# Clinical trials of pentasaccharide for thrombosis prevention in all type of patients

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## 1 synthetic oligosaccharide

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **fondaparinux vs control** | | | |
| NCT00333021 *ongoing*<br>[NCT00333021]<br>n=NA<br>follow-up: | - | Abdominal Surgery | Parallel groups<br>open<br>japan |
| NCT00320398 *ongoing*<br>[NCT00320398]<br>n=NA<br>follow-up: | - | patients undergoing either an elective primary total hip replacement (THR) surgery or a revision of a THR | double-blind<br>Japan |
| **fondaparinux vs no treatment** | | | |
| