

# Clinical trials of antithrombotics for venous thrombosis in patients with cancer

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## 1 extended LMWH

Trial	Treatments	Patients	Trials design and methods
<b>extended dalteparin vs standard treatment</b>			
<b>CLOT (Lee) , 2003</b> n=NA follow-up: 6 months	Dalteparin 200 IU/kg daily for 1 month followed by 150 IU/kg daily for 5 months versus Dalteparin 200 IU/kg daily for 5-7 days followed by warfarin or acecumarol (target INR 2-3) for 6 months	patients with active cancer and with DVT or pulmonary embolism or both, and ECOG 1 or 2	Parallel groups outcome assessment blinded
<b>extended enoxaparin vs standard treatment</b>			
<b>Cesarone , 2003</b> n=NA follow-up: 3 months	Enoxaparin 100UL/Kg twice daily for 3 months versus coumadin (target INR 3) for 3 months.	patients with cancer with DVT	Parallel groups NA
<b>Deitcher , 2006</b> n=NA follow-up: 12 months	Enoxaparin 1mg/kg twice daily for 5 days followed by 1-1.5mg/kg daily for 175 days versus Enoxaparin 1mg/kg twice daily for 5 days followed by warfarin (target INR 2-3) for a total of 180 days	patients with cancer with DVT and/or PE	Parallel groups none
<b>Meyer , 2002</b> n=NA follow-up: 3 months	Enoxaparin 1.5 mg/kg daily for 3 monthsmag versus Enoxaparin 1.5 mg/kg daily for 4 days followed by warfarin (target INR 2-3) for 3 months	patients with cancer (solid or hematological; active or in remission but on treatment); with pulmonary embolism and/or DVT and a minimum life expectancy of 3 months	Parallel groups outcome assessment blinded
<b>extended nadroparin vs standard treatment</b>			
<b>Lopez Beret , 2001</b> n=NA follow-up: 12 months	Nadroparin 1.025 antiXa IU/10Kg twice daily after aadroparin 1.025AXa IU/10Kg twice daily for 3 days. After 3 months, nadroparin was switched to once daily versus acenocoumarol (target INR 2-3) for 3-6 months after nadroparin 1.025AXa IU/10Kg twice daily for 3 days	patients with known malignancy treated for symptomatic DVT of the lower limb	Parallel groups outcome assessment blinded
<b>extended tinzaparin vs standard treatment</b>			
<b>Hull , 2006</b> n=NA follow-up: 3 months	Tinzaparin 175 antiXa/kg SQ daily for 12 weeks versus UFH for 5 days followed by vitamin K antagonist (target INR 2-3) for 12 weeks	patients with cancer (solid or hematological) with proximal DVT with or without PE and with a minimum life expectancy of 3 months imag	Parallel groups outcome assessment blinded

## References

### CLOT (Lee), 2003:

Lee AY, Levine MN, Baker RI, Bowden C, Kakkar AK, Prins M, Rickles FR, Julian JA, Haley S, Kovacs MJ, Gent M Low-molecular-weight heparin versus a coumarin for the prevention of recurrent venous thromboembolism in patients with cancer. *N Engl J Med* 2003;349:146-53 [[12853587](#)]

### Cesarone, 2003:

Cesarone MR, Ledda A, Nicolaides A, Belcaro G, Geroulakos G.s=40 Three-month, outpatient, oral anticoagulant treatment in comparison with low-molecular-weight heparin in cancer patients Supplement to *Circulation*. 2003; Vol. 108, issue 17:Abstract 2875.

