

Clinical trials of TP

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1 obesity and overweight

| Trial | Treatments | Patients | Trials design and methods |
|--|--|----------|---------------------------|
| PHEN/TPM high dose vs placebo | | | |
| CONQUER (high-dose) (OB 303) [NCT00553787] n=995/994 follow-up: 56 weeks | PHEN/TPM 15/92 mg versus placebo | | |
| OB 301 (high-dose) <i>unpublished</i> n=108/109 follow-up: 28 weeks | PHEN/TPM 15/92 mg versus placebo | | |
| OB 302 (high-dose) <i>unpublished</i> n=512/514 follow-up: 56 weeks | PHEN/TPM 15/92 mg versus placebo | | |
| PHEN/TPM low-dose vs placebo | | | |
| OB 302 (low-dose) <i>unpublished</i> n=241/514 follow-up: 56 weeks | PHEN/TPM 3.75/23 mg versus placebo | - | |
| PHEN/TPM mid-dose vs placebo | | | |
| CONQUER (mid-dose) (OB 303) [NCT00553787] n=498/994 follow-up: 56 weeks | PHEN/TPM 7.5/46 mg versus placebo | - | |
| OB 301 (mid-dose) <i>unpublished</i> n=107/109 follow-up: 28 weeks | PHEN/TPM 7.5/46 mg versus placebo | - | Parallel groups |

More details and results :

- All mechanism for obesity and overweight in all type of patients at <http://www.trialresultscenter.org/go-Q265>

References

CONQUER (high-dose) (OB 303), 0:

Gadde KM, Allison DB, Ryan DH, Peterson CA, Troupin B, Schwiers ML, Day WW Effects of low-dose, controlled-release, phentermine plus topiramate combination on weight and associated comorbidities in overweight and obese adults (CONQUER): a randomised, placebo-controlled, phase 3 trial. Lancet 2011;377:1341-52 [21481449] [10.1016/S0140-6736\(11\)60205-5](https://doi.org/10.1016/S0140-6736(11)60205-5)

OB 301 (high-dose), 0:

unpublished

OB 302 (high-dose), 0:

unpublished

OB 302 (low-dose), 0:

unpublished

CONQUER (mid-dose) (OB 303), :

Gadde KM, Allison DB, Ryan DH, Peterson CA, Troupin B, Schwiers ML, Day WW Effects of low-dose, controlled-release, phentermine plus topiramate combination on weight and associated comorbidities in overweight and obese adults (CONQUER): a randomised, placebo-controlled, phase 3 trial. Lancet 2011;377:1341-52 [21481449] [10.1016/S0140-6736\(11\)60205-5](https://doi.org/10.1016/S0140-6736(11)60205-5)

OB 301 (mid-dose), 0:

unpublished

2

2 thrombosis prevention

| Trial | Treatments | Patients | Trials design and methods |
|---|---|-------------------------------|---------------------------|
| Footpump (monotherapy) vs control | | | |
| Scurr , 1981 n=33/33 follow-up: | Plantar flexion and dorsiflexion of the feet while the patient is on the operating table by the use of a mechanical device (the Pedi-Pulsor) versus control | abdominal or thoracic surgery | open |
| Wilson , 1992 n=28/32 | - | Elective knee replacement | open |
| Footpump vs LMWH | | | |
| Stone , 1996 n=NA follow-up: | intermittent pneumatic calf compression versus Enoxaparin | total hip replacement | Parallel groups open |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|--|--|--|--|
| Warwick , 1998 n=143/147 follow-up: 8 days | A-V Impulse System foot pump versus LMWH | primary total hip replacement | Parallel groups open |
| Blanchard , 1999 n=130 follow-up: 12 days | continuous intermittent pneumatic compression of the foot by means of the arteriovenous impulse system versus one daily subcutaneous injection of nadroparin calcium (dosage adapted to body-weight) | patients undergoing total knee arthroplasty | Parallel groups open (blinded assessment) |
| Footpump (adjunctive therapy) vs UFH then aspirin | | | |
| Stannard (vs UFH+asp) , 1996 n=25/25 follow-up: | intermittent pulsatile pneumatic-pump compression of the plantar venous plexus versus UFH followed by aspirin | patients undergoing elective total hip replacement arthroplasty | Parallel groups open |

More details and results :

- mechanical devices for thromboprophylaxis for thrombosis prevention in all type of patients at <http://www.trialresultscenter.org/go-Q402>

References

Scurr, 1981:

Scurr JH, Robbe IJ, Ellis H, Goldsmith HS Simple mechanical method for decreasing the incidence of thromboembolism. Am J Surg 1981;141:582-5 [7223954]

Wilson, 1992:

Wilson NV, Das SK, Kakkar VV, Maurice HD, Smibert JG, Thomas EM, Nixon JE Thrombo-embolic prophylaxis in total knee replacement. Evaluation of the A-V Impulse System. J Bone Joint Surg Br 1992 Jan;74:50-2 [1732265]

Stone, 1996:

Stone MH, Limb D, Campbell P, Stead D, Culleton G A comparison of intermittent calf compression and enoxaparin for thromboprophylaxis in total hip replacement. A pilot study. Int Orthop 1996;20:367-9 [9049766]

Warwick, 1998:

Warwick D, Harrison J, Glew D, Mitchelmore A, Peters TJ, Donovan J Comparison of the use of a foot pump with the use of low-molecular-weight heparin for the prevention of deep-vein thrombosis after total hip replacement. A prospective, randomized trial. J Bone Joint Surg Am 1998 Aug;80:1158-66 [9730125]

Blanchard, 1999:

Blanchard J, Meuwly JY, Leyvraz PF, Miron MJ, Bounameaux H, Hoffmeyer P, Didier D, Schneider PA Prevention of deep-vein thrombosis after total knee replacement. Randomised comparison between a low-molecular-weight heparin (nadroparin) and mechanical prophylaxis with a foot-pump system. J Bone Joint Surg Br 1999;81:654-9 [10463739]

Stannard (vs UFH+asp), 1996:

Stannard JP, Harris RM, Bucknell AL, Cossi A, Ward J, Arrington ED Prophylaxis of deep venous thrombosis after total hip arthroplasty by using intermittent compression of the plantar venous plexus. Am J Orthop (Belle Mead NJ) 1996;25:127-34 [8640382]

3 venous thrombosis

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---|
| tPA vs no fibrinolysis | | | |
| 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 |
| tPA+heparin vs no fibrinolysis | | | |
| 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]

Hirsh J. Thrombolytic therapy for venous thrombosis and pulmonary embolism Thrombosis Haemostasis 1989;62(1):547-Abstract No 1739

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]

4 pulmonary embolism

| Trial | Treatments | Patients | Trials design and methods |
|--|--|--|--|
| outpatient treatment vs inpatient treatment | | | |
| OTPE (Aujesky) , 2011 [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 |
| Otero , 2010 [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, phentermine and topiramate, Qnexa