

Clinical trials of antithrombotics for thrombosis prevention in abdominal surgery

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1 extended prophylaxis

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| extended prophylaxis vs standard prophylaxis | | | |
| Lausen , 1998 n=58/60 follow-up: 28 days | Tinzaparin 3500 UI/qd sc for 28 days started in preop versus Tinzaparin 3500 UI/qd + GES for 1 week started in preop | >18 years, open major abdominal surgery and non cardiac thoracic surgery of >1hour duration. | Parallel groups Open, blinded evaluation |
| ENOXACAN II (Bergqvist) , 2002 n=253/248 follow-up: 3 months | Enoxaparin 40 mg UI/qd sc for 25-31 days started in preop versus Enoxaparin 40 mg IU/qd sc for 6 to 10 days (GES optional) started in preop | >40 years, open major abdominal oncologic elective surgery of >45 minutes duration (includes gynecological surgery) | Parallel groups double blind |
| FAME (Rasmussen) , 2006 n=205/222 follow-up: 3 months | Dalteparin 5000 UI/qd SC for 28 days started in preop versus Dalteparin 5000 UI/qd SC for 7 days + GES started in preop | >18 years, major abdominal surgery of >1 hour duration | Parallel groups Open, blinded evaluation |

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Rasmussen MS, Jorgensen LN, Wille-Jrgensen P, Nielsen JD, Horn A, Mohn AC, Smød L, Olsen B Prolonged prophylaxis with dalteparin to prevent late thromboembolic complications in patients undergoing major abdominal surgery: a multicenter randomized open-label study. J Thromb Haemost 2006;4:2384-90 [[16881934](#)]

2 low molecular weight heparin

| Trial | Treatments | Patients | Trials design and methods |
|---|------------|----------|---------------------------|
| 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 |
| 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 |
| Kopenhagen , 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 |
| Kopenhagen , 1992 n=336/337 | Certoparin 3000 anti Xa units versus UFH 15 000 units | Abdominal surgery | Blind |
| dalteparin vs unfractionated heparin | | | |
| 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 |

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| Trial | Treatments | Patients | Trials design and methods |
|--|---|------------------------------|----------------------------------|
| 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 |
| Hartl , 1990 n=126/124 follow-up: >7 days | Dalteparin 2500 versus UFH 10 000 units | Abdominal surgery | Blind |
| Kakkar , 1993 n=1894/1915 | Dalteparin 2500 anti Xa units versus UFH 10 000 units | Abdominal surgery | Blind |
| enoxaparin vs unfractionated heparin | | | |
| 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 |
| nadroparin vs unfractionated heparin | | | |
| EFS , 1988 n=968/941 follow-up: 1 month | Nadroparin 2850 versus UFH 15 000 units | Abdominal surgery | Open |
| parnaparin vs unfractionated heparin | | | |
| 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 |

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3 synthetic oligosaccharide

| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|---------------------------------------|
| fondaparinux vs control | | | |
| NCT00333021 <i>ongoing</i> [NCT00333021] n=NA follow-up: | - | Abdominal Surgery | Parallel groups open japan |
| fondaparinux vs placebo (on top intermittent pneumatic comp.) | | | |
| APOLLO (Turpie) , 2007 n=650/659 follow-up: 10 days | fondaparinux 2.5 mg s.c. for 5-9 days, starting 6-8 h postoperatively + intermittent pneumatic compression versus placebo s.c. for 5-9 days, starting 6-8 h postoperatively + intermittent pneumatic compression | Patients aged at least 40 years undergoing abdominal surgery | Parallel groups double blind US |
| fondaparinux vs enoxaparin | | | |

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| Trial | Treatments | Patients | Trials design and methods |
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| PEGASUS , 2005 n=1465/1462 follow-up: 10 days (30 days) | once-daily subcutaneous injections of fondaparinux 25 mg started 6 h after surgery for 59 days versus once-daily subcutaneous injections of dalteparin 5000 units for 59 days (2500 units each, given 2 h before surgery and 12 h after the preoperative administration) | patients undergoing major abdominal surgery | Parallel groups double blind 22 countries |

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4 About TrialResults-center.org

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