

Clinical trials of systematic ballon angioplasty

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
immediate systematic ballon angioplasty vs no immediate angioplasty			
ECSG , 1988 n=183/184 follow-up: 1 y	angioplasty as soon as possible (after rtPA) versus non-invasive strategy without immediate CA and PTCA	patients with acute myocardial infarction within 5 h after onset of symptoms	parallel group open Europe
Belenkie , 1991 n=50/39 follow-up: 4 months	immediate PTCA versus delayed PTCA (18-38h)	patients with a patent infarct-related artery after thrombolytic therapy suitable for angioplasty	parallel group open Canada
Ellis , 1994 n=78/73 follow-up:	balloon angioplasty supplemented by further thrombolytic therapy as needed versus conservative therapy	patients with first anterior wall infarction treated with any accepted intravenous thrombolytic regimen and angiographically demonstrated to have an occluded infarct vessel within 8 hours of chest pain onset	
Erbel , 1989 n=103/103 follow-up: 3 years	combined intravenous and intracoronary streptokinase with immediate coronary angioplasty versus combined intravenous and intracoronary streptokinase without immediate coronary angioplasty	patients with acute transmural myocardial infarction	Parallel groups
MERLIN (Sutton) , 2004 n=NA follow-up: 30 days	emergency coronary angiography with rescue PCI versus conservative treatment	patients with STEMI and failed fibrinolysis	Parallel groups
SHOCK (Hochman) , 1999 [NCT00000552] n=152/150 follow-up: 30 days (6y)	emergency revascularization versus initial medical stabilization	patients with cardiogenic shock complicating acute MI	Parallel groups open US

continued...

Trial	Treatments	Patients	Trials design and methods
SWISS-SMASH , 1999 n=32/23 follow-up: 30 days (1y)	emergency angiography, followed immediately by revascularization when indicated versus initial medical management	Patients with acute myocardial infarction and early shock	Parallel groups open Europe
TAMI 1 pilot , 1987 n=99/98 follow-up: in hospital	Angioplasty within 120 min (after rtPA) versus deferred CA (7-10 days) and angioplasty if indicated	patients with acute myocardial infarction.	parallel group open USA
TAMI-5 (Califf) , 1991 n=287/288 follow-up:	immediate catheterization with angioplasty for failed thrombolysis (90min after rtPA/urokinase) versus deferred predischage catheterization on days 5-10, no PTCA planned	patient with acute myocardial infarction	Factorial plan
TIMI 2A , 1988 n=195/194 follow-up: 21 days	CA within 120 min of the start of the rtPA infusion. PTCA whether the artery is open or closed versus CA within 18-48hrs. PTCA only if artery open (TIMI 2 or 3)	patient thrombolized for a AMI	parallel group open USA
Topol , 1987 n=15/13 follow-up: in hospital	immediate PTCA versus no PTCA	patients with evolving transmural myocardial infarction	parallel group open USA
systematic ballon angioplasty vs no systematic angioplasty			
SWIFT , 1991 n=397/403 follow-up: 1 y	CA 72h with a view to PTCA or CABG versus elective angioplasty (only if required by clinical indication)	patients presenting with clinical and electrocardiographic features of acute myocardial infarction up to three hours after the onset of major symptoms	Parallel groups Open UK
SIAM , 1992 n=158/166 follow-up: <3 years	CA with CABG/PTCA 14-48 hours versus no CA within the first 21days unless evidence of ischemia	patients treated by thrombolysis for AMI	Parallel groups Open Europe
TAMI 6 , 1992 n=34/37	PTCA 6-24h after rtPA versus no PTCA planned	-	

continued...

Trial	Treatments	Patients	Trials design and methods
Barbash , 1990 n=97/104	PTCA>72h after rtPA if stenosis>70% versus PTCA>72h after rtPA if stenosis>50% and ischemia	-	
Guerci , 1987 n=42/43 follow-up: 10 days	PTCA at 4 day versus no PTCA during the 10 days study period	patients candidate to PTCA determined at the 1st day CA	Factorial plan United states
TIMI 2 , 1989 n=1636/1626 follow-up: 6 we	CA 18 to 48 hrs versus no CA unless spontaneous or exercise induced ischemia	patients treated with intravenous recombinant tissue plasminogen activator (rt-PA) within four hours of the onset of chest pain thought to be caused by myocardial infarction	Factorial plan Open United states
TIMI II-A (deferred) n=194/197 follow-up:	delayed invasive strategy, deferred angiography and PTCA for 18-48 hours versus conservative approach	-	
TOPS , 1992 n=42/45 follow-up: 12 months	PTCA to be performed 4-14 days after MI versus conservative management, no PTCA	patients with residual stenoses after thrombolytic treatment of myocardial infarction	Parallel groups
Van den Brand , 1991 n=113/104 follow-up: 3 mo	CA at 2-5 days, PTCA if suitable lesion versus CA at 2-5 days but no PTCA	suitable lesion	Parallel groups NA Europe
Vermeer , 1999 n=NA follow-up: 42 days	alteplase followed by transfer to the PTCA centre and (if indicated) rescue PTCA versus thrombolytic treatment with alteplase	patients with acute myocardial infarction initially admitted to a hospital without PTCA facilities	Parallel groups

