

Clinical trials of LMWH for DVT prophylaxis in orthopedic surgery

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1 Low molecular weight heparin

Trial	Treatments	Patients	Trials design and methods
nadroparin vs enoxaparin			
FX140, Simonneau G , 2006 n=NA follow-up:	-	-	
semuloparin vs enoxaparin			
SAVE-HIP1 , 2012 [NCT00697099] n=1161/1165 follow-up:	Semuloparin 20 mg once-daily versus Enoxaparin 40 mg once-daily	-	
SAVE-KNEE , 2012 [NCT00718224] n=-576/574 follow-up:	Semuloparin 20 mg once-daily versus Enoxaparin 30 mg twice-daily	-	
SAVE-HIP 2 , 2012 [NCT00721760] n=500/503 follow-up:	Semuloparin 20 mg once-daily versus Enoxaparin 40 mg once-daily	hip fracture surgery	Parallel groups
enoxaparin vs no treatment			
Warwick , 1995 n=78/78 follow-up: 8-10 days	enoxaparin 4000x1 + elastic stockings versus no treatment + elastic stockings	Elective hip	open
nadroparin vs no treatment			
Yoo , 1997 n=50/50 follow-up: 10 days	nadroparin 41/kgx1 days 1-3, 62/kg x1 days 4-11+elastic stockings versus no treatment	Elective hip	open
ardeparin vs placebo			
Levine , 1996 n=122/124 follow-up: 14 days	ardeparin 50/kgx2 +elastic stockings versus Placebo+elastic stockings	Knee	double blind
dalteparin vs placebo			
Jorgensen , 1989 n=30/38 follow-up: 9 days	dalteparin 5000 x1 versus Placebo	Hip fracture	double blind
Torholm , 1991 n=58/54 follow-up: 9 days	dalteparin 5000x1 versus Placebo	Elective hip	double blind

continued...

Trial	Treatments	Patients	Trials design and methods
enoxaparin vs placebo			
Kalodiki , 1996 n=13/14 follow-up: discharge (8-12 days)	enoxaparin 4000x1 versus Placebo	Elective hip	double blind
Leclerc , 1991 n=65/64 follow-up: 14 days	Enoxaparin 3000 x2 versus Placebo	Knee	double blind
Samama , 1997 n=85/85 follow-up: 8-12 days	enoxaparin 4000x1+elastic stockings versus Placebo+elastic stockings	Elective hip	double blind
Turpie , 1986 n=50/50 follow-up: 14 days or discharge	Enoxaparin 3000 x2 versus Placebo	Elective hip	double blind
nadroparin vs placebo			
Sourmelis , 1995 n=72/78 follow-up: 10-12 days	nadroparin 3075x1 preop, 6150x1 post op versus Placebo	Hip fracture	double blind
tinzaparin vs placebo			
Lassen , 1991 n=105/105 follow-up: 8-10 days	tinzaparin 50/kg x1 +elastic stockings versus Placebo+elastic stockings	Elective hip	double blind
dalteparin vs Dextran			
Matzsch , 1991 n=120/123	dalteparin versus Dextran	Elective hip	
Eriksson , 1988 n=50/50	dalteparin versus Dextran	Elective hip	
Matzsch , 1988 n=48/52	dalteparin versus Dextran	Elective hip	
enoxaparin vs Dextran			
DES Group , 1991 n=120/126	Enoxaparin versus Dextran	Elective hip	
certoparine + DHE vs Unfractionated heparin			
Haas , 1987 n=80/80	Sandoz +0.5mg DHE versus Unfractionated heparin	Elective hip	
Lassen , 1989 n=68/71 follow-up: 6 days	certoparin 3000+0.5mg DHE x1 versus placebo	Hip fracture	double blind

continued...

Trial	Treatments	Patients	Trials design and methods
Lassen , 1988 n=118/122 follow-up: 6 days	certoparin 3000+0.5mg DHE, x1 versus Placebo	Elective hip	double blind
dalteparin vs Unfractionated heparin			
Binsack , 1986 n=48/47	dalteparin versus Unfractionated heparin	Elective hip	
Barre , 1987 n=40/40	dalteparin versus Unfractionated heparin	Elective hip	
Dechavanne , 1989 n=82/40	dalteparin versus Unfractionated heparin	Elective hip	
Eriksson , 1989 n=67/69	dalteparin versus Unfractionated heparin	Elective hip	
Haas , 1985 n=65/65	dalteparin versus Unfractionated heparin	Elective hip	
Monreal , 1989 n=46/44	dalteparin versus Unfractionated heparin	Hip	
enoxaparin vs Unfractionated heparin			
Levine , 1991 n=333/332	Enoxaparin versus Unfractionated heparin	Elective hip	
Planes , 1988 n=124/113	Enoxaparin versus Unfractionated heparin	Elective hip	
fluxum vs Unfractionated heparin			
Chiapuzzo , 1988 n=70/70	Fluxum versus Unfractionated heparin	Elective hip	
Pini , 1989 n=25/24	Fluxum versus Unfractionated heparin	Hip	
nadroparin vs Unfractionated heparin			
Leyvrax , 1991 n=203/206 follow-up:	Fraxiparin versus Unfractionated heparin	Elective hip	

