Clinical trials of t-PA

TrialResults-center www.trialresultscenter.org

1 acute myocardial infarction

Trial	Treatments	Patients	Trials design and methods
t-PA vs placebo			
ASSET , 1988 n=2516/2495 follow-up: 6 months	rt-PA 100 mg versus Placebo	patient with suspected acute myocardial infarction	Parallel groups double blind
LATE , 1993 n=2836/2875 follow-up: 6 mo	intravenous alteplase (100 mg over 3 h) versus placebo	patients with symptoms and electrocardiographic criteria consistent with AMI between 6 and 24 h from symptom onset	Parallel groups double blind
TAMI 6 , 1992 n=96/101 follow-up: 6 months	tissue-type plasminogen activator 100 mg over 2 hours versus placebo	patients with 6 to 24 hours of symptoms and ECG ST elevation	Parallel groups double blind USA
bolus t-PA vs accelerated t-PA			
COBALT , 1997 n=3585/3584 follow-up: 30 days	of 50 mg of alteplase over a period of 1 to 3 minutes followed 30 minutes later by a second bolus of 50 mg (or 40 mg for patients who weighed less than 60 kg). versus weight-adjusted, accelerated infusion of 100 mg of alteplase	patients with acute myocardial infarction	Parallel groups double blind
accelerated t-PA vs APSAC			
TAPS , 1992 n=199/202 follow-up:	front-loaded administration of rt-PA versus APSAC	patients with acute myocardial infarction.	Parallel groups open
TIMI 4 , 1994 n=NA follow-up: hospital stay	front-loaded rt-PA versus APSAC	patients with acute myocardial infarction	double blind
accelerated t-PA vs streptokinase			

continued...

Trial	Treatments	Patients	Trials design and methods
GUSTO tPA Hiv , 1993 n=10396/20251 follow-up: 30 d	tPA acclr (15 mg en bolus, puis 0.75 mg/kg en 30 min sans dpasser 50 mg puis 0.5 mg/kg en 60 min sans dpasser 35 mg) + hparine en IV (5000 U en bolus, 1000 U/h (de prfrence 1200 U/h si >80 kg), poursuivi au moins 48 h) versus Streptokinase 1.5 MU en 60 min + hparine SC (12500 U 2 fois/j commence 4h aprs thrombolytique) combin streptokinase (1.5 MU en 60 min) + hparine en IV (5000 U en bolus, puis 1000 U/h (1200 U/h si >80 kg) poursuivi au moins 48 h)	Hommes et femmes	Parallel groups International 15 countries
t-PA vs streptokinase			
International Study Group , 1990 n=10372/10396 follow-up: 6 mo	tPA 100 mg en IV en 3 h (10 mg en bolus, puis 50 mg en 1 h, puis 20 mg/h pendant 2 h) versus Streptokinase 1.5 MU en IV de 30 60 min	patients with suspected acute myocardial infarction of less than 6 h duration	Plan factoriel 2*2 double blind
Centre Illinois , 1993 n=123/130 follow-up:	t-PA 10 mg bolus, followed by 50 mg in the first hour, and 20 mg/hour for the next 2 hours versus SK 375 000 IU bolus, followed by 1 125 000 IU/1 hage/pj	patients with AMI within 3h from onset of chest pain	Parallel groups single blind USA
Cherng , 1992 n=59/63 follow-up: hospital stay	100 mg of rTPA over 3 hours (with early heparinization) versus 1,500,000 units of streptokinase over 1 hour	patients with acute myocardial infarction	Parallel groups open Taiwan
ECSG , 1985 n=64/65 follow-up:	0.75 mg rt-PA/kg over 90 min versus 1 500 000 IU streptokinase over 60 min	patients with acute myocardial infarction of less than 6 h duration	Parallel groups single-blind Europe
GISSI II , 1990 n=6182/6199 follow-up: 6 mo	alteplase 100 mg infused intravenously over 3 h versus streptokinase 1.5 MU infused intravenously over 30-60 min	patients with acute myocardial infarction within 6 h from onset of symptoms	Plan factoriel 2*2 open International 14 countries

continued...

