Clinical trials of fibrinolysis for acute myocardial infarction in all type of patients

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1 fibrinolysis

Trial	Treatments	Patients	Trials design and methods
APSAC vs control			
APSIM , 1989 n=112/119 follow-up: 3 weeks	APSAC 30 U over 5 min versus control (conventional heparin therapy, 5,000 IU in a bolus injection)	patients with a first acute myocardial infarction within 5 h after the onset of symptoms	Parallel groups open France
urokinase vs control			
USIM , 1991 n=1128/1073 follow-up: in hospital	urokinase bolus dose of 1 million U repeated after 60 minutes plus heparin versus control (heparin alone)	patients with acute myocardial infarction within 4 hours of the onset of pain	Parallel groups open Italy
APSAC vs placebo			
AIMS , 1988 n=624/634 follow-up: 1 y	APSAC 30U IV in 5 min versus Placebo	Hommes et femmes, <70 ans	Parallel groups double blind
German Multicenter Trial , 1988 n=162/151 follow-up: 28 jours	APSAC 30 units en IV en 5 min, puis hparine en IV (17 U/kg/h) 4 h aprs l'injection d'APSAC versus Hparine 5000 U en bolus en IV, puis 17 U/kg/h	Hommes et femmes, <70 ans	Parallel groups
streptokinase vs placebo			
EMERAS (7-12h) , 1993 n=2257/2277 follow-up:	intravenous streptokinase 1.5 MU versus placebo	patients presenting 7-12 h from symptom onset	Parallel groups double blind
EMERAS (all delay) , 1993 n=2257/2277 follow-up:	streptokinase 1.5 MU versus placebo	patients entering hospital up to 24 h after the onset of suspected acute myocardial infarction	Parallel groups double blind south america
GISSI I , 1986 n=5860/5852 follow-up: 1 y	Streptokinase 1.5 MU en perfusion IV en 1 heure versus usual care	patients within 12 h after the onset of symptoms and with no contraindications to SK	Parallel groups open
ISAM , 1986 n=859/882 follow-up: 21 days	1.5 million IU of streptokinase over 1h versus Placebo	patients within six hours after the onset of symptoms of myocardial infarction	Parallel groups double blind

continued...

Trial	Treatments	Patients	Trials design and methods
ISIS 2 pilot , 1987 n=NA follow-up:	streptokinase 1.5 MU versus placebo	patients with suspected acute myocardial infarction	Parallel groups double blind
ISIS-2 (SK) , 1988 n=8592/8595 follow-up: 15 mo	1-hour intravenous infusion of 1.5 MU of streptokinase versus Placebo	patients within 24h of the onset of suspected acute myocardial infarction	plan factoriel 2*2 double blind
Western Washington Intravenous Trial , 1988 [NCT00000507] n=191/177 follow-up: 1.4 y	Streptokinase en IV, 1.5 M UI en 60 min aprs injection de benadryl 50 mg en IV et hydrocortisone 100 mg en IV; hparine en IV 1000 UI/h 2h aprs la streptokinase puis warfarine pendant au moins 3 mois versus Traitement standard, avec ou sans anticoagulant (dcid par le mdecin)	Hommes et femmes, <ou = 75 ans	Parallel groups
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
lanoteplase vs accelerated t-PA			
InTIME-II , 2000 n=10038/5022 follow-up: 30 days	lanoteplase 120 KU. kg(-1) as a single intravenous bolus versus up to 100 mg accelerated alteplase given over 90 min	patients presenting within 6 h of onset of ST elevation acute myocardial infarction	Parallel groups double blind worldwide
reteplase vs accelerated t-PA			
GUSTO III , 1997 n=10138/4921 follow-up: 30 days	reteplase, in two bolus doses or 10 MU each given 30 minutes apart versus alteplase, up to 100 mg infused over a period of 90 minutes	patients within 6 hours after the onset of symptoms with ST-segment elevation or bundle-branch block	Parallel groups open 20 countries

