Clinical trials of LMWH for DVT prophylaxis in general surgery

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1 low molecular weight heparin

Trial	Treatments	Patients	Trials design and methods
enoxaparin vs no treatment			
Ho [43] n=134/169	Enoxaparin 4000 anti-Xa units versus No treatment	-	Open
nadroparin vs no treatment			
Marassi [41] n=31/33	Nadroparin 2850 anti-Xa units versus No treatment	-	Open
dalteparin vs placebo			
Ockelford , 1989 n=102/95	Dalteparin 2500 anti-Xa units versus Placebo	general surgery	Blind
fluxum vs placebo			
Valle , 1988 n=50/50	Parnaparin 3200 anti-Xa units versus Placebo	general surgery	Blind
nadroparin vs placebo			
Balas [40] n=94/95	Nadroparin 2850 anti-Xa units versus Placebo	-	Blind
Pezzuoli , 1989 n=2247/2251 follow-up:	Nadroparin 2850 anti-Xa units versus Placebo	general surgery	Blind
tinzaparin vs placebo			
Bergqvist [42] n=39/41 follow-up:	Tinzaparin 3500 anti-Xa units versus Placebo	-	Parallel groups Blind
antixarin vs unfractionated heparin			
Limmer , 1994 n=103/100	Antixarin 2500 anti Xa units versus UFH 15 000 units	General surgery	Open
ardeparin vs unfractionated heparin			
Godwin , 1993 n=595/309	Ardeparin 90 and 50 units/kg b.i.d versus UFH 10 000 units	Abdominopelvic surgery	Blind
certoparin vs unfractionated heparin			

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Trial	Treatments	Patients	Trials design and methods
Schmitz-Huebner , 1984 n=84/42 follow-up: 1 month	Certoparin (dose 1 and dose 2) b.i.d. versus UFH 10 000 units	Abdominal surgery	Blind
Sasahara , 1986 n=137/132 follow-up: 7 days	Certoparin 3000 + DHE versus UFH 10 000 units +DHE	Abdominal surgery	Blind
Voigt , 1986 n=103/97 follow-up: 10 days	Certoparin 3000 + DHE versus UFH 10 000 units	Abdominal surgery	Blind
Welzel , 1988 n=98/103 follow-up: 7 days	Certoparin 2500 + DHE versus UFH 10 000 units+DHE	Abdominal surgery	Open
Kakkar , 1989 n=88/91 follow-up:	Certoparin 3000 + DHE versus UFH 10 000 units+DHE	Abdominal surgery	Blind
Adolf , 1989 n=205/205 follow-up: 1 month	Certoparin 3000 versus UFH 15 000 units	Abdominal surgery	Blind
Heilmann , 1989 n=150/150 follow-up: 10 days	Certoparin 3000 versus UFH 15 000 units	Gynaecological surgery	Blind
Baumgartner , 1989 n=99/102 follow-up: 10 days	Certoparin 3000 + DHE versus UFH 5 000 units+DHE	Abdominal surgery	Blind
Hoffmann and Largiade , 1990 n=464/452 follow-up:	Certoparin 3000 + DHE versus UFH 10 000 units	Abdominal surgery	NA
Koppenhagen , 1990 n=51/53	Certoparin 3000 anti Xa units versus UFH 15 000 units	Abdominal surgery	Blind
Schielke , 1991 n=47/51	Certoparin 3000 anti Xa units + DHE versus UFH 10 000 units + DHE	Abdominal surgery	Open
Koppenhagen , 1992 n=336/337	Certoparin 3000 anti Xa units versus UFH 15 000 units	Abdominal surgery	Blind
Hoffmann and Largiader , 1992 n=298/296	Certoparin 3000 anti Xa units versus UFH 10 000 units	Abdominothoracic surgery	Blind
Heilmann , 1997 n=179/179	Certoparin 3000 anti Xa units versus UFH 15 000 units	Gynaecological and breast surgery	Blind

continued...

