Assessment of benefits and risks of an additional 18-month treatment with warfarin versus placebo in patients with a first unprovoked proximal deep-vein thrombosis initially treated for 6 months

Multicenter, randomized, double-blind, controlled trial

104 patients with an unprovoked proximal deep-vein thrombosis initially treated for 6 months

104 patients with an unprovoked proximal deep-vein thrombosis initially treated for 6 months			
	warfarin	placebo	
	Os	Pa	~17 months treatment
	50	54	~24 months follow-up
Primary outcome			
 Composite of recurrent venous thromboembolism or major bleeding at 18 months 	0/50	16/54	
Cumulative risk	-	29.6%	HR, 0.03; 95% CI, 0.01-0.51 p<0.001
Secondary outcome			
Composite of recurrent venous thromboembolism or major bleeding during the 24-month follow-up	14/50	17/54	
Cumulative risk	36.8%	31.5%	HR, 0.72; 95% CI, 0.35-1.46

After a first unprovoked proximal deep-vein thrombosis treated during 6 months, an additional 18 months of warfarin therapy reduced the composite of recurrent venous thrombosis and major bleeding compared to placebo