

# Clinical trials of primary ballon angioplasty

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## 1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
<b>primary ballon angioplasty vs accelerated t-PA</b>			
<b>Ribichini , 1996</b> n=24/26 follow-up: discharge	primary PTCA versus accelerated alteplase 90 min (15 mg IV bolus followed by an infusion of 0.75 mg/kg over 30min not to exceed 50mg, and then 0.5 mg/kg over the next 60min not to exceed 35mg for a total maximum of 100mg)	-	Parallel groups open Italy
<b>Garcia , 1997</b> n=95/94 follow-up: 30 d	primary PTCA versus accelerated t-PA 90 min (15 mg IV bolus followed by an infusion of 0.75 mg/kg over 30min not to exceed 50mg, and then 0.5 mg/kg over the next 60min not to exceed 35mg for a total maximum of 100mg)	patients with anterior AMI	Parallel groups open Spain
<b>GUSTO 2B , 1997</b> n=573/565 follow-up: 30 d	primary PTCA versus accelerated t-PA 90 min (15 mg IV bolus followed by an infusion of 0.75 mg/kg over 30min not to exceed 50mg, and then 0.5 mg/kg over the next 60min not to exceed 35mg for a total maximum of 100mg)	patients within 12 hours of acute myocardial infarction (with ST-segment elevation on the electrocardiogram)	factorial design open USA, Europe, Australia
<b>DANAMI-2 , 1997</b> n=NA follow-up: 2.4y	angioplasty versus accelerated treatment with intravenous alteplase	patients who received thrombolytic treatment for a first acute myocardial infarction and with inducible myocardial ischemia (either symptomatic angina pectoris presenting spontaneously >36 hours after admission or during a predischarge exercise test or ST changes during exercise compatible with ischemia)	Parallel groups open
<b>primary ballon angioplasty vs duteplase</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
DeWood , 1989 n=46/44 follow-up: 30 d	primary PTCA versus duteplase 0.5 MU/kg for 1 h then 0.7 MU/kg/h for 3h	-	Parallel groups open USA
Gibbons , 1993 n=47/56 follow-up: discharge	primary PTCA versus duteplase 0.6 MU/kg over 5h	patients with acute myocardial infarction	Parallel groups open USA
<b>primary ballon angioplasty vs intracoronary streptokinase</b>			
O'Neill , 1986 n=NA follow-up:	coronary angioplasty versus intracoronary streptokinase	patients within 12 hours of their first symptoms of acute myocardial infarction	Parallel groups open
<b>primary ballon angioplasty vs streptokinase</b>			
Zwolle , 1994 n=152/149 follow-up: discharge	primary PTCA versus streptokinase 1.5 M IU over 1h	patients with acute myocardial infarction	Parallel groups open The Netherland
Ribeiro , 1993 n=50/50 follow-up: discharge	primary PTCA versus streptokinase 1.2 M IU over 1h	patients with ST segment elevation within 6 h of the onset of chest pain	Parallel groups open Brazil
Grinfeld , 1996 n=54/58 follow-up: 30 d	primary PTCA versus streptokinase 1.5 M IU over 1h	-	Parallel groups open Argentina
Zijlstra , 1997 n=45/50 follow-up: 6 months	primary PTCA versus streptokinase 1.5 M IU over 1h	atients with acute myocardial infarction	Parallel groups open The Netherland
Zijlstra , 1993 n=70/72 follow-up:	immediate coronary angioplasty (without previous thrombolytic therapy) versus intravenous streptokinase	patients with acute myocardial infarction	Parallel groups open
Akhras , 1997 n=42/45 follow-up:	primary angioplasty versus streptokinase	patient within 12hr from onset of AMI	Parallel groups open Saudi Arabia
<b>primary ballon angioplasty vs t-PA</b>			

continued...