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>
- myocardial revascularization for acute myocardial infarction in patients in cardiogenic shock at <http://www.trialresultscenter.org/go-Q248>

References

ECSG, 1988:

Simoons ML, Arnold AE, Betriu A, de Bono DP, Col J, Dougherty FC, von Essen R, Lambertz H, Lubsen J, Meier B, et al, Thrombolysis with tissue plasminogen activator in acute myocardial infarction: no additional benefit from immediate percutaneous coronary angioplasty. *Lancet* 1988; 1:197-203 [2893037]

Arnold AE, Simoons ML, Van de Werf F, de Bono DP, Lubsen J, Tijssen JG, Serruys PW, Verstraete M Recombinant tissue-type plasminogen activator and immediate angioplasty in acute myocardial infarction. One-year follow-up. The European Cooperative Study Group. *Circulation* 1992 Jul;86:111-20 [1617763]

Belenkie, 1991:

Belenkie I, Knudtson ML, Roth DL, Hansen JL, Traboulsi M, Hall CA, Manyari D, Filipchuck NG, Schnurr LP, Rosenal TW Relation between flow grade after thrombolytic therapy and the effect of angioplasty on left ventricular function: a prospective randomized trial. *Am Heart J* 1991 Feb;121:407-16 [1990744]

Ellis, 1994:

Ellis SG, da Silva ER, Heyndrickx G, Talley JD, Cernigliaro C, Steg G, Spaulding C, Nobuyoshi M, Erbel R, Vassanelli C Randomized comparison of rescue angioplasty with conservative management of patients with early failure of thrombolysis for acute anterior myocardial infarction. *Circulation* 1994;90:2280-4 [7955184]

Erbel, 1989:

Erbel R, Pop T, Diefenbach C, Meyer J Long-term results of thrombolytic therapy with and without percutaneous transluminal coronary angioplasty. *J Am Coll Cardiol* 1989;14:276-85; discussion 286-8 [2526830]

MERLIN (Sutton), 2004:

Sutton AG, Campbell PG, Graham R, Price DJ, Gray JC, Grech ED, Hall JA, Harcombe AA, Wright RA, Smith RH, Murphy JJ, Shyam-Sundar A, Stewart MJ, Davies A, Linker NJ, de Belder MA A randomized trial of rescue angioplasty versus a conservative approach for failed fibrinolysis in ST-segment elevation myocardial infarction: the Middlesbrough Early Revascularization to Limit Infarction (MERLIN) trial. *J Am Coll Cardiol* 2004;44:287-96 [15261920]

SHOCK (Hochman), 1999:

Hochman JS, Sleeper LA, Webb JG, Sanborn TA, White HD, Talley JD, Buller CE, Jacobs AK, Slater JN, Col J, McKinlay SM, LeJemtel TH Early revascularization in acute myocardial infarction complicated by cardiogenic shock. SHOCK Investigators. Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock. *N Engl J Med* 1999;341:625-34 [10460813]

Hochman JS, Sleeper LA, Webb JG, Dzavik V, Buller CE, Aylward P, Col J, White HD Early revascularization and long-term survival in cardiogenic shock complicating acute myocardial infarction. *JAMA* 2006 Jun 7;295:2511-5 [16757723]

Hochman JS, Sleeper LA, White HD, Dzavik V, Wong SC, Menon V, Webb JG, Steingart R, Picard MH, Menegus MA, Boland J, Sanborn T, Buller CE, Modur S, Forman R, Desvigne-Nickens P, Jacobs AK, Slater JN, LeJemtel TH One-year survival following early revascularization for cardiogenic shock. *JAMA* 2001 Jan 10;285:190-2 [11176812]

SWISS-SMASH, 1999:

Urban P, Stauffer JC, Bleed D, Khatchatrian N, Amann W, Bertel O, van den Brand M, Danchin N, Kaufmann U, Meier B, Machecourt J, Pfisterer M A randomized evaluation of early revascularization to treat shock complicating acute myocardial infarction. The (Swiss) Multicenter Trial of Angioplasty for Shock-(S)MASH. *Eur Heart J* 1999 Jul;20:1030-8 [10383377]

