

# Clinical trials of LMWH for venous thrombosis in all type of patients

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## 1 extended LMWH

Trial	Treatments	Patients	Trials design and methods
<b>Enoxaparin vs acenocoumarol</b>			
Veiga , 2000 n=50/50 follow-up: 6-9 mo	UFH, APTT 1.52.0d followed by Enoxaparin 4,000 IU qd versus UFH, APTT 1.52.0d followed by Acenocoumarol target INR 2-3	patients with objective diagnosis of DVT by Venography	open
<b>Nadroparin vs acenocoumarol</b>			
Lopez-Beret , 2001 n=81/77 follow-up: 6-9 mo	LMWH, 1,025 IU/10 kg bid followed by Nadroparin 1,025 IU/10 kg bid versus LMWH, 1,025 IU/10 kg bid followed by Acenocoumarol target INR 2-3	patients with objective diagnosis of DVT by compression ultrasonography	open
Lopaciuk , 1999 n=101/101 follow-up: 9 mo	LMWH, 85 UI/kg bid followed by Nadroparin 85 IU/kg qd versus LMWH, 85 UI/kg bid followed by Acenocoumarol target INR 2-3	patients with objective diagnosis of DVT by Venography	open
<b>Tinzaparin vs acenocoumarol</b>			
Romera , 2009 n=119/122 follow-up: 12 months	tinzaparin SC 175 IU anti-Xa per kg once daily for 6 months versus acenocoumarol for target INR 2-3 for 6 months after initial LMWH (until INR 2-3)	patients with symptomatic proximal DVT of the lowerlimbs confirmed by compression duplex ultrasound scan	Parallel groups open Spain
<b>Enoxaparin vs coumarin</b>			
Gonzlez-Fajardo , 2008 n=85/80 follow-up: 1y, 5y	long-term anticoagulant treatment with enoxaparin during at least 3 months versus long-term anticoagulant treatment with coumarin during at least 3 months	patients with symptomatic, unilateral, first-episode DVT	Parallel groups open, blind assessment Spain
<b>Bemiparin vs warfarin</b>			
Kakkar , 2003 n=221/103 follow-up: 3 mo	LMWH, 115 IU/kg qd followed by Bemiparin 3,500 IU qd versus A: UFH, 30/40,000IU qd; B: LMWH, 115 IU/kg qd followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT by Venography/compression ultrasonography	open
<b>Dalteparin vs warfarin</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Lee , 2003</b> n=336/336 follow-up: 6 mo	LMWH, 200 IU/kg qd followed by Dalteparin 150 IU/kg qd versus LMWH, 200 IU/kg qd followed by Warfarin target INR 2-3	patients with cancer and objective diagnosis of DVT by Venography/compression ultrasonography	open
<b>Das , 1996</b> n=50/55 follow-up: 3 mo	UFH followed by Dalteparin 5,000 IU qd versus UFH followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT by Venography	open
<b>Enoxaparin vs warfarin</b>			
<b>Deitcher , 2003</b> n=51/30 follow-up: 6 mo	LMWH: 1a, 1 mg/kg q12h; 1b, 1 mg/kg qd12h followed by Enoxaparin 1a: 1 mg/kg qd; 1b: 1.5 mg/kg qd versus LMWH, 1 mg/kg q12h followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT	open
<b>Meyer , 2002</b> n=71/58 follow-up: 3 mo	LMWH, 1.5 mg/kg qd followed by Enoxaparin 1.5 mg/Kg qd versus LMWH, 1.5 mg/kg qd followed by Warfarin target INR 2-3	patients with cancer and objective diagnosis of DVT by Venography/compression ultrasonography	open
<b>Gonzalez-Fajardo , 1999</b> n=93/92 follow-up: 9 mo	LMWH, 4,000 IU bid followed by Enoxaparin 4,000 IU qd versus UFH followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT by Venography	Parallel groups open
<b>Pini , 1994</b> n=93/94 follow-up: 9 mo	UFH, APTT 1.31.9 followed by Enoxaparin 4,000 IU qd versus UFH, APTT 1.31.9 followed by Warfarin target INR 2-3.5	patients with objective diagnosis of DVT by Venography (diagnosed by strain-gauge plethysmography plus D-dimer latex assay and confirmed by venography)	open
<b>Tinzaparin vs warfarin</b>			
<b>Hull , 2002</b> n=369/368 follow-up: 9 mo	LMWH, 175 IU/kg qd followed by Tinzaparin 175 IU/kg qd versus UFH 5 d, followed by UFH therapeutic APTT followed by Warfarin target INR 2-3	patients with objective diagnosis of DVT by Venography/compression ultrasonography	open

