

# Clinical trials of antithrombotics for thrombosis prevention in abdominal surgery

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## 1 extended prophylaxis

Trial	Treatments	Patients	Trials design and methods
<b>extended prophylaxis vs standard prophylaxis</b>			
<b>Lausen , 1998</b> 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
<b>ENOXACAN II (Bergqvist) , 2002</b> 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
<b>FAME (Rasmussen) , 2006</b> 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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## 2 low molecular weight heparin

Trial	Treatments	Patients	Trials design and methods
<b>certoparin vs unfractionated heparin</b>			

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
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
<b>dalteparin vs unfractionated heparin</b>			
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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<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>Koller , 1986</b> n=75/75 follow-up: 30 days	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Fricker , 1988</b> n=40/40 follow-up: 1-2 months	Dalteparin 5000 versus UFH 15 000 units	Abdominopelvic surgery	Open
<b>Bergqvist , 1988</b> n=505/497 follow-up: 1 month	Dalteparin 5000 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Caen , 1988</b> n=195/190 follow-up: 1 month	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Hartl , 1990</b> n=126/124 follow-up: >7 days	Dalteparin 2500 versus UFH 10 000 units	Abdominal surgery	Blind
<b>Kakkar , 1993</b> n=1894/1915	Dalteparin 2500 anti Xa units versus UFH 10 000 units	Abdominal surgery	Blind
<b>enoxaparin vs unfractionated heparin</b>			
<b>McLeod (Canadian) , 1995</b> n=674/675	Enoxaparin 4000 anti Xa units versus UFH 15 000 units	Colorectal surgery	Blind
<b>Gonzalez , 1996</b> n=84/82	Bemiparin 2500 anti Xa units versus UFH 10 000 units	Abdominal surgery	Blind
<b>nadroparin vs unfractionated heparin</b>			
<b>EFS , 1988</b> n=968/941 follow-up: 1 month	Nadroparin 2850 versus UFH 15 000 units	Abdominal surgery	Open
<b>parnaparin vs unfractionated heparin</b>			
<b>Catania , 1988</b> n=88/85 follow-up:	Parnaparin 3200 versus UFH 15 000 units	Abdominal surgery	Open
<b>Salcuni , 1988</b> n=73/68 follow-up:	Parnaparin 3200 versus UFH 15 000 units	Abdominal surgery	Open
<b>Verardi , 1989</b> n=44/44 follow-up:	Parnaparin 6400 versus UFH 10 000 units	Abdominal/urological surgery	NA
<b>Garcea , 1992</b> 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
<b>fondaparinux vs control</b>			
NCT00333021 <i>ongoing</i> [NCT00333021] n=NA follow-up:	-	Abdominal Surgery	Parallel groups open japan
<b>fondaparinux vs placebo (on top intermittent pneumatic comp.)</b>			
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
<b>fondaparinux vs enoxaparin</b>			

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Trial	Treatments	Patients	Trials design and methods
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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The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

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