

# Clinical trials of extended prophylaxis

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## 1 thrombosis prevention

| Trial   | Treatments  | Patients  | Trials design and methods                   |
|---|---|---|---|
| <b>extended prophylaxis vs standard prophylaxis</b>                       |   |   |   |
| <b>PENTHIFRAPLUS (Eriksson) , 2003</b><br>n=656<br>follow-up: 19-23 days  | 25-31 days of fondaparinux 2.5-mg once-daily<br>versus<br>6-8 days of fondaparinux 2.5-mg once-daily  | patients undergoing hip fracture surgery  | Parallel groups<br>double blind             |
| <b>Lausen , 1998</b><br>n=58/60<br>follow-up: 28 days                     | Tinzaparin 3500 UI/qd sc for 28 days started in preop<br>versus<br>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<br>Open, blinded evaluation |
| <b>ENOXACAN II (Bergqvist) , 2002</b><br>n=253/248<br>follow-up: 3 months | Enoxaparin 40 mg UI/qd sc for 25-31 days started in preop<br>versus<br>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<br>double blind             |
| <b>FAME (Rasmussen) , 2006</b><br>n=205/222<br>follow-up: 3 months        | Dalteparin 5000 UI/qd SC for 28 days started in preop<br>versus<br>Dalteparin 5000 UI/qd SC for 7 days + GES started in preop                     | >18 years, major abdominal surgery of >1 hour duration  | Parallel groups<br>Open, blinded evaluation |

More details and results :

- antithrombotics for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q37>
- antithrombotics for thrombosis prevention in hip Fracture at <http://www.trialresultscenter.org/go-Q40>
- antithrombotics for thrombosis prevention in abdominal surgery at <http://www.trialresultscenter.org/go-Q96>
- pentasaccharide for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q188>
- pentasaccharide for thrombosis prevention in all type of patients at <http://www.trialresultscenter.org/go-Q396>

## References

### **PENTHIFRAPLUS (Eriksson), 2003:**

Eriksson BI, Lassen MR Duration of prophylaxis against venous thromboembolism with fondaparinux after hip fracture surgery: a multicenter, randomized, placebo-controlled, double-blind study. *Arch Intern Med* 2003 Jun 9;163:1337-42 [[12796070](#)]

### **Lausen, 1998:**

Lausen I, Jensen R, Jorgensen LN, Rasmussen MS, Lyng KM, Andersen M, Raaschou HO, Wille-Jrgensen P Incidence and prevention of deep venous thrombosis occurring late after general surgery: randomised controlled study of prolonged thromboprophylaxis. *Eur J Surg* 1998;164:657-63 [[9728784](#)]

### **ENOXACAN II (Bergqvist), 2002:**

Bergqvist D, Agnelli G, Cohen AT, Eldor A, Nilsson PE, Le Moigne-Amrani A, Dietrich-Neto F Duration of prophylaxis against venous thromboembolism with enoxaparin after surgery for cancer. *N Engl J Med* 2002;346:975-80 [[11919306](#)]

### **FAME (Rasmussen), 2006:**

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](#)]