Trial	Treatments	Patients	Trials design and methods
ISIS III (SK/tPA) , 1992 n=13780/13746 follow-up: 6 mo	Streptokinase 1.5 MU en IV d'une heure versus tPA 0.04 MU/kg en IV en bolus d'1 min, puis 0.36 MU/kg en 1 h, puis 0.067 MU/kg/h pendant 3 h	Hommes et femmes	Plan factoriel 3 (ou 4) *2 double blind International 17 countries
PAIMS , 1989 n=86/85 follow-up:	intravenous cumulative dose of 100 mg rt-PA versus .5 million units streptokinase	patients with acute myocardial infarction less than 3 h old	Parallel groups open Italy
TIMI-1 , 1987 [NCT00000505] n=157/159 follow-up:	rt-PA, 40, 20, and 20 mg in successive hours versus SK 1.5 million units over 1 hr	patients with evolving acute myocardial infarction within 7 hr of the onset of symptoms	Parallel groups double blind USA
White , 1989 n=135/135 follow-up:	rt-PA 100 mg over three hours versus streptokinase 1.5 million units over 30 minutes	patients with AMI	Parallel groups double blind New Zealand
t-PA + streptokinase vs streptokinase			
GUSTO tPA-SK Hiv , 1993 n=10374/20251 follow-up: 30 d	tPA en IV 1 mg/kg, sans dpasser 90 mg, dont 10 % en bolus + streptokinase 1 MU en 60 min + hparine en IV (5000 U en bolus, 1000 U/h (de prfrence 1200 U/h si >80 kg), poursuivi au moins 48 h) versus Streptokinase 1.5 MU en 60 min + hparine SC (12500 U 2 fois/j commence 4h aprs thrombolytique) combin streptokinase (1.5 MU en 60 min) + hparine en IV (5000 U en bolus, puis 1000 U/h (1200 U/h si >80 kg) poursuivi au moins 48 h)	Hommes et femmes	Parallel groups International 15 countries
accelerated t-PA vs t-PA			
RAAMI , 1992 n=143/138 follow-up: hospital stay	100 mg of rt-PA accelerated 90-min regimen (15-mg bolus followed by 50 mg over 30 min, then 35 mg over 60 min) versus 100 mg of rt-PA standard 3-h infusion regimen (an initial 10-mg bolus followed by 50 mg for the 1st h, then 20 mg/h for 2 h	patients with acute myocardial infarction within 6h from onset of chest pain	Parallel groups open US

continued...

Trial	Treatments	Patients	Trials design and methods
t-PA + urokinase vs t-PA			
TAMI 5 (t-PA+uroK vs tPA) , 1991 n=194/191 follow-up:	t-PA + urokinase versus t-PA	patient with acute myocardial infarction	open
t-PA half dose vs t-PA			
KAMIT , 1991 n=109/107 follow-up: hospital stay	half-dose (50 mg) t-PA with streptokinase (1.5 MU) during 1 hour versus t-PA (100 mg) during 3 hours	patients within 6 hours of myocardial infarction	Parallel groups open USA
t-PA vs urokinase			
TAMI 5 (t-PA vs uroK) , 1991 n=191/190 follow-up:	accelerated t-PA 100mg over 3h versus urokinase IV bolus 1.5 MU followed by 1.5 MU over 90min	patient with acute myocardial infarction	open

More details and results :

- myocardial revascularization for acute myocardial infarction in all type of patients at http://www.trialresultscenter.org/go-Q129
- Late revascularisation for acute myocardial infarction in late reperfusion at http://www.trialresultscenter.org/go-Q134
- myocardial revascularization for acute myocardial infarction in ¿6h from onset of symptoms at http://www.trialresultscenter.org/go-Q249
- fibrinolysis for acute myocardial infarction in all type of patients at http://www.trialresultscenter.org/go-Q260
- fibrinolysis for acute myocardial infarction in ¿6h from onset of symptoms at http://www.trialresultscenter.org/go-Q261

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2 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
t-PA vs placebo			
Nicklas , 1989 n=20/20 follow-up:	rt-PA, 150 mg/8 h versus placebo	patients with rest angina, angiographically documented coronary artery disease and pacing-induced ischemia	Parallel groups Double blind USA

continued...

Trial	Treatments	Patients	Trials design and methods
Gold , 1987 n=12/12 follow-up:	intravenous recombinant human tissue-type plasminogen activator (rt-PA). versus placebo	chest pain at rest with transient ST segment deviation of at least 1 mm	Parallel groups
Williams , 1990 n=45/22 follow-up:	tissue-type plasminogen activator (rt-PA) (0.75 mg/kg over 1 hour or (0.75 mg/kg over 1 hour; total dose, 100 mg over 6 hours) versus placebo	rest angina and angiographic evidence of coronary stenosis	Parallel groups double blind USA
Freeman , 1992 n=35/35 follow-up: in hospital	tissue-type plasminogen activator (t-PA) (0.49 MU/kg for 1 hour followed by 0.07 MU/kg per hour for 9 hours) versus placebo	patients with unstable angina	Parallel groups double blind USA
van der Brand , 1991 n=19/17 follow-up: hospital stay	alteplase 100 mg in 3 h versus placebo	patients with angina at rest, despite bedrest and medical treatment	Parallel groups double blind The Netherlands
charbonnier , 1992 n=25/25 follow-up:	rt-PA 100 mg/90 minutes (10 mg bolus + 90 mg/90 minutes versus placebo	unstable angina pectoris	Parallel groups double blind
Ardissino , 1990 n=12/12 follow-up: in hospital	recombinant tissue-type plasminogen activator (rt-PA) followed by heparin versus heparin alone	unstable angina refractory to conventional medical treatment	Parallel groups double blind Italy
TIMI 3B , 1995 n=729/744 follow-up: 1 year	tissue-type plasminogen activator (t-PA) versus placebo	patients with unstable angina and non-Q wave myocardial infarction	Factorial plan Double blind
Topol , 1988 n=20/20 follow-up: hospital stay	intravenous tissue plasminogen activator (t-PA) versus placebo	patients with angina at rest and provocable ischemia (pacing induced)	Parallel groups open USA
TIMI 3A , 1993 n=150/156 follow-up: hospital stay	90-minute front-loaded infusion of t-PA (0.8 mg/kg i.v.; maximum, 80 mg) versus placebo	patients with unstable angina or non-Q wave myocardial infarction	Parallel groups double blind USA, canada

More details and results :

- myocardial revascularization for acute coronary syndrome in all type of patients at http://www.trialresultscenter.org/go-Q22

- fibrinolysis for acute coronary syndrome in all type of patients at http://www.trialresultscenter.org/go-Q223

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3 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
half-dose t-PA vs no fibrinolysis			
MOPETT , 2012 n=NA follow-up: 28 months	half-dose thrombolysis versus standard regimen of anticoagulants alone	patients presenting with moderate PE	Parallel groups open
rt-PA vs no fibrinolysis			
PAIMS 2 , 1992 n=NA follow-up: 7 days	rt-PA 100 mg IV over 2 h and heparin versus Heparin 1750 IU/hr i.v. for 7 to 10 days	patients with angiographically documented pulmonary embolism	Parallel groups open Italy
Goldhaber , 1993 n=46/55 follow-up: 14 days	rt-PA 100 mg IV over 2 h then 1000 U/hr heparin,when PTT or TT was <2 times control. Subsequent heparin dose achieved PTT = 1.5 to 2.5 times the upperlimit of normal. versus heparin, initial dose 5000 U bolus followed by 1000 U/hr continuous i.v., 4 hr after the dose of heparin according to PTT. Target PTT = 1.5 to 2.5 times of normal	haemodynamically stable patients with acute pulmonary embolism	Parallel groups open US
rt-PA vs placebo			
Konstantinides , 2002 n=118/138 follow-up: <30 days	100 mg alteplase given as 10 mg bolus followed by 90 mg i.v. infusion over 2 hours then i.v. heparin 1000 U/hr adjusted to maintain APTT of 2.0 to 2.5times the upper normal limit. Oral anticoagulation was started on day 3 versus placebo + i.v. heparin 1000 U/hr adjusted to maintain APTT of 2.0 to 2.5times the upper normal limit. Oral anticoagulation was started on day 3	patients with acute pulmonary embolism and pulmonary hypertensionor right ventricular dysfunction but withoutarterial hypotension or shock	Parallel groups double blind Germany
PIOPED , 1990 n=9/4 follow-up: 7 days	rt-PA 4080 mg IV over 90 min plus heparin versus placebo+heparin	patients with acute pulmonary embolism	Parallel groups double blind US

continued...

Trial	Treatments	Patients	Trials design and methods
Levine , 1990 n=33/25 follow-up: 10 days	rt-PA 0.6 mg/kg IV over 2 min and heparin, initial bolus of 5000 U, then 30,000 U for first 24 hr continuous infusion,only interrupted for the duration of the study drug infusion versus placebo + heparin bolus of 5000 U, then 30,000 U for first 24 hr continuous infusion	patients with objectively established acute symptomatic pulmonary embolism	Parallel groups double blind Canada

More details and results :

- fibrinolysis for pulmonary embolism in all type of patients at http://www.trialresultscenter.org/go-Q110

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4 cardiac arrest

Trial	Treatments	Patients	Trials design and methods
t-PA vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
Abu-Laban , 2002 n=117/116 follow-up:	t-PA 100mg over a 15-minute period versus placebo	Victims of cardiac arrest with pulseless electrical activity for more than one minute and had had no palpable pulse for more than three minutes during resuscitative efforts and at the time of the initiation of the study drug	Parallel groups double blind Canda

More details and results :

- fibrinolysis for cardiac arrest in all type of patients at http://www.trialresultscenter.org/go-Q239

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Entry terms: rt-PA, Tissue Plasminogen Activator, Tissue Activator D-44, Tissue Activator D 44, Tisokinase, Tissue-Type Plasminogen Activator, Tissue Type Plasminogen Activator, TTPA, T-Plasminogen Activator, T Plasminogen Activator, Alteplase, Activase, Actilyse, Lysatec rt-PA, Lysatec rt PA, Lysatec rtPA, , streptokinase, t-pa