

# Clinical trials of fibrinolysis for venous thrombosis in all type of patients

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## 1 local fibrinolysis

Trial	Treatments	Patients	Trials design and methods
<b>streptokinase vs no fibrinolysis</b>			
<b>Arneson , 1978</b> n=43 follow-up:	streptokinase 250,000 U loading IV, then 100,000 IU/hour IV 72-96 hours versus heparin 15,000 IU IV bolus, 30,000 IU infusion IV 72-90 hours	inpatients with venographically confirmed DVT extending proximally beyond the calf <5 days duration?	Parallel groups single blind Norway
<b>Common , 1976</b> n=50 follow-up:	hydrocortisone 100 mg IV then streptokinase IV 250,000 U over 30 minutes, then 100,000 U/hour titrated for 72 hours. Followed by IV heparin titrated over 7 days versus IV heparin 150 U/kg loading dose then titrated for 10 days	patients with venographically confirmed DVT duration <14 days	Parallel groups single blind US
<b>Elsharawy , 2002</b> n=35 follow-up:	catheter-directed thrombolysis with streptokinase using popliteal approach. versus heparin IV bolus 5000 U, then adjusted continuous infusion. Warfarin begun the same evening	iliofemoral venous thrombosis confirmed by duplex or venography duration <10 days	Parallel groups single blind Egypt
<b>Schulman , 1986</b> n=38 follow-up:	streptokinase 50,000 IU IV over 15 minutes then 100,000 IU over 12 hours for up to 7 days, titrated. Given with 5000 IU heparin IV over 12 hours. Warfarin begun after streptokinase ended versus heparin 5000 IU IV bolus then 30,000 IU per day, titrated for 7 days. Warfarin begun simultaneously	patients with venographically confirmed calf vein thrombosis of duration <7 days.	Parallel groups single blind Sweden
<b>Tsapogas , 1973</b> n=34 follow-up:	titrated dose of streptokinase IV into ankle vein versus heparin IV into affected limb	patients with DVT confirmed by venogram of duration <5 days.	Parallel groups open US
<b>Kakkar (streptokinase) , 1969</b> n=NA follow-up:	streptokinase 500,000 U IV over 30 minutes, 900,000 U every 6 hours for 5 days versus heparin 10,000 U over 5 minutes, then 10,000 to 15,000 U every 6 hours for 5 days	patients with venographically confirmed DVT of leg of duration <4 days	Parallel groups single blind UK

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Schweizer (systemic SK) , 2000 n=NA follow-up:	Systemic streptokinase 3,000,000 U/day over 6 hours in conjunction with heparin for up to 7 days. Premedication: hydrocortisone 100 mg, ranitidine 50 mg, clemastine 2 mg versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany
<b>tPA vs no fibrinolysis</b>			
Goldhaber (tPA alone) , 1990 n=NA follow-up:	tPA alone 0.05 mg/kg/hour IV over 24 hours, then heparin 100U/kg bolus, then 1000 U/hour, adjusted versus heparin alone 100 U/kg bolus, then 1000 U/hour	venographically documented DVT, in popliteal or more proximal veins <14 days duration	Parallel groups single blind US
Schweizer (local tPA) , 2000 n=NA follow-up:	local tPA 20 mg/day, over 4 hours via pedal vein for 4-7 days. IV heparin given simultaneously at 1000 IU/hour, adjusted versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany
Turpie , 1990 n=83 follow-up:	tPA + IV heparin versus 5000 U bolus then 30,000 U/24 hours, adjusted for 7-10 days (+placebo)	patients with venographically confirmed proximal DVT of lower limb of duration <7 days	Parallel groups double blind Canada
Verhaeghe (high dose) , 1989 n=NA follow-up:	IV tPA 100 mg on day 1, 50 mg tPA on day 2. 10% of dose given as bolus; heparin 5000 U IV bolus then continuous infusion of 1000 U per hour for up to 72 hours versus heparin 5000 U IV bolus then continuous infusion of 1000 U per hour for up to 72 hours (+placebo)	hospitalised patients with DVT of popliteal or more proximal veins of the lower leg, confirmed by venography of duration <10 days.	Parallel groups double blind France, Belgium, Switzerland
Goldhaber (tPA+heparin) , 1990 n=NA follow-up:	tPA 0.05 mg/kg/hour IV over 24 hours and heparin 100U/kg bolus, then 1000 U/hour, adjusted versus heparin alone 100 U/kg bolus, then 1000 U/hour.	patients with venographically documented DVT, in popliteal or more proximal veins <14 days duration	Parallel groups single blind US
Verhaeghe (low dose) , 1989 n=NA follow-up:	IV tPA 50 mg on day 1, repeated on day 2. 10% of dose given as bolus; heparin 5000 U IV bolus then continuous infusion of 1000 U per hour for up to 72 hours versus heparin 5000 U IV bolus then continuous infusion of 1000 U per hour for up to 72 hours (+placebo)	hospitalised patients with DVT of popliteal or more proximal veins of the lower leg, confirmed by venography of duration <10 days.	Parallel groups double blind France, Belgium, Switzerland
<b>tPA+heparin vs no fibrinolysis</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
Schweizer tPA , 1998 n=NA follow-up:	tPA 20 mg IV into pedal vein over 4 hours each day for 7 days. Heparin IV given concomitantly, with adjustment versus heparin IV, adjusted for 7 days	patients with venographically confirmed DVT of leg duration <7 days.	Parallel groups single blind Germany
<b>urokinase vs no fibrinolysis</b>			
Kiil , 1981 n=20 follow-up:	urokinase 200,000 U IV over 24 hours. After 18 hours, heparin loading dose of 15,000 units then 40,000 U/day for 5 days (+placebo) versus heparin 40,000 U/day IV for 6 days (+placebo)	patients with venographically confirmed DVT duration <72 hours	Parallel groups Double blind Denmark
Schweizer (urokinase) , 1998 n=NA follow-up:	Urokinase 100,000 IU/hr IV into pedal vein continuously for 7 days. Heparin IV for 7 days. Plasminogen monitored. Warfarin from day 7 to 12 monthsd=132 versus heparin IV, adjusted for 7 days	patients with venographically confirmed DVT of leg duration <7 days	Parallel groups single blind Germany
Schweizer (local urokinase) , 2000 n=NA follow-up:	Local urokinase 100,000 IU/day infused continuously. Fibrinogen and plasminogen monitored. Heparin IV given concomitantly versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany
Schweizer (systemic urokinase) , 2000 n=NA follow-up:	Systemic urokinase 5,000,000 IU/day over 4 hours for up to 7 days. IV heparin given concomitantly versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany

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**Goldhaber (tPA alone), 1990:**

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**Schweizer (systemic urokinase), 2000:**

