

# Clinical trials of tPA

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## 1 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
<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

continued...

Trial	Treatments	Patients	Trials design and methods
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>			
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

More details and results :

- fibrinolysis for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q100>

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## References

### Goldhaber (tPA alone), 1990:

Goldhaber SZ, Meyerovitz MF, Green D, Vogelzang RL, Citrin P, Heit J, Sobel M, Wheeler HB, Plante D, Kim H Randomized controlled trial of tissue plasminogen activator in proximal deep venous thrombosis. Am J Med 1990;88:235-40 [2106783]

### Schweizer (local tPA), 2000:

Schweizer J, Kirch W, Koch R, Elix H, Hellner G, Forkmann L, Graf A Short- and long-term results after thrombolytic treatment of deep venous thrombosis. J Am Coll Cardiol 2000;36:1336-43 [11028492]

### Turpie, 1990:

Turpie AG, Levine MN, Hirsh J, Ginsberg JS, Cruickshank M, Jay R, Gent M Tissue plasminogen activator (rt-PA) vs heparin in deep vein thrombosis. Results of a randomized trial. Chest 1990;97:172S-175S [2108855]

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### Verhaeghe (high dose), 1989:

Verhaeghe R, Besse P, Bounameaux H, Marbet GA Multicenter pilot study of the efficacy and safety of systemic rt-PA administration in the treatment of deep vein thrombosis of the lower extremities and/or pelvis. Thromb Res 1989;55:5-11 [2506661]

### Goldhaber (tPA+heparin), 1990:

Goldhaber SZ, Meyerovitz MF, Green D, Vogelzang RL, Citrin P, Heit J, Sobel M, Wheeler HB, Plante D, Kim H Randomized controlled trial of tissue plasminogen activator in proximal deep venous thrombosis. Am J Med 1990;88:235-40 [2106783]

### Verhaeghe (low dose), 1989:

Verhaeghe R, Besse P, Bounameaux H, Marbet GA Multicenter pilot study of the efficacy and safety of systemic rt-PA administration in the treatment of deep vein thrombosis of the lower extremities and/or pelvis. *Thromb Res* 1989;55:5-11 [2506661]

### Schweizer tPA, 1998:

Schweizer J, Elix H, Altmann E, Hellner G, Forkmann L Comparative results of thrombolysis treatment with rt-PA and urokinase: a pilot study. *Vasa* 1998;27:167-71 [9747153]

## 2 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
<b>outpatient treatment vs inpatient treatment</b>			
<b>OTPE (Aujesky) , 2011</b> [NCT00425542] n=171/168 follow-up: 90 days	initial outpatient treatment with subcutaneous enoxaparin (5 days) followed by oral anticoagulation (90 days). versus inpatient treatment with subcutaneous enoxaparin (5 days) followed by oral anticoagulation (90 days)	patients with acute, symptomatic pulmonary embolism and a low risk of death (pulmonary embolism severity index risk classes I or II)	Parallel groups open-label Switzerland, France, Belgium, and the USA
<b>Otero , 2010</b> [NCT00214929] n=72/60 follow-up: 3 months	early discharge versus standard hospitalization	low-risk patients with acute symptomatic PE	Parallel groups open-label Spain

More details and results :

- antithrombotics for pulmonary embolism in all type of patients at <http://www.trialresultscenter.org/go-Q102>

## References

### OTPE (Aujesky), 2011:

Aujesky D, Roy PM, Verschuren F, Righini M, Osterwalder J, Egloff M, Renaud B, Verhamme P, Stone RA, Legall C, Sanchez O, Pugh NA, N'gako A, Cornuz J, Hugli O, Beer HJ, Perrier A, Fine MJ, Yealy DM Outpatient versus inpatient treatment for patients with acute pulmonary embolism: an international, open-label, randomised, non-inferiority trial. *Lancet* 2011;378:41-8 [21703676] [10.1016/S0140-6736\(11\)60824-6](https://doi.org/10.1016/S0140-6736(11)60824-6)

### Otero, 2010:

Otero R, Uresandi F, Jimnez D, Cabezudo MA, Oribe M, Nauffal D, Conget F, Rodriguez C, Cayuela A Home treatment in pulmonary embolism. *Thromb Res* 2010;126:e1-5 [19853892] [10.1016/j.thromres.2009.09.026](https://doi.org/10.1016/j.thromres.2009.09.026)

Entry terms: heparin, Heparin, Unfractionated Heparin, Heparinic Acid, Liquaemin, Sodium Heparin, Heparin Sodium, alpha-Heparin, alpha Heparin, , t-pa