

# 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><br>n=43<br>follow-up:                | streptokinase 250,000 U loading IV, then 100,000 IU/hour IV 72-96 hours<br>versus<br>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<br>single blind<br>Norway |
| <b>Common , 1976</b><br>n=50<br>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<br>versus<br>IV heparin 150 U/kg loading dose then titrated for 10 days  | patients with venographically confirmed DVT duration <14 days  | Parallel groups<br>single blind<br>US     |
| <b>Elsharawy , 2002</b><br>n=35<br>follow-up:              | catheter-directed thrombolysis with streptokinase using popliteal approach.<br>versus<br>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<br>single blind<br>Egypt  |
| <b>Schulman , 1986</b><br>n=38<br>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<br>versus<br>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<br>single blind<br>Sweden |
| <b>Tsapogas , 1973</b><br>n=34<br>follow-up:               | titrated dose of streptokinase IV into ankle vein<br>versus<br>heparin IV into affected limb  | patients with DVT confirmed by venogram of duration <5 days.   | Parallel groups<br>open<br>US             |
| <b>Kakkar (streptokinase) , 1969</b><br>n=NA<br>follow-up: | streptokinase 500,000 U IV over 30 minutes, 900,000 U every 6 hours for 5 days<br>versus<br>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<br>single blind<br>UK     |

continued...

| <b>Trial</b>   | <b>Treatments</b>   | <b>Patients</b>  | <b>Trials design and methods</b>                                |
|--|---|--|---|
| Schweizer (systemic SK) , 2000<br>n=NA<br>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<br>single blind<br>Germany                      |
| <b>tPA vs no fibrinolysis</b>                        |   |  |   |
| Goldhaber (tPA alone) , 1990<br>n=NA<br>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<br>single blind<br>US                           |
| Schweizer (local tPA) , 2000<br>n=NA<br>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<br>single blind<br>Germany                      |
| Turpie , 1990<br>n=83<br>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<br>double blind<br>Canada                       |
| Verhaeghe (high dose) , 1989<br>n=NA<br>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<br>double blind<br>France, Belgium, Switzerland |
| Goldhaber (tPA+heparin) , 1990<br>n=NA<br>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<br>single blind<br>US                           |
| Verhaeghe (low dose) , 1989<br>n=NA<br>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<br>double blind<br>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<br>n=NA<br>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<br>single blind<br>Germany |
| <b>urokinase vs no fibrinolysis</b>                         |  |   |  |
| Kiil , 1981<br>n=20<br>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<br>Double blind<br>Denmark |
| Schweizer (urokinase) , 1998<br>n=NA<br>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<br>single blind<br>Germany |
| Schweizer (local urokinase) , 2000<br>n=NA<br>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<br>single blind<br>Germany |
| Schweizer (systemic urokinase) , 2000<br>n=NA<br>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<br>single blind<br>Germany |

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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><br>n=NA<br>follow-up: | streptokinase 500,000 U IV over 30 minutes, 900,000 U every 6 hours for 5 days<br>versus<br>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<br>single blind<br>UK     |
| <b>streptokinase vs no fibrinolysis</b>            |   |  |   |
| <b>Arneson , 1978</b><br>n=43<br>follow-up:        | streptokinase 250,000 U loading IV, then 100,000 IU/hour IV 72-96 hours<br>versus<br>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<br>single blind<br>Norway |
| <b>Common , 1976</b><br>n=50<br>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<br>versus<br>IV heparin 150 U/kg loading dose then titrated for 10 days  | patients with venographically confirmed DVT duration <14 days  | Parallel groups<br>single blind<br>US     |
| <b>Elsharawy , 2002</b><br>n=35<br>follow-up:      | catheter-directed thrombolysis with streptokinase using popliteal approach.<br>versus<br>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<br>single blind<br>Egypt  |
| <b>Schulman , 1986</b><br>n=38<br>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<br>versus<br>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<br>single blind<br>Sweden |
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continued...

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| <b>tPA vs no fibrinolysis</b>                        |   |  |   |
| Goldhaber (tPA alone) , 1990<br>n=NA<br>follow-up:   | tPA alone 0.05 mg/kg/hour IV over 24 hours, then heparin 100U/kg bolus, then 1000 U/hour, adjusted<br>versus<br>heparin alone 100 U/kg bolus, then 1000 U/hour  | venographically documented DVT, in popliteal or more proximal veins <14 days duration  | Parallel groups<br>single blind<br>US                           |
| Schweizer (local tPA) , 2000<br>n=NA<br>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<br>versus<br>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<br>single blind<br>Germany                      |
| Turpie , 1990<br>n=83<br>follow-up:                  | tPA + IV heparin<br>versus<br>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<br>double blind<br>Canada                       |
| Verhaeghe (high dose) , 1989<br>n=NA<br>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<br>versus<br>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<br>double blind<br>France, Belgium, Switzerland |
| Goldhaber (tPA+heparin) , 1990<br>n=NA<br>follow-up: | tPA 0.05 mg/kg/hour IV over 24 hours and heparin 100U/kg bolus, then 1000 U/hour, adjusted<br>versus<br>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<br>single blind<br>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><br>n=20<br>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)<br>versus<br>heparin 40,000 U/day IV for 6 days (+placebo)  | patients with venographically confirmed DVT duration <72 hours   | Parallel groups<br>Double blind<br>Denmark                      |
| <b>Schweizer (urokinase) , 1998</b><br>n=NA<br>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<br>versus<br>heparin IV, adjusted for 7 days   | patients with venographically confirmed DVT of leg duration <7 days  | Parallel groups<br>single blind<br>Germany                      |
| <b>Schweizer (local urokinase) , 2000</b><br>n=NA<br>follow-up:    | Local urokinase 100,000 IU/day infused continuously. Fibrinogen and plasminogen monitored. Heparin IV given concomitantly<br>versus<br>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<br>single blind<br>Germany                      |
| <b>Schweizer (systemic urokinase) , 2000</b><br>n=NA<br>follow-up: | Systemic urokinase 5,000,000 IU/day over 4 hours for up to 7 days. IV heparin given concomitantly<br>versus<br>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<br>single blind<br>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.

TrialResults-center is non-profit and self-funded.