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## 2 home treatment

Trial	Treatments	Patients	Trials design and methods
<b>LMWH at home vs UFH in hospital</b>			
Koopman , 1996 n=202/198 follow-up: 12 weeks	home treatment with twice daily injections of nadroparin at a dose adjusted for patients weight; versus UH (APTT adjusted dose, continuous intravenous infusion of 1250 IU per hour after initial intravenous bolus of 5000 IU) in hospital.	patients with acute symptomatic proximal DVT proven by venography or duplex scan	Parallel groups open The Netherlands, France, Italy, New Zealand Australia
Boccalon , 2000 n=99/101 follow-up: 6 months	home treatment with sub-cutaneous injection of LMWH (dalteparin sodium, enoxaparin sodium or nadroparin calcium as chosen by the attending physician) at the recommended dose followed by anticoagulant for 6 months versus Sub-cutaneous injection of LMWH (dalteparin sodium, enoxaparin sodium or nadroparin calcium as chosen by attending physician) at the recommended dose followed by anticoagulant for 6 months initially in hospital for 10 +/- 2 days then at home	patientst with confirmed diagnosis (by ultrasonography or venography) of proximal DVT not more than 30 days before enrolment	Parallel groups NA France
Levine , 1996 n=247/253 follow-up: 90 days	home treatment by Sub-cutaneous enoxaparin 1 mg per kg body weight twice a day for at least 5 days versus UH (APTT adjusted dose, continuous intravenous infusion of 20,000 IU after initial intravenous bolus of 5000 IU) in hospital for at least 5 days	patients with acute proximal DVT proven on venography or duplex scan	Parallel groups open Canada
Ramacciotti , 2004 n=104/97 follow-up:	home treatment by once daily Subcutaneous injection of enoxaparin at a dose of 1.5 mg/kg for 5-10 days versus in hospital intravenous bolus injection of 5000 IU of UFH followed by intravenous 500 IU/kg/day adjusted to maintain an aPTT of 1.5-2.5 times the normal value for 5-10 days.	patientst with DVT symptoms for greater than or equal to 10 days and proximal lower limb DVT confirmed by duplex ultrasound or venography	Parallel groups open Brazil
Daskalopoulos , 2005 n=55/53 follow-up:	home treatment with single sub- cutaneous injection of LMWH (tinzaparin sodium) in a weight adjusted dose (175 anti Xa IU/Kg) daily for 6 months versus Intravenous bolus of 5000IU UFH followed by intravenous infusion of UFH for 5-7 days. APTT was measured after 4 hours of the initiation of heparin administration and was repeated 6 hours thereafter to reach the therapeutic range (ratio: 1.5-2.5). Oral an	patients with acute proximal DVT confirmed by colour duplex UScan not more than 1 week onset	Parallel groups open Greece

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Trial	Treatments	Patients	Trials design and methods
Chong , 2005 n=150/148 follow-up: 24 months	once daily sub-cutaneous injection of enoxaparin 1.5mg/kg for a minimum of 5 days plus 10mg of warfarin for 3 months adjusted to achieve INR above 2 and within range accepted by the investigator versus 5000 IU bolus of unfractionated heparin (UFH) for a minimum of 5 days plus 10mg warfarin started on day 1 of the treatment for 3 months	patients with diagnosis of symptomatic lower extremity DVT (proximal or distal) confirmed by either contrast venography and/or ultrasonography, be suitable for treatment in an outpatient setting	Parallel groups open Australia, New Zealand, Poland, South Africa

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## 3 Low molecular weight heparin