Trial	Treatments	Patients	Trials design and methods
Haas , 1999 n=11542/11536	Certoparin 3000 anti Xa units versus UFH 15 000 units	General surgery	Blind
dalteparin vs unfractionated heparin			
Briel , 1988 n=95/98 follow-up:	Dalteparin 5000 versus UFH 10 000 units+DHE	Gynaecological surgery	NA
Bergqvist , 1986 n=215/217 follow-up: 1 month	Dalteparin 5000 versus UFH 10 000 units	Abdominal surgery	Blind
Onarheim , 1986 n=25/27 follow-up: 1 month	Dalteparin 5000 versus UFH 10 000 units	Abdominal surgery	Blind
Koller , 1986 n=23/20 follow-up: 30 days	Dalteparin 7500 versus UFH 10 000 units	Abdominal surgery	Blind
Koller , 1986 n=75/75 follow-up: 30 days	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
Fricker , 1988 n=40/40 follow-up: 1-2 months	Dalteparin 5000 versus UFH 15 000 units	Abdominopelvic surgery	Open
Bergqvist , 1988 n=505/497 follow-up: 1 month	Dalteparin 5000 versus UFH 10 000 units	Abdominal surgery	Blind
Caen , 1988 n=195/190 follow-up: 1 month	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
Borstad , 1988 n=105/110 follow-up:	Dalteparin 5000 versus UFH 10 000 units	Gynaecological surgery	Blind
Creperio , 1990 n=20/20 follow-up:	Dalteparin 2500 versus UFH 10 000 units	General surgery	Blind
Hartl , 1990 n=126/124 follow-up: >7 days	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
Borstad , 1992 n=77/75	Dalteparin 2500 anti Xa units versus UFH 10 000 units	Gynaecological surgery	Blind
Kakkar , 1993 n=1894/1915	Dalteparin 2500 anti Xa units versus UFH 10 000 units	Abdominal surgery	Blind
enoxaparin vs unfractionated heparin			

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Trial	Treatments	Patients	Trials design and methods
Samama 2 , 1988 n=127/123 follow-up: 7 days	Enoxaparin 4000 versus UFH 15 000 units	General surgery	Open
Samama 1 , 1988 n=168/167 follow-up: 7 days	Enoxaparin 2000 versus UFH 15 000 units	General surgery	Open
Samama 3 , 1988 n=160/147 follow-up: 7 days	Enoxaparin 6000 versus UFH 15 000 units	General surgery	Open
Kaaja , 1992 n=37/31	Enoxaparin 2000 anti Xa units versus UFH 10 000 units	Gynaecological surgery	Blind
Gazzaniga (ISG) , 1993 n=561/561	Enoxaparin 2000 anti Xa units versus UFH 10 000 units	General and vascular surgery	Open
Nurmohamed , 1995 n=737/734	Enoxaparin 2000 anti Xa units versus UFH 15 000 units	General surgery	Blind
McLeod (Canadian) , 1995 n=674/675	Enoxaparin 4000 anti Xa units versus UFH 15 000 units	Colorectal surgery	Blind
Gonzalez , 1996 n=84/82	Bemiparin 2500 anti Xa units versus UFH 10 000 units	Abdominal surgery	Blind
ENOXACAN , 1997 n=555/560	Enoxaparin 4000 anti Xa units versus UFH 15 000 units	Abdominopelvic surgery	Blind
nadroparin vs unfractionated heparin			
Kakkar and Murray , 1985 n=200/200 follow-up: 10 days	Nadroparin 2850 versus UFH 10 000 units	General surgery	Blind
EFS , 1988 n=968/941 follow-up: 1 month	Nadroparin 2850 versus UFH 15 000 units	Abdominal surgery	Open
Dahan , 1989 n=46/41 follow-up:	Nadroparin 2850 versus UFH 15 000 units	Thoracic surgery	Open
Barbui , 1990 n=171/173	Nadroparin 2850 anti Xa units versus UFH 10 000 units	General surgery	Open
Eurin , 1994 n=241/239	Nadroparin 2850 anti Xa units versus UFH 15 000 units	Abdominopelvic surgery	Open
parnaparin vs unfractionated heparin			

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Trial	Treatments	Patients	Trials design and methods
Catania , 1988 n=88/85 follow-up:	Parnaparin 3200 versus UFH 15 000 units	Abdominal surgery	Open
Salcuni , 1988 n=73/68 follow-up:	Parnaparin 3200 versus UFH 15 000 units	Abdominal surgery	Open
Verardi , 1989 n=44/44 follow-up:	Parnaparin 6400 versus UFH 10 000 units	Abdominal/urological surgery	NA
Garcea , 1992 n=45/45	Parnaparin 3200 anti Xa units versus UFH 15 000 units	Abdominal surgery	Open
reviparin vs unfractionated heparin			
Kakkar , 1993 n=672/679	Reviparin 1750 anti Xa units versus UFH 10 000 units	General and gynaecological surgery	Blind
SSHA vs unfractionated heparin			
Torngren , 1984 n=309/162 follow-up: Discharge	SSHA 50 mg and 37.5 mg versus UFH 10 000 units	General surgery	Blind
tinzaparin vs unfractionated heparin			
Leizorovicz , 1991 n=861/429	Tinzaparin 2500 and 3500 anti Xa units versus UFH 10 000 units	Abdominothoracic and gynaecological surgery	Blind

