with acute myocardial infarction presenting to a community hospital without a catheterization laboratory. The PRAGUE study. Eur Heart J 2000;21:823-31 [[10781354](#)]

**GRACIA (Fernandez-Aviles,), 2004:**

Fernandez-Aviles F, Alonso JJ, Castro-Beiras A, et al.pj Primary versus facilitated percutaneous coronary intervention (tenecteplase plus stenting) in patients with ST-elevated myocardial infarction: the final results of the GRACIA-2 randomized trial Eur Heart J 2004; 25 (suppl): 33 (abstrg)

## 4 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.

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