Trial	Treatments	Patients	Trials design and methods
<b>Dalteparin vs unfractionated heparin</b>			
Holm et al , 1986 n=29/27 follow-up: Hospital Stay	Dalteparin Subcutaneous twice daily adjusted for 7 Days, 57-107 U/kg BID versus unfractionated heparin subcutaneous twice daily 16000-30000 U	-	
Bratt et al , 1985 n=25/29 follow-up: 23 Months (mean)	Dalteparin Intravenous (adjusted) for $\geq 5$ Days, 120 U/kg BID versus unfractionated heparin intravenous APPTx1.7-3.5	-	
Bratt et al , 1990 n=60/60 follow-up: 65279;Hospital stay	Dalteparin Subcutaneous twice daily adjusted for $\geq 5$ Days, 120 U/kg BID versus unfractionated heparin intravenous APPTx2-4	-	
Lindmarker et al , 1993 n=101/103 follow-up: 6 Months	Dalteparin Subcutaneous once daily for $\geq 5$ Days, 200 U/kg BID versus unfractionated heparin intravenous APPTx1.5-3	-	
<b>Enoxaparin vs unfractionated heparin</b>			
Simonneau et al , 1993 n=67/67 follow-up: 3 Months	Enoxaparin Subcutaneous twice daily for 0 Days, 100 U/kg BID versus unfractionated heparin intravenous APPTx1.5-2.5	-	
<b>Minoctoparine vs unfractionated heparin</b>			
Faivre et al , 1988 n=33/37 follow-up: 10 Days	Minoctoparine (CY222) Subcutaneous twice daily for 10 Days, 155 U/kg BID versus unfractionated heparin subcutaneous twice daily APPTx2-3	-	
<b>Nadroparin vs unfractionated heparin</b>			
Collaborative European Multicentre , 1991 n=70/66 follow-up: 12 Weeks	Nadroparin Subcutaneous twice daily for 10 Days, 90 U/kg BID versus unfractionated heparin intravenous APPTx1.5-2	-	
Prandoni et al , 1992 n=85/85 follow-up: 6 Months	Nadroparin Subcutaneous twice daily for $\geq 0$ Days, 90 U/kg BID versus unfractionated heparin intravenous APPTx1.5-2	-	

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Trial	Treatments	Patients	Trials design and methods
Lopaciuk et al , 1992 n=74/75 follow-up: 3 Months	Nadroparin Subcutaneous twice daily for 10 Days, 92 U/kg BID versus unfractionated heparin subcutaneous twice daily APPTx1.5-2.5	-	
<b>Tinzaparin vs unfractionated heparin</b>			
Hull et al , 1992 n=213/219 follow-up: 3 Months	Tinzaparin Subcutaneous once daily for >= Days, 175 U/kg BID versus unfractionated heparin intravenous APPTx2-3	-	

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## 4 once daily LMWH

Trial	Treatments	Patients	Trials design and methods
<b>once daily dalteparin vs twice daily dalteparin</b>			
Holmstrm , 1992 n=50/51 follow-up:	once daily dalteparin 200 U (anti-FXa)/kg for at least 5 days versus twice daily dalteparin 100 U (anti-FXa)/kg for at least 5 days	Patients with a first occurrence of DVT in the lower limb, confirmed with phlebography	Parallel groups open Sweden
Partsch , 1996 n=76/64 follow-up:	Fragmin administered 200 IU/kg once daily for at least 7 days versus Fragmin 100 IU/kg twice daily for at least 7 days	patients presented with DVT extending into the iliofemoral segment diagnosed by duplex ultrasonography	Parallel groups NA Austria
<b>once daily enoxaparin vs twice daily enoxaparin</b>			
Merli , 2001 n=298/312 follow-up:	enoxaparin 1.5 mg/kg body weight once daily versus S.c. enoxaparin at fixed dosages of 1.0 mg/kg of body weight twice daily	patients with a symptomatic lower-extremity DVT confirmed by venography or ultrasonography (including patients with confirmed PE)	Parallel groups double blind Europe, United States of America and Australia, image/pj
<b>once daily logiparin vs twice daily logiparin</b>			
Siegbahn , 1989 n=10/10 follow-up:	Once daily logiparin 150 XaI U/kgp, imag versus twice daily logiparin 75 XaI U/kg	patients with a venographically confirmed episode of DVT	Parallel groups single blind Sweden and Denmark
<b>once daily nadroparin vs twice daily nadroparin</b>			
Charbonnier , 1998 n=316/335 follow-up:	Once daily nadroparin 20,500 (AXa IU/ml)continued for at least 5 days versus twice daily nadroparin 10,250 (AXa IU/ml)continued for at least 5 days	patients with acute symptomatic proximal DVT in popliteal vein or above documented by venography	Parallel groups double blind Europe
<b>once daily enoxaparin vs UFH</b>			
Merli (once daily vs UFH) , 2001 n=298/290 follow-up: 3 months	Initial therapy with enoxaparin 1.5 mg/kg body weight once daily versus Initial therapy with dose-adjusted intravenous unfractionated heparin	patients with a symptomatic lower-extremity DVT confirmed by venography or ultrasonography (including patients with confirmed PE)	Parallel groups partially blinded Europe, United States of America and Australia, image/pj

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## 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.

TrialResults-center is non-profit and self-funded.