### Deitcher, 2006:

Deitcher SR, Kessler CM, Merli G, Rigas JR, Lyons RM, Fareed J Secondary prevention of venous thromboembolic events in patients with active cancer: enoxaparin alone versus initial enoxaparin followed by warfarin for a 180-day period. *Clin Appl Thromb Hemost* 2006;12:389-96 [[17000884](#)]

### Meyer, 2002:

Meyer G, Marjanovic Z, Valcke J, Lorcerie B, Gruel Y, Solal-Celigny P, Le Maignan C, Extra JM, Cottu P, Farge D Comparison of low-molecular-weight heparin and warfarin for the secondary prevention of venous thromboembolism in patients with cancer: a randomized controlled study. *Arch Intern Med* 2002;162:1729-35 [[12153376](#)]

### Lopez Beret, 2001:

Lpez-Beret P, Orgaz A, Fontcuberta J, Doblaz M, Martinez A, Lozano G, Romero A Low molecular weight heparin versus oral anticoagulants in the long-term treatment of deep venous thrombosis. *J Vasc Surg* 2001;33:77-90 [[11137927](#)]

### Hull, 2006:

Hull RD, Pineo GF, Brant RF, Mah AF, Burke N, Dear R, Wong T, Cook R, Solymoss S, Poon MC, Raskob G Long-term low-molecular-weight heparin versus usual care in proximal-vein thrombosis patients with cancer. *Am J Med* 2006;119:1062-72 [[17145251](#)]

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## 2 idraparinux

Trial	Treatments	Patients	Trials design and methods
<b>idraparinux vs standard treatment</b>			
<b>Van Gogh (subgroup) , 2011</b> n=220/201 follow-up: 6 months	once-weekly subcutaneous injection of idraparinux (2.5 mg) for 6 months versus standard treatment for three months (8% ) or six months (92% )	non-active and active cancer patients with deep venous thrombosis and without pulmonary embolism, included in the Van Gogh DVT clinical trial	Parallel groups

## References

### Van Gogh (subgroup), 2011:

van Doormaal FF, Cohen AT, Davidson BL, Decousus H, Gallus AS, Gent M, Piovella F, Prins MH, Raskob GE, Bller HR Idraparinux versus standard therapy in the treatment of deep venous thrombosis in cancer patients: a subgroup analysis of the Van Gogh DVT trial. *Thromb Haemost* 2010;104:86-91 [[20508907](#)] [10.1160/TH09-12-0870](#)

## 3 LMWH

Trial	Treatments	Patients	Trials design and methods
<b>tinzaparin vs dalteparin</b>			
Wells (subgroup) , 2005 n=NA follow-up: 3 months	Tinzaparin 175 IU/kg SQ daily (warfarin started simultaneously and continued for 90 days) versus dalteparin 200 IU/kg daily for at least 5 days ((warfarin started simultaneously and continued for 90 days)	study subgroup of patients with cancer treated for upper or lower extremity DVT or PE in the outpatient setting	Parallel groups outcome assessment blinded

## References

### Wells (subgroup), 2005:

Wells PS, Anderson DR, Rodger MA, Forgie MA, Florack P, Touchie D, Morrow B, Gray L, O'Rourke K, Wells G, Kovacs J, Kovacs MJ A randomized trial comparing 2 low-molecular-weight heparins for the outpatient treatment of deep vein thrombosis and pulmonary embolism. Arch Intern Med 2005;165:733-8 [[15824291](#)]

## 4 oral direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
<b>ximelagatran vs placebo</b>			
Schulman (subgroup) , 2003 n=NA follow-up: 18 months	extended treatment with Ximelagatran 24mg twice daily after initial anticoagulant treatment for 6 months versus placebo (initial anticoagulant treatment for 6 months)	study subgroup of patients with active cancer in the previous 5 years treated for DVT or pulmonary embolism for 6 months without recurrence	Parallel groups single blind and outcome ass.

## References

### Schulman (subgroup), 2003:

Schulman S, Whlander K, Lundstrm T, Clason SB, Eriksson H Secondary prevention of venous thromboembolism with the oral direct thrombin inhibitor ximelagatran. N Engl J Med 2003;349:1713-21 [[14585939](#)]

## 5 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.

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