References

Ho [43], :

Ho YH, Seow-Choen F, Leong A, Eu KW, Nyam D, Teoh MK Randomized, controlled trial of low molecular weight heparin vs. no deep vein thrombosis prophylaxis for major colon and rectal surgery in Asian patients. Dis Colon Rectum 1999;42:196-202; discussion 202-3 [10211496]

Marassi [41], :

Marassi A, Balzano G, Mari G, D'Angelo SV, Della Valle P, Di Carlo V, D'Angelo A Prevention of postoperative deep vein thrombosis in cancer patients. A randomized trial with low molecular weight heparin (CY 216). Int Surg 1993;78:166-70 [8394842]

Ockelford , 1989:

Ockelford PA, Patterson J, Johns AS A double-blind randomized placebo controlled trial of thromboprophylaxis in major elective general surgery using once daily injections of a low molecular weight heparin fragment (Fragmin). Thromb Haemost 1989;62:1046-9 [2559484]

Valle , 1988:

Valle I, Sola G, Origone A Controlled clinical study of the efficacy of a new low molecular weight heparin administered subcutaneously to prevent post-operative deep venous thrombosis. Curr Med Res Opin 1988;11:80-6 [2851413]

Balas [40], :

BalasPEet al. Efcacy and safety of nadroparin (Fraxiparine) versus placebo in the prophylactic treatment of deep vein thrombosis in patients with high thrombo-embolic risk undergoing general surgery.01 Thromb Res 1992; 65(Suppl 1): S113 (Abstract)ag

Pezzuoli, 1989:

Pezzuoli G, Neri Serneri GG, Settembrini P, Coggi G, Olivari N, Buzzetti G, Chierichetti S, Scotti A, Scatigna M, Carnovali M Prophylaxis of fatal pulmonary embolism in general surgery using low-molecular weight heparin Cy 216: a multicentre, double-blind, randomized, controlled, clinical trial versus placebo (STEP). STEP-Study Group. Int Surg 1989 Oct-Dec;74:205-10 [2560470]

Pezzuoli G, Neri Serneri GG, Settembrini PG, Coggi G, Olivari N, Negri G, Codemo R, Galli G, Roveri S Effectiveness and safety of the low-molecular-weight heparin CY 216 in the prevention of fatal pulmonary embolism and thromboembolic death in general surgery. A multicentre, double-blind, randomized, controlled clinical trial versus placebo (STEP). STEP Study Group. Haemostasis 1990;20 Suppl 1:193-204 [1964662]

Bergqvist [42], :

Bergqvist D, Flordal PA, Friberg B, Frisell J, Hedberg M, Ljungstrm KG, Mtzsch T, Trngren S Thromboprophylaxis with a low molecular weight heparin (tinzaparin) in emergency abdominal surgery. A double-blind multicenter trial. Vasa 1996;25:156-60 [8659218]

Limmer, 1994:

Godwin, 1993:

Schmitz-Huebner, 1984:

Schmitz-Huebner U, Bnte H, Freise G, Reers B, Rschemeyer C, Scherer R, Schulte H, van de Loo J Clinical efficacy of low molecular weight heparin in postoperative thrombosis prophylaxis. Klin Wochenschr 1984;62:349-53 [6374278]

Sasahara, 1986:

Sasahara AA, Koppenhagen K, Hring R, Welzel D, Wolf H Low molecular weight heparin plus dihydroergotamine for prophylaxis of postoperative deep vein thrombosis. Br J Surg 1986;73:697-700 [3530367]

Voigt, 1986:

Voigt J, Hamelmann H, Hedderich J, Seifert J, Buchhammer T, Khler A [Effectiveness and side effects of low-molecular weight heparin-dihydroergotamine in preventing thromboembolism in abdominal surgery] Zentralbl Chir 1986;111:1269-305 [3544605]

Welzel, 1988:

