Clinical trials of antithrombotics for venous thrombosis in secondary prevention of VTE

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1 anticoagulant

Trial	Treatments	Patients	Trials design and methods
warfarin vs discontinuation			
PROLONG (Palareti) , 2006 [NCT00264277] n=105/122 follow-up: 1.4 yeras	prolongation versus no anticoagulation	patients with an abnormal d-dimer level 1 month after the discontinuation of anticoagulation in patients with a first unprovoked proximal deep-vein thrombosis or pulmonary embolism who had received a vitamin K antagonist for at least 3 months	Parallel groups
PREVENT (Ridker) , 2003 n=255/253 follow-up: 2.1 years	extension with low-intensity warfarin (target INR, 1.5 to 2.0) versus placebo	Patients with idiopathic venous thromboembolism who had received full-dose anticoagulation therapy for a median of 6.5 months	Parallel groups
Agnelli , 2003 n=NA follow-up: 33 months	continuation for 3 or 9 additionnal months of warfarin or other oral anticoagulant was adjusted to achieve a target INR between 2.0 and 3.0. versus discontinuation (after 3 months)	patients who had had 3 months of oral anticoagulant therapy without experiencing recurrence or bleeding after a first episode of pulmonary embolism	Parallel groups open Italy
Agnelli , 2001 n=NA follow-up: 33 months	continuation for 9 additional months; warfarin or acenocoumarol adjusted to achieve a target INR between 2.0 and 3.0 versus discontinuation (after 3 months months)	Patients with a first episode of idiopathic proximal deep venous thrombosis who had completed three months of oral anticoagulant therapy	Parallel groups open Italy
LAFIT (Kearon) , 1999 n=NA follow-up:	Continuation of the oral anticoagulant therapy up to 24 months, warfarin was adjusted to achieve a target INR between 2.0 and 3.0. versus discontinuation (after 3 months)	patients who had completed 3 months of anticoagulant therapy for a first episode of idiopathic venous thromboembolism	
Levine , 1995 n=NA follow-up: 11 months after randomization.	continuation for 2 months of warfarin adjusted INR value of 2.0 to 3.0 versus Discontinue oral anticoagulant therapy (after 1 months)	Patients with venographically confirmed acute proximal DVT who had received four weeks of warfarin after initial heparin and whose four week IPG was normal	Parallel groups double blind Canada, Italy

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Trial	Treatments	Patients	Trials design and methods
DURAC (Schulman) , 1997 n=NA follow-up: Four years after randomization	indefinite warfarin or dicoumarol adjusted for a target INR between 2.0 and 2.85 versus 6 months warfarin or dicoumarol adjusted for a target INR between 2.0 and 2.85	-	Parallel groups open Sweden

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2 antiplatelet

Trial	Treatments	Patients	Trials design and methods
aspirin vs discontinuation			
WARFASA , 2012 [NCT00222677] n=205/197 follow-up: 24.6 mo (median)	aspirin, 100 mg daily for 2 years versus placebo	patients with first-ever unprovoked venous thromboembolism who had completed 6 to 18 months of oral anticoagulant treatment	Parallel groups double-blind

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Trial	Treatments	Patients	Trials design and methods
ASPIRE , 2012 [ACTRN12605000004662] n=411/411 follow-up: 37.2 montsh (median)	-	patients who had completed initial anticoagulant therapy after a first episode of unprovoked venous thromboembolism	

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3 direct anti-Xa

Trial	Treatments	Patients	Trials design and methods
apixaban 2.5mg vs discontinuation			
AMPLIFY-EXT 2.5mg , 2012 [NCT00633893] n=842/829 follow-up: 12 mo	Extended Treatment with apixaban 2.5 mg twice daily 12 months versus placebo	patients who have completed their intended treatment for deep vein thrombosis or pulmonary embolism	Parallel groups double blind
apixaban 5mg vs discontinuation			
AMPLIFY-EXT 5mg , 2012 [NCT00633893] n=815/829 follow-up: 12 mo	Extended Treatment with apixaban 5 mg twice daily 12 months versus placebo	patients who have completed their intended treatment for deep vein thrombosis or pulmonary embolism	double blind
rivaroxaban vs discontinuation			
EINSTEIN-extension , 2009 [NCT00439725] n=602/595 follow-up:	rivaroxaban 20 mg once-daily for an additional 6 or 12 months versus placebo	patients who had completed six to 12 months of anticoagulant treatment for an acute episode of VTE	Parallel groups double blind 28 countries

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4 oral direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
dabigatran vs warfarin			
RE-MEDY , 2011 [NCT00329238] n=1430/1426 follow-up: 6 to 36 months	dabigatran 150 mg twice daily for an additional period of 6 to 36 months versus warfarin (to maintain an international normalized ratio of 2.0 to 3.0) for an additional period of 6 to 36 months	Secondary prevention of VTE in patients with VTE who had initially received 3 to 12 months of anticoagulant therapy	Parallel groups double-blind
dabigatran vs discontinuation			
RE-SONATE , 2011 [NCT00558259] n=681/662 follow-up:	dabigatran 150 mg twice daily for an additional period of 6 months versus placebo	Secondary prevention of VTE in patients with VTE who had completed 6-18 months of anticoagulant therapy	Parallel groups double-blind
ximelagatran vs discontinuation			
THRIVE III , 2003 n=612/611 follow-up: 18 months	ximelagatran 24 mg twice daily for 18 months versus placebo for 18 months	patients with venous thromboembolism who had undergone six months of anticoagulant therapy	Parallel groups double blind 18 countries

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5 synthetic pentasaccharide

Trial	Treatments	Patients	Trials design and methods
idraparinux vs discontinuation			
VanGogh extension , 2007 [NCT00071279] n=594/621 follow-up: 6 months	once-weekly injections of 2.5 mg of idraparinux for 6 months versus placebo	patients who had completed 6 months of prophylaxis with idraparinux or a vitamin K antagonist and in whom extended anticoagulation was warranted	Parallel groups

References

VanGogh extension, 2007:

6 About TrialResults-center.org

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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.

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