TAMI 1 pilot, 1987:

Topol EJ, Califf RM, George BS, Kereiakes DJ, Abbottsmith CW, Candela RJ, Lee KL, Pitt B, Stack RS, O'Neill WW A randomized trial of immediate versus delayed elective angioplasty after intravenous tissue plasminogen activator in acute myocardial infarction. *N Engl J Med* 1987 Sep 3;317:581-8 [2956516]

TAMI-5 (Califf), 1991:

Califf RM, Topol EJ, Stack RS, Ellis SG, George BS, Kereiakes DJ, Samaha JK, Worley SJ, Anderson JL, Harrelson-Woodlief L Evaluation of combination thrombolytic therapy and timing of cardiac catheterization in acute myocardial infarction. Results of thrombolysis and angioplasty in myocardial infarction—phase 5

randomized trial. TAMI Study Group. *Circulation* 1991;83:1543-56 [[1902405](#)]

TIMI 2A, 1988:

Immediate vs delayed catheterization and angioplasty following thrombolytic therapy for acute myocardial infarction. TIMI II A results. The TIMI Research Group. *JAMA* 1988 Nov 18;260:2849-58 [[2972848](#)]

Topol, 1987:

Topol EJ, O'Neill WW, Langburd AB, Walton JA Jr, Bourdillon PD, Bates ER, Grines CL, Schork AM, Kline E, Pitt B A randomized, placebo-controlled trial of intravenous recombinant tissue-type plasminogen activator and emergency coronary angioplasty in patients with acute myocardial infarction. *Circulation* 1987 Feb;75:420-8 [[2948735](#)]

SWIFT, 1991:

, SWIFT trial of delayed elective intervention v conservative treatment after thrombolysis with anistreplase in acute myocardial infarction. SWIFT (Should We Intervene Following Thrombolysis?) Trial Study Group. *BMJ* 1991; 302:555-60 [[2021717](#)]

SIAM, 1992:

JACC 1992 19:239A(abstract) [[0](#)]

TAMI 6, 1992:

Topol EJ, Califf RM, Vandormael M, Grines CL, George BS, Sanz ML, Wall T, O'Brien M, Schwaiger M, Aguirre FV A randomized trial of late reperfusion therapy for acute myocardial infarction. Thrombolysis and Angioplasty in Myocardial Infarction-6 Study Group. *Circulation* 1992 Jun;85:2090-9 [[1591828](#)]

Barbash, 1990:

Barbash GI, Roth A, Hod H, Modan M, Miller HI, Rath S, Zahav YH, Keren G, Motro M, Shachar A Randomized controlled trial of late in-hospital angiography and angioplasty versus conservative management after treatment with recombinant tissue-type plasminogen activator in acute myocardial infarction. *Am J Cardiol* 1990 Sep 1;66:538-45 [[2118299](#)]

Guerci, 1987:

Guerci AD, Gerstenblith G, Brinker JA, Chandra NC, Gottlieb SO, Bahr RD, Weiss JL, Shapiro EP, Flaherty JT, Bush DE, et al, A randomized trial of intravenous tissue plasminogen activator for acute myocardial infarction with subsequent randomization to elective coronary angioplasty. *N Engl J Med* 1987; 317:1613-8 [[2960897](#)] [10.1056/NEJM198712243172601](#)

TIMI 2, 1989:

, Comparison of invasive and conservative strategies after treatment with intravenous tissue plasminogen activator in acute myocardial infarction. Results of the thrombolysis in myocardial infarction (TIMI) phase II trial. The TIMI Study Group. *N Engl J Med* 1989; 320:618-27 [[2563896](#)] [10.1056/NEJM198903093201002](#)

TIMI II-A (deferred), 0:

Rogers WJ, Baim DS, Gore JM, Brown BG, Roberts R, Williams DO, Chesebro JH, Babb JD, Sheehan FH, Wackers FJ Comparison of immediate invasive, delayed invasive, and conservative strategies after tissue-type plasminogen activator. Results of the Thrombolysis in Myocardial Infarction (TIMI) Phase II-A trial. *Circulation* 1990;81:1457-76 [[2110033](#)]

TOPS, 1992:

Ellis SG, Mooney MR, George BS, da Silva EE, Talley JD, Flanagan WH, Topol EJ Randomized trial of late elective angioplasty versus conservative management for patients with residual stenoses after thrombolytic treatment of myocardial infarction. Treatment of Post-Thrombolytic Stenoses (TOPS) Study Group. *Circulation* 1992 Nov;86:1400-6 [[1423952](#)]

Van den Brand, 1991:

Eur Heart J 1991;12:96 (abstract) [0]

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](#)]

Entry terms: PTCA