Trial	Treatments	Patients	Trials design and methods
<b>PAMI , 1993</b> n=195/200 follow-up: discharge	primary PTCA versus t-PA 100mg (or 1.25mg/kg for patients weighting less than 65kg) over 3 h	patients who presented within 12 hours of the onset of myocardial infarction	Parallel groups open USA,Europe
<b>primary ballon angioplasty vs tenecteplase</b>			
<b>TRIANA , 2009</b> [NCT00257309] n=132/134 follow-up: 30 days (12 months)	Tenecteplase + UFH (+/- clopidogrel) versus Primary angioplasty	>=75 years old with ST-segment elevation or LBBB AMI <6 hours of evolution without contraindications for thrombolytic therapy	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>

## References

### Ribichini, 1996:

JACC 1996; 211A [0]

### Garcia, 1997:

Garca E, Elzaga J, Prez-Castellano N, Serrano JA, Soriano J, Abeytua M, Botas J, Rubio R, Lpez de S E, Lpez-Sendn JL, Delcn JL Primary angioplasty versus systemic thrombolysis in anterior myocardial infarction. J Am Coll Cardiol 1999;33:605-11 [10080458]

### GUSTO 2B, 1997:

A clinical trial comparing primary coronary angioplasty with tissue plasminogen activator for acute myocardial infarction. The Global Use of Strategies to Open Occluded Coronary Arteries in Acute Coronary Syndromes (GUSTO Iib) Angioplasty Substudy Investigators. N Engl J Med 1997;336:1621-8 [9173270]

### DANAMI-2, 1997:

Fosbl EL, Thune JJ, Kelbaeak H, Andersen HR, Saunamki K, Nielsen TT, Mortensen LS, Kber L Long-term outcome of primary angioplasty compared with fibrinolysis across age groups: a Danish Multicenter Randomized Study on Fibrinolytic Therapy Versus Acute Coronary Angioplasty in Acute Myocardial Infarction (DANAMI-2) substudy. Am Heart J 2008;156:391-6 [18657676]

Madsen JK, Grande P, Saunamki K, Thayssen P, Kassiss E, Eriksen U, Rasmussen K, Hauns S, Nielsen TT, Haghfelt T, Fritz-Hansen P, Hjelms E, Paulsen PK, Alstrup P, Arendrup H, Niebuhr-Jrgensen U, Andersen LI Danish multicenter randomized study of invasive versus conservative treatment in patients with inducible ischemia after thrombolysis in acute myocardial infarction (DANAMI). DANish trial in Acute Myocardial Infarction. Circulation 1997 Aug 5;96:748-55 [9264478]

Madsen JK, Nielsen TT, Grande P, Eriksen UH, Saunamki K, Thayssen P, Kassis E, Rasmussen K, Hauns S, Haghfelt T, Fritz-Hansen P, Hjelms E, Paulsen PK, Alstrup P, Arendrup H, Niebuhr-Jrgensen U, Andersen LI Revascularization compared to medical treatment in patients with silent vs. symptomatic residual ischemia after thrombolized myocardial infarction—the DANAMI study. *Cardiology* 2007;108:243-51 [[17114878](#)]

Andersen HR, Nielsen TT, Rasmussen K, Thuesen L, Kelbaek H, Thayssen P, Abildgaard U, Pedersen F, Madsen JK, Grande P, Villadsen AB, Krusell LR, Haghfelt T, Lomholt P, Husted SE, Vigholt E, Kjaergard HK, Mortensen LS A comparison of coronary angioplasty with fibrinolytic therapy in acute myocardial infarction. *N Engl J Med* 2003 Aug 21;349:733-42 [[12930925](#)]

Nielsen PH, Maeng M, Busk M, Mortensen LS, Kristensen SD, Nielsen TT, Andersen HR Primary angioplasty versus fibrinolysis in acute myocardial infarction: long-term follow-up in the Danish acute myocardial infarction 2 trial. *Circulation* 2010;121:1484-91 [[20308618](#)] [10.1161/CIRCULATIONAHA.109.873224](#)

#### **DeWood, 1989:**

DeWood MA, Fisher MJ for the spokane Heart Research Group *Circulation* 1989; 80(suppl 2):II418