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Trial	Treatments	Patients	Trials design and methods
RAPID-2 , 1996 n=169/155 follow-up: 35 days	10 plus 10 megaunits double bolus of reteplase versus front-loaded alteplase	patients with acute myocardial infarction within 12h from onset of ischemic chest pain	Parallel groups open USA, Germany
tenecteplase vs accelerated t-PA			
ASSENT-2 , 1999 n=8461/8488 follow-up: 30d	Tenecteplase en IV bolus (dose en fonction du poids: 30 mg si <60 kg; 35 mg si poids entre 60 et 69.9 kg; 40 mg pour les 80-89.9 kg; 50 mg si >ou = 90 kg versus Alteplase en IV, bolus de 15 mg, puis 0.75 mg/kg (sans dpasser 50 mg) en 30 min puis 0.50 mg/kg (sans dpasser 35 mg) en 60 min	patients with acute myocardial infarction of less than 6 h duration	Parallel groups double blind 29 countries
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			
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
anistreplase vs streptokinase			
TEAM 2 , 1991 n=183/176 follow-up:	anistreplase (30 units/2-5 min) versus streptokinase (1.5 million units/60 min	less than 76 years of age with electrocardiographic ST segment elevation who could be treated within 4 hours of symptom onset	double blind
APSAC vs streptokinase			
ISIS III (SK/APSAC) , 1992 n=13780/13773 follow-up: 6 mo	Streptokinase 1.5 MU infused over about 1 h versus anisoylated plasminogen-streptokinase activator complex (APSAC), anistreplase: 30 U over about 3 min	patients within 24 h of the onset of suspected acute myocardial infarction	Plan factoriel 3 (ou 4) *2 double blind International 17 countries
reteplase vs streptokinase			

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Trial	Treatments	Patients	Trials design and methods
INJECT , 1995 n=3004/3006 follow-up: 6 mo	Reteplase 2 bolus de 10 MU 30 min d'intervalle versus Streptokinase 1.5 MU en IV en 60 min	patients with symptoms and electrocardiographic criteria consistent with acute myocardial infarction within 12 h from onset of symptoms	Parallel groups double blind Europe
saruplase vs streptokinase			
COMPASS , 1998 n=1542/1547 follow-up: 1 y	saruplase 20-mg bolus and 60-mg infusion over 60 min versus streptokinase 1.5-MU infusion over 60 min	patients with symptoms compatible with those of acute myocardial infarction for <6 h	Parallel groups double blind
PRIMI (vs SK) , 1989 n=198/203 follow-up: ND	sarupalse 20 mg bolus followed by 60 mg infusion for 60 min versus 1.5 million IU streptokinase infused over 60 min	patients with acute myocardial infarction were within 4 h of onset of symptoms	Parallel groups double blind
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
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

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Trial	Treatments	Patients	Trials design and methods
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
APSAC vs t-PA			
TEAM 3 , 1992 n=325 follow-up: 1 months	APSAC, 30 U/2 to 5 min versus rt-PA, 100 mg/3 h,	patient with ST elevalation within 4h of the onset of symptoms	double blind
recombinant staphylokinase vs t-PA			
STAR , 1995 n=48/52 follow-up: 90 min	recombinant staphylokinase (10 or 20 mg given intravenously over 30 minutes) versus weight-adjusted rt-PA over 90 minutes	patients with evolving myocardial infarction of <6 hours' duration and with ST-segment elevation	Parallel groups open Belgium
saruplase vs t-PA			

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Trial	Treatments	Patients	Trials design and methods
SESAM , 1997 n=236/237 follow-up: hospital stay	saruplase 80 mg/hour versus alteplase 100 mg every 3 hours	patients with acute myocardial infarction	Parallel groups open Europe
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
saruplase vs urokinase			
PRIMI (vs UK) , 1989 n=198 follow-up:	20 mg bolus followed by 60 mg infusion for 60 min versus 80 mg recombinant pro-urokinase	with a first acute myocardial infarction within 4 h of onset of symptoms	Parallel groups double blind
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

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2 About TrialResults-center.org

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