Welzel D, Wolf H, Koppenhagen K Antithrombotic defense during the postoperative period. Clinical documentation of low molecular weight heparin. Arzneimittelforschung 1988;38:120-3 [2835055]

Kakkar, 1989:

Kakkar VV, Stringer MD, Hedges AR, Parker CJ, Welzel D, Ward VP, Sanderson RM, Cooper D, Kakkar S Fixed combinations of low-molecular weight or unfractionated heparin plus dihydroergotamine in the prevention of postoperative deep vein thrombosis. Am J Surg 1989;157:413-8 [2539025]

Adolf, 1989:

Adolf J, Knee H, Roder JD, van de Flierdt E, Siewert JR [Thromboembolism prophylaxis with low molecular weight heparin in abdominal surgery] Dtsch Med Wochenschr 1989;114:48-53 [2535983]

Heilmann, 1989:

Heilmann L, Kruck M, Schindler AE [Prevention of thrombosis in gynecology: double-blind comparison of low molecular weight heparin and unfractionated heparin] Geburtshilfe Frauenheilkd 1989;49:803-7 [2553528]

Baumgartner, 1989:

Baumgartner A, Jacot N, Moser G, Krhenbhl B Prevention of postoperative deep vein thrombosis by one daily injection of low molecular weight heparin and dihydroergotamine. Vasa 1989;18:152-6 [2545054]

Hoffmann and Largiade, 1990:

Koppenhagen, 1990:

Schielke, 1991:

Koppenhagen, 1992:

Hoffmann and Largiader, 1992:

Heilmann, 1997:

Haas, 1999:

Briel, 1988:

Briel RC, Doller P, Hermann CP [Prevention of thromboembolism in hysterectomies with low molecular weight heparin Fragmin] Geburtshilfe Frauenheilkd 1988;48:160-4 [2836259]

Bergqvist, 1986:

Bergqvist D, Burmark US, Frisell J, Hallbk T, Lindblad B, Risberg B, Trngren S, Wallin G Low molecular weight heparin once daily compared with conventional low-dose heparin twice daily. A prospective double-blind multicentre trial on prevention of postoperative thrombosis. Br J Surg 1986;73:204-8 [3512031]

Onarheim, 1986:

Onarheim H, Lund T, Heimdal A, Arnesj B A low molecular weight heparin (KABI 2165) for prophylaxis of postoperative deep venous thrombosis. Acta Chir Scand 1986;152:593-6 [3544625]

Koller, 1986:

Koller M, Schoch U, Buchmann P, Largiadr F, von Felten A, Frick PG Low molecular weight heparin (KABI 2165) as thromboprophylaxis in elective visceral surgery. A randomized, double-blind study versus unfractionated heparin. Thromb Haemost 1986;56:243-6 [3551180]

Koller, 1986:

Koller M, Schoch U, Buchmann P, Largiadr F, von Felten A, Frick PG Low molecular weight heparin (KABI 2165) as thromboprophylaxis in elective visceral surgery. A randomized, double-blind study versus unfractionated heparin. Thromb Haemost 1986;56:243-6 [3551180]

Fricker, 1988:

Fricker JP, Vergnes Y, Schach R, Heitz A, Eber M, Grunebaum L, Wiesel ML, Kher A, Barbier P, Cazenave JP Low dose heparin versus low molecular weight heparin (Kabi 2165, Fragmin) in the prophylaxis of thromboembolic complications of abdominal oncological surgery. Eur J Clin Invest 1988;18:561-7 [2852111]

Bergqvist, 1988:

Bergqvist D, Mtzsch T, Burmark US, Frisell J, Guilbaud O, Hallbk T, Horn A, Lindhagen A, Ljungnr H, Ljungstrm KG Low molecular weight heparin given the evening before surgery compared with conventional low-dose heparin in prevention of thrombosis. Br J Surg 1988;75:888-91 [2846113]

Caen, 1988:

Caen JP A randomized double-blind study between a low molecular weight heparin Kabi 2165 and standard heparin in the prevention of deep vein thrombosis in general surgery. A French multicenter trial. Thromb Haemost 1988;59:216-20 [2838923]

Borstad, 1988:

Borstad E, Urdal K, Handeland G, Abildgaard U Comparison of low molecular weight heparin vs. unfractionated heparin in gynecological surgery. Acta Obstet Gynecol Scand 1988;67:99-103 [2845707]

