

# Clinical trials of antithrombotics for thrombosis prevention in patients with immobilization of the lower extremities

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## 1 Low molecular weight heparin

Trial	Treatments	Patients	Trials design and methods
<b>certoparin vs control</b>			
Kock , 1995 n=176/163 follow-up: 15 days	Certoparin 3000 IU versus no prophylaxis	patients with minor injuries treated with plaster-cast immobilisation of the leg	Parallel groups open
<b>nadroparin vs control</b>			
Kujath , 1993 n=126/126 follow-up: 65279;16 days	Nadroparin 2850 IU versus no prophylaxis	patients with injuries of the lower limb immobilized by a plaster cast	Parallel groups open
<b>tinzaparin vs control</b>			
Jorgensen , 2002 n=99/106 follow-up: 38 days	Tinzaparin 3500 IU versus no prophylaxis	patients over 18 years of age with planned plaster cast on a lower extremity of at least 3 weeks	Parallel groups open, assessor-blinded
<b>nadroparin vs no treatment</b>			
PROTECT (nadroparin) <i>ongoing</i> [NCT00881088] n=NA follow-up: 6 weeks	nadroparin 0,3 cc daily during immobilization versus no treatment	patients with a nonsurgical fracture of the lower extremity requiring immobilisation in a below-knee plaster cast	Parallel groups single blind
<b>dalteparin vs placebo</b>			
D-KAf (Selby) , 2007 [NCT00187408] n=134/131 follow-up:	dalteparin 5000U daily versus placebo	below-knee fractures repaired surgically	
Lapidus , 2007 n=47/44 follow-up: 43 days	Dalteparin 5000 IU versus Placebo	patients surgically treated for Achilles tendon rupture	Parallel groups double-blind
Lapidus , 2007 n=101/96 follow-up: 44 days	Dalteparin 5000 IU versus Placebo	patients undergoing ankle fracture surgery	Parallel groups double-blind
<b>reviparin vs placebo</b>			
Lassen , 2002 n=183/188 follow-up: 43 days	Reviparin 1750 IU versus Placebo	patients who required immobilization in a plaster cast or brace for at least five weeks after a leg fracture or rupture of the Achilles tendon	Parallel groups double-blind

## References

### Kock, 1995:

Kock HJ, Schmit-Neuerburg KP, Hanke J, Rudofsky G, Hirche H Thromboprophylaxis with low-molecular-weight heparin in outpatients with plaster-cast immobilisation of the leg. *Lancet* 1995;346:459-61 [[7637478](#)]

### Kujath, 1993:

Kujath P, Spannagel U, Habscheid W Incidence and prophylaxis of deep venous thrombosis in outpatients with injury of the lower limb. *Haemostasis* 1993;23 Suppl 1:20-6 [[8388353](#)]

### Jorgensen, 2002:

Jrgensen PS, Warming T, Hansen K, Paltved C, Vibeke Berg H, Jensen R, Kirchhoff-Jensen R, Kjaer L, Kerbouche N, Leth-Espensen P, Narvestad E, Rasmussen SW, Sloth C, Trholm C, Wille-Jrgensen P Low molecular weight heparin (Innohep) as thromboprophylaxis in outpatients with a plaster cast: a venografic controlled study. *Thromb Res* 2002;105:477-80 [[12091045](#)]

### PROTECT (nadroparin), :

### D-KAf (Selby), 2007:

Geerts WH, Pineo GF, Heit JA, Bergqvist D, Lassen MR, Colwell CW, Ray JG Prevention of venous thromboembolism: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest* 2004;126:338S-400S [[15383478](#)] [10.1378/chest.126.3\\_suppl.338S](#)

### Lapidus, 2007:

Lapidus LJ, Rosfors S, Ponzer S, Levander C, Elvin A, Lrfars G, de Bri E Prolonged thromboprophylaxis with dalteparin after surgical treatment of achilles tendon rupture: a randomized, placebo-controlled study. *J Orthop Trauma* 2007;21:52-7 [[17211270](#)] [10.1097/01.bot.0000250741.65003.14](#)

### Lapidus, 2007:

Lapidus LJ, Ponzer S, Elvin A, Levander C, Lrfars G, Rosfors S, de Bri E Prolonged thromboprophylaxis with Dalteparin during immobilization after ankle fracture surgery: a randomized placebo-controlled, double-blind study. *Acta Orthop* 2007;78:528-35 [[17966008](#)] [10.1080/17453670710014185](#)

### Lassen, 2002:

Lassen MR, Borris LC, Nakov RL Use of the low-molecular-weight heparin reviparin to prevent deep-vein thrombosis after leg injury requiring immobilization. *N Engl J Med* 2002;347:726-30 [[12213943](#)] [10.1056/NEJMoa011327](#)

## 2 synthetic oligosaccharide

Trial	Treatments	Patients	Trials design and methods
<b>fondaparinux vs no treatment</b>			
<b>PROTECT (fundaparinux) ongoing</b> [NCT00881088] n=NA follow-up:	fondaparinux 2,5 mg daily group during immobilization versus no treatment	Patients with a nonsurgical fracture of the lower extremity immobilised in a below-knee plaster cast	Parallel groups single blind
<b>fondaparinux vs nadroparin</b>			
<b>FONDACAST ongoing</b> [NCT00843492] n=NA follow-up: 5 weeks	subcutaneously, once daily, fondaparinux 2.5 mg for at least 21 Days, up to complete mobilization, with a maximal duration of treatment of 45 days versus daily nadroparin 2850 anti-Xa IU (0.3 mL) for at least 21 Days, up to complete mobilization	patients requiring rigid or semi-rigid immobilization for at least 21 days and up to 45 days because of isolated non-surgical below-knee injury	Parallel groups open Europe

## References

**PROTECT (fundaparinux), :**

**FONDACAST, :**

## 3 About TrialResults-center.org

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