## 2 systemic fibrinolysis

Trial	Treatments	Patients	Trials design and methods
<b>arvin vs no fibrinolysis</b>			
<b>Kakkar (arvin) , 1969</b> n=NA follow-up:	streptokinase 500,000 U IV over 30 minutes, 900,000 U every 6 hours for 5 days versus heparin 10,000 U over 5 minutes, then 10,000 to 15,000 U every 6 hours for 5 days	patients with venographically confirmed DVT of leg of duration <4 days	Parallel groups single blind UK
<b>streptokinase vs no fibrinolysis</b>			
<b>Arneson , 1978</b> n=43 follow-up:	streptokinase 250,000 U loading IV, then 100,000 IU/hour IV 72-96 hours versus heparin 15,000 IU IV bolus, 30,000 IU infusion IV 72-90 hours	inpatients with venographically confirmed DVT extending proximally beyond the calf <5 days duration?	Parallel groups single blind Norway
<b>Common , 1976</b> n=50 follow-up:	hydrocortisone 100 mg IV then streptokinase IV 250,000 U over 30 minutes, then 100,000 U/hour titrated for 72 hours. Followed by IV heparin titrated over 7 days versus IV heparin 150 U/kg loading dose then titrated for 10 days	patients with venographically confirmed DVT duration <14 days	Parallel groups single blind US
<b>Elsharawy , 2002</b> n=35 follow-up:	catheter-directed thrombolysis with streptokinase using popliteal approach. versus heparin IV bolus 5000 U, then adjusted continuous infusion. Warfarin begun the same evening	iliofemoral venous thrombosis confirmed by duplex or venography duration <10 days	Parallel groups single blind Egypt
<b>Schulman , 1986</b> n=38 follow-up:	streptokinase 50,000 IU IV over 15 minutes then 100,000 IU over 12 hours for up to 7 days, titrated. Given with 5000 IU heparin IV over 12 hours. Warfarin begun after streptokinase ended versus heparin 5000 IU IV bolus then 30,000 IU per day, titrated for 7 days. Warfarin begun simultaneously	patients with venographically confirmed calf vein thrombosis of duration <7 days.	Parallel groups single blind Sweden
<b>Tsapogas , 1973</b> n=34 follow-up:	titrated dose of streptokinase IV into ankle vein versus heparin IV into affected limb	patients with DVT confirmed by venogram of duration <5 days.	Parallel groups open US

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<b>Schweizer (systemic SK) , 2000</b> n=NA follow-up:	Systemic streptokinase 3,000,000 U/day over 6 hours in conjunction with heparin for up to 7 days. Premedication: hydrocortisone 100 mg, ranitidine 50 mg, clemastine 2 mg versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany
<b>tPA vs no fibrinolysis</b>			
<b>Goldhaber (tPA alone) , 1990</b> n=NA follow-up:	tPA alone 0.05 mg/kg/hour IV over 24 hours, then heparin 100U/kg bolus, then 1000 U/hour, adjusted versus heparin alone 100 U/kg bolus, then 1000 U/hour	venographically documented DVT, in popliteal or more proximal veins <14 days duration	Parallel groups single blind US
<b>Schweizer (local tPA) , 2000</b> n=NA follow-up:	local tPA 20 mg/day, over 4 hours via pedal vein for 4-7 days. IV heparin given simultaneously at 1000 IU/hour, adjusted versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany
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<b>Goldhaber (tPA+heparin) , 1990</b> n=NA follow-up:	tPA 0.05 mg/kg/hour IV over 24 hours and heparin 100U/kg bolus, then 1000 U/hour, adjusted versus heparin alone 100 U/kg bolus, then 1000 U/hour.	patients with venographically documented DVT, in popliteal or more proximal veins <14 days duration	Parallel groups single blind US

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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<b>urokinase vs no fibrinolysis</b>			
<b>Kiil , 1981</b> n=20 follow-up:	urokinase 200,000 U IV over 24 hours. After 18 hours, heparin loading dose of 15,000 units then 40,000 U/day for 5 days (+placebo) versus heparin 40,000 U/day IV for 6 days (+placebo)	patients with venographically confirmed DVT duration <72 hours	Parallel groups Double blind Denmark
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<b>Schweizer (local urokinase) , 2000</b> n=NA follow-up:	Local urokinase 100,000 IU/day infused continuously. Fibrinogen and plasminogen monitored. Heparin IV given concomitantly versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany
<b>Schweizer (systemic urokinase) , 2000</b> n=NA follow-up:	Systemic urokinase 5,000,000 IU/day over 4 hours for up to 7 days. IV heparin given concomitantly versus heparin IV, adjusted	patients with thrombosis of popliteal or more proximal veins confirmed by venogram at more than one level of duration <9 days	Parallel groups single blind Germany

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### **3 About TrialResults-center.org**

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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