#### **Gibbons, 1993:**

Gibbons RJ, Holmes DR, Reeder GS, Bailey KR, Hopfenspirger MR, Gersh BJ Immediate angioplasty compared with the administration of a thrombolytic agent followed by conservative treatment for myocardial infarction. The Mayo Coronary Care Unit and Catheterization Laboratory Groups. *N Engl J Med* 1993;328:685-91 [[8433727](#)]

#### **O’Neill, 1986:**

O’Neill W, Timmis GC, Bourdillon PD, Lai P, Ganghadarhan V, Walton J Jr, Ramos R, Laufer N, Gordon S, Schork MA A prospective randomized clinical trial of intracoronary streptokinase versus coronary angioplasty for acute myocardial infarction. *N Engl J Med* 1986;314:812-8 [[2936956](#)]

#### **Zwolle, 1994:**

de Boer MJ, Hoorntje JC, Ottervanger JP, Reiffers S, Suryapranata H, Zijlstra F Immediate coronary angioplasty versus intravenous streptokinase in acute myocardial infarction: left ventricular ejection fraction, hospital mortality and reinfarction. *J Am Coll Cardiol* 1994;23:1004-8 [[8144761](#)]

#### **Ribeiro, 1993:**

Ribeiro EE, Silva LA, Carneiro R, D’Oliveira LG, Gasquez A, Amino JG, Tavares JR, Petrizzo A, Torossian S, Duprat Filho R Randomized trial of direct coronary angioplasty versus intravenous streptokinase in acute myocardial infarction. *J Am Coll Cardiol* 1993;22:376-80 [[8335807](#)]

#### **Grinfeld, 1996:**

Grinfeld L et al. abstract *JACC* 1996;27:222A

#### **Zijlstra, 1997:**

Zijlstra F, Beukema WP, van ’t Hof AW, Liem A, Reiffers S, Hoorntje JC, Suryapranata H, de Boer MJ Randomized comparison of primary coronary angioplasty with thrombolytic therapy in low risk patients with acute myocardial infarction. *J Am Coll Cardiol* 1997;29:908-12 [[9120174](#)]

#### **Zijlstra , 1993:**

Zijlstra F, de Boer MJ, Hoorntje JC, Reiffers S, Reiber JH, Suryapranata H A comparison of immediate coronary angioplasty with intravenous streptokinase in acute myocardial infarction. *N Engl J Med* 1993;328:680-4 [[8433726](#)]

#### **Akhras, 1997:**

Akhras F, AbuOusa A, Swann G, Duncan H, ChamsiPasha H, Jabbad H. Primary coronary angioplasty or intravenous thrombolysis for patients with acute myocardial infarction? acute and late follow-up results in a new cardiac unit [abstract4 *J Am Coll Cardiol.* 1997;29(suppl 1):A235

#### **PAMI, 1993:**

Grines CL, Browne KF, Marco J, Rothbaum D, Stone GW, O'Keefe J, Overlie P, Donohue B, Chelliah N, Timmis GC A comparison of immediate angioplasty with thrombolytic therapy for acute myocardial infarction. The Primary Angioplasty in Myocardial Infarction Study Group. N Engl J Med 1993;328:673-9 [8433725]

**TRIANA, 2009:**

Clauw et al The efficacy and safety of milnacpran in the treatment of fibromyalgia 2007, poster 716

Bueno H, Betriu A, Heras M, Alonso JJ, Cequier A, Garca EJ, Lpez-Sendn JL, Macaya C, Hernndez-Antoln R Primary angioplasty vs. fibrinolysis in very old patients with acute myocardial infarction: TRIANA (TRatamiento del Infarto Agudo de miocardio eN Ancianos) randomized trial and pooled analysis with previous studies. Eur Heart J 2010;: [20971744] 10.1093/eurheartj/ehq375

Entry terms: primary angioplasty, primary ballon angioplasty, primary PTCA