Creperio, 1990:

Creperio G, Marabini M, Ciocia G, Bergonzi M, Fincato M [Evaluation of the effectiveness and safety of Fragmin (Kabi 2165) versus calcium heparin in the prevention of deep venous thrombosis in general surgery] Minerva Chir 1990;45:1101-6 [2177861]

Hartl, 1990:

Hartl P, Brcke P, Dienstl E, Vinazzer H Prophylaxis of thromboembolism in general surgery: comparison between standard heparin and Fragmin. Thromb Res 1990;57:577-84 [2158151]

Borstad, 1992:

Kakkar, 1993:

Samama 2, 1988:

Samama M, Bernard P, Bonnardot JP, Combe-Tamzali S, Lanson Y, Tissot E Low molecular weight heparin compared with unfractionated heparin in prevention of postoperative thrombosis. Br J Surg 1988;75:128-31 [2832030]

Samama MM Prevention of postoperative thromboembolism in general surgery with enoxaparin. Eur J Surg Suppl 1994;:31-3 [7519086]

Samama 1, 1988:

Samama M, Bernard P, Bonnardot JP, Combe-Tamzali S, Lanson Y, Tissot E Low molecular weight heparin compared with unfractionated heparin in prevention of postoperative thrombosis. Br J Surg 1988;75:128-31 [2832030]

Samama MM Prevention of postoperative thromboembolism in general surgery with enoxaparin. Eur J Surg Suppl 1994;:31-3 [7519086]

Samama M, Combe S Prevention of thromboembolic disease in general surgery with enoxaparin (Clexane). Acta Chir Scand Suppl 1990;556:91-5 [1963022]

Samama 3, 1988:

Samama M, Bernard P, Bonnardot JP, Combe-Tamzali S, Lanson Y, Tissot E Low molecular weight heparin compared with unfractionated heparin in prevention of postoperative thrombosis. Br J Surg 1988;75:128-31 [2832030]

Samama MM Prevention of postoperative thromboembolism in general surgery with enoxaparin. Eur J Surg Suppl 1994;:31-3 [7519086]

Kaaja, 1992:

Gazzaniga (ISG), 1993:

Creperio G, Marabini M, Ciocia G, Bergonzi M, Fincato M [Evaluation of the effectiveness and safety of Fragmin (Kabi 2165) versus calcium heparin in the prevention of deep venous thrombosis in general surgery] Minerva Chir 1990;45:1101-6 [2177861]

Creperio G, Marabini M, Ciocia G, Bergonzi M, Fincato M [Evaluation of the effectiveness and safety of Fragmin (Kabi 2165) versus calcium heparin in the prevention of deep venous thrombosis in general surgery] Minerva Chir 1990;45:1101-6 [2177861]

Nurmohamed, 1995:

McLeod (Canadian), 1995:

Gonzalez, 1996:

ENOXACAN, 1997:

Kakkar and Murray, 1985:

Kakkar VV, Murray WJ Efficacy and safety of low-molecular-weight heparin (CY216) in preventing postoperative venous thrombo-embolism: a co-operative study. Br J Surg 1985;72:786-91 [3899240]

EFS, 1988:

Comparison of a low molecular weight heparin and unfractionated heparin for the prevention of deep vein thrombosis in patients undergoing abdominal surgery. The European Fraxiparin Study (EFS) Group. Br J Surg 1988;75:1058-63 [2905187]

Dahan, 1989:

Barbui, 1990:

Eurin, 1994:

Catania, 1988:

Catania G, Salanitri G Prevention of postoperative deep vein thrombosis by two different heparin types. Int J Clin Pharmacol Ther Toxicol 1988;26:304-9 [2842266]

Salcuni, 1988:

Verardi, 1989:

Verardi S, Cortese F, Baroni B, Boffo V, Casciani CU [Role of low molecular weight heparin in the prevention of postoperative deep venous thrombosis. Our experience in 88 cases] G Chir 1989;10:674-8 [2562010]

Garcea, 1992:

Kakkar, 1993:

Torngren, 1984:

Trngren S, Kettunen K, Lahtinen J, Koppenhagen K, Brcke P, Hartl P, Hutter O, Haller U, Lahnborg G, Forsskhl B A randomized study of a semisynthetic heparin analogue and heparin in prophylaxis of deep vein thrombosis. Br J Surg 1984;71:817-20 [6437467]

Leizorovicz, 1991:

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