

# Clinical trials of LMWH at home

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## 1 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
<b>LMWH at home vs UFH in hospital</b>			
<a href="#">Koopman , 1996</a> 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
<a href="#">Boccalon , 2000</a> 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 6months 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
<a href="#">Levine , 1996</a> 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

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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
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 extrimity DVT (proimal 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

More details and results :

- antithrombotics for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q101>
- LMWH for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q203>
- heparin (UFH or LMWH) for venous thrombosis in all type of patients at <http://www.trialresultscenter.org/go-Q204>

## References

Koopman, 1996:

Koopman MM, Prandoni P, Piovella F, Ockelford PA, Brandjes DP, van der Meer J, Gallus AS, Simonneau G, Chesterman CH, Prins MH Treatment of venous thrombosis with intravenous unfractionated heparin administered in the hospital as compared with subcutaneous low-molecular-weight heparin administered at home. The Tasman Study Group. *N Engl J Med* 1996;334:682-7 [8594426]

van den Belt AG, Bossuyt PM, Prins MH, Gallus AS, Bller HR Replacing inpatient care by outpatient care in the treatment of deep venous thrombosis—an economic evaluation. TASMEN Study Group. *Thromb Haemost* 1998;79:259-63 [9493572]

**Boccalon, 2000:**

Boccalon H, Elias A, Chal JJ, Cadne A, Gabriel S Clinical outcome and cost of hospital vs home treatment of proximal deep vein thrombosis with a low-molecular-weight heparin: the Vascular Midi-Pyrenees study. *Arch Intern Med* 2000;160:1769-73 [10871969]

**Levine, 1996:**

Levine M, Gent M, Hirsh J, Leclerc J, Anderson D, Weitz J, Ginsberg J, Turpie AG, Demers C, Kovacs M A comparison of low-molecular-weight heparin administered primarily at home with unfractionated heparin administered in the hospital for proximal deep-vein thrombosis. *N Engl J Med* 1996;334:677-81 [8594425]

O'Brien B, Levine M, Willan A, Goeree R, Haley S, Blackhouse G, Gent M Economic evaluation of outpatient treatment with low-molecular-weight heparin for proximal vein thrombosis. *Arch Intern Med* 1999;159:2298-304 [10547169]

**Ramacciotti, 2004:**

Ramacciotti E, Arajo GR, Lastoria S, Maffei FH, Karaoglan de Moura L, Michaelis W, Sandri JL, Dietrich-Neto F An open-label, comparative study of the efficacy and safety of once-daily dose of enoxaparin versus unfractionated heparin in the treatment of proximal lower limb deep-vein thrombosis. *Thromb Res* 2004;114:149-53 [15342210]

**Daskalopoulos, 2005:**

Daskalopoulos ME, Daskalopoulou SS, Tzortzis E, Sfridis P, Nikolaou A, Dimitroulis D, Kakissis I, Liapis CD Long-term treatment of deep venous thrombosis with a low molecular weight heparin (tinzaparin): a prospective randomized trial. *Eur J Vasc Endovasc Surg* 2005;29:638-50 [15878544]

**Chong, 2005:**

Chong BH, Brighton TA, Baker RI, Thurlow P, Lee CH Once-daily enoxaparin in the outpatient setting versus unfractionated heparin in hospital for the treatment of symptomatic deep-vein thrombosis. *J Thromb Thrombolysis* 2005;19:173-81 [16082604]