

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

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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	Retepase 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	saruplase 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
ECSCG , 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 prference 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 elevation 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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