References

FX140, Simonneau G, 2006:

Simonneau G, Laporte S, Mismetti P, Derlon A, Samii K, Samama CM, Bergman JF A randomized study comparing the efficacy and safety of nadroparin 2850 IU (0.3 mL) vs.

enoxaparin 4000 IU (40 mg) in the prevention of venous thromboembolism after colorectal surgery for cancer. *J Thromb Haemost* 2006;4:1693-700 [[16796710](#)]

Simonneau G, Laporte S, Mismetti P, Derlon A, Samii K, Samama CM, Bergman JF A randomized study comparing the efficacy and safety of nadroparin 2850 IU (0.3 mL) vs. enoxaparin 4000 IU (40 mg) in the prevention of venous thromboembolism after colorectal surgery for cancer. *J Thromb Haemost* 2006 Aug;4:1693-700 [[16796710](#)]

SAVE-HIP1, 2012:

Lassen MR, Fisher W, Mouret P, Agnelli G, George D, Kakkar A, Mismetti P, Turpie AG Semuloparin for prevention of venous thromboembolism after major orthopedic surgery: results from three randomized clinical trials, SAVE-HIP1, SAVE-HIP2 and SAVE-KNEE. *J Thromb Haemost* 2012;10:822-32 [[22429800](#)] [10.1111/j.1538-7836.2012.04701.x](#)

SAVE-KNEE, 2012:

Lassen MR, Fisher W, Mouret P, Agnelli G, George D, Kakkar A, Mismetti P, Turpie AG Semuloparin for prevention of venous thromboembolism after major orthopedic surgery: results from three randomized clinical trials, SAVE-HIP1, SAVE-HIP2 and SAVE-KNEE. *J Thromb Haemost* 2012 May;10:822-32 [[22429800](#)] [10.1111/j.1538-7836.2012.04701.x](#)

SAVE-HIP 2, 2012:

Lassen MR, Fisher W, Mouret P, Agnelli G, George D, Kakkar A, Mismetti P, Turpie AG Semuloparin for prevention of venous thromboembolism after major orthopedic surgery: results from three randomized clinical trials, SAVE-HIP1, SAVE-HIP2 and SAVE-KNEE. *J Thromb Haemost* 2012 May;10:822-32 [[22429800](#)] [10.1111/j.1538-7836.2012.04701.x](#)

Warwick, 1995:

Warwick D, Bannister GC, Glew D, Mitchelmore A, Thornton M, Peters TJ, Brookes S Perioperative low-molecular-weight heparin. Is it effective and safe. *J Bone Joint Surg Br* 1995 Sep;77:715-9 [[7559695](#)]

Yoo, 1997:

Yoo MC, Kang CS, Kim YH, Kim SK A prospective randomized study on the use of nadroparin calcium in the prophylaxis of thromboembolism in Korean patients undergoing elective total hip replacement. *Int Orthop* 1997;21:399-402 [[9498151](#)]

Levine, 1996:

Levine MN, Gent M, Hirsh J, Weitz J, Turpie AG, Powers P, Neemeh J, Willan A, Skingley P Ardeparin (low-molecular-weight heparin) vs graduated compression stockings for the prevention of venous thromboembolism. A randomized trial in patients undergoing knee surgery. *Arch Intern Med* 1996 Apr 22;156:851-6 [[8774203](#)]

Jorgensen, 1989:

Torholm, 1991:

Torholm C, Broeng L, Jorgensen PS, Bjerregaard P, Josephsen L, Jorgensen PK, Hagen K, Knudsen JB Thromboprophylaxis by low-molecular-weight heparin in elective hip surgery. A placebo controlled study. *J Bone Joint Surg Br* 1991 May;73:434-8 [[1670445](#)]

Kalodiki, 1996:

Kalodiki EP, Hoppensteadt DA, Nicolaides AN, Fareed J, Gill K, Regan F, al-Kutoubi A, Cunningham DA, Birch R, Harris N, Hunt D, Johnson J, Marx C Deep venous thrombosis prophylaxis with low molecular weight heparin and elastic compression in patients having total hip replacement. A randomised controlled trial. *Int Angiol* 1996 Jun;15:162-8 [[8803642](#)]

Leclerc, 1991:

Leclerc JR, Geerts WH, Desjardins L, Jobin F, Laroche F, Delorme F, Haviernick S, Atkinson S, Bourgouin J Prevention of deep vein thrombosis after major knee surgery—a randomized, double-blind trial comparing a low molecular weight heparin fragment (enoxaparin) to placebo. *Thromb Haemost* 1992 Apr 2;67:417-23 [[1321509](#)]

Samama, 1997:

Samama CM, Clergue F, Barre J, Montefiore A, Ill P, Samii K Low molecular weight heparin associated with spinal anaesthesia and gradual compression stockings in total hip replacement surgery. Arar Study Group. *Br J Anaesth* 1997 Jun;78:660-5 [[9215015](#)]

Turpie, 1986:

Turpie AG, Levine MN, Hirsh J, Carter CJ, Jay RM, Powers PJ, Andrew M, Hull RD, Gent M A randomized controlled trial of a low-molecular-weight heparin (enoxaparin) to prevent deep-vein thrombosis in patients undergoing elective hip surgery. *N Engl J Med* 1986 Oct 9;315:925-9 [[3531851](#)]

Sourmelis, 1995:

Lassen, 1991:

Lassen MR, Borris LC, Christiansen HM, Boll KL, Eiskjaer SP, Nielsen BW, Schtt P, Olsen AD, Rodenberg JC, Lucht U Prevention of thromboembolism in 190 hip arthroplasties. Comparison of LMW heparin and placebo. *Acta Orthop Scand* 1991;62:33-8 [[1848385](#)]

Matzsch , 1991:

Eriksson , 1988:

Eriksson BI, Zachrisson BE, Teger-Nilsson AC, Risberg B Thrombosis prophylaxis with low molecular weight heparin in total hip replacement. Br J Surg 1988 Nov;75:1053-7 [2463035]

Matzsch , 1988:

DES Group , 1991:

Haas , 1987:

Haas S, Stemberger A, Fritsche HM, Welzel D, Wolf H, Lechner F, Blumel G Prophylaxis of deep vein thrombosis in high risk patients undergoing total hip replacement with low molecular weight heparin plus dihydroergotamine. Arzneimittelforschung 1987 Jul;37:839-43 [2823840]

Lassen, 1989:

Lassen MR, Borris LC, Christiansen HM, Moller-Larsen F, Knudsen VE, Boris P, Nehen AM, Jurik AG, de Carvalho A, Nielsen BW Prevention of thromboembolism in hip-fracture patients. Comparison of low-dose heparin and low-molecular-weight heparin combined with dihydroergotamine. Arch Orthop Trauma Surg 1989;108:10-3 [2913977]

Lassen, 1988:

Lassen MR, Borris LC, Christiansen HM, Moller-Larsen F, Knudsen VE, Boris P, Nehen AM, de Carvalho A, Jurik AG, Nielsen BW Heparin/dihydroergotamine for venous thrombosis prophylaxis: comparison of low-dose heparin and low molecular weight heparin in hip surgery. Br J Surg 1988 Jul;75:686-9 [2843255]

Binsack , 1986:

Barre , 1987:

Dechavanne , 1989:

Dechavanne M, Ville D, Berruyer M, Trepo F, Dalery F, Clermont N, Lerat JL, Moyen B, Fischer LP, Kher A Randomized trial of a low-molecular-weight heparin (Kabi 2165) versus adjusted-dose subcutaneous standard heparin in the prophylaxis of deep-vein thrombosis after elective hip surgery. Haemostasis 1989;19:5-12 [2537787]

Eriksson , 1989:

Haas , 1985:

Monreal , 1989:

Monreal M, Lafoz E, Navarro A, Granero X, Caja V, Caceres E, Salvador R, Ruiz J A prospective double-blind trial of a low molecular weight heparin once daily compared with conventional low-dose heparin three times daily to prevent pulmonary embolism and venous thrombosis in patients with hip fracture. J Trauma 1989 Jun;29:873-5 [2544742]

Levine , 1991:

Planes , 1988:

Planes A, Vochelle N, Mazas F, Mansat C, Zucman J, Landais A, Pascariello JC, Weill D, Butel J Prevention of postoperative venous thrombosis: a randomized trial comparing unfractionated heparin with low molecular weight heparin in patients undergoing total hip replacement. Thromb Haemost 1988 Dec 22;60:407-10 [2853459]

Chiapuzzo , 1988:

Chiapuzzo E, Orengo GB, Ottria G, Chiapuzzo A, Palazzini E, Fusillo M The use of low molecular weight heparins for postsurgical deep vein thrombosis prevention in orthopaedic patients. J Int Med Res 1988 Sep-Oct;16:359-66 [3197913]

Pini , 1989:

Pini M, Tagliaferri A, Manotti C, Lasagni F, Rinaldi E, Dettori AG Low molecular weight heparin (Alfa LHWH) compared with unfractionated heparin in prevention of deep-vein thrombosis after hip fractures. Int Angiol 1989 Jul-Sep;8:134-9 [2556484]

Leyvraz, 1991:

Leyvraz PF, Bachmann F, Hoek J, Buller HR, Postel M, Samama M, Vandebroek MD Prevention of deep vein thrombosis after hip replacement: randomised comparison between unfractionated heparin and low molecular weight heparin. BMJ 1991 Sep 7;303:543-8 [1655136]

2 About TrialResults-center.org

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