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OB 301 (high-dose) *unpublished* n=108/109 follow-up: 28 weeks	PHEN/TPM 15/92 mg versus placebo		
OB 302 (high-dose) *unpublished* n=512/514 follow-up: 56 weeks	PHEN/TPM 15/92 mg versus placebo		
PHEN/TPM low-dose vs placebo			
OB 302 (low-dose) *unpublished* n=241/514 follow-up: 56 weeks	PHEN/TPM 3.75/23 mg versus placebo	-	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OB 301 (mid-dose) *unpublished* n=107/109 follow-up: 28 weeks	PHEN/TPM 7.5/46 mg versus placebo	-	Parallel groups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

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unpublished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unpublished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unpublished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

OB 301 (mid-dose), 0:

unpublished

2 DVT prophylaxis

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 remplacement	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 DVT prophylaxis 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 heparin100U/kg bolus, then 1000 U/hour, adjusted versus heparin alone 100 U/kg bolus, then 1000 U/hour	venographically documented DVT, in popliteal ormore 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 ormore 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

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

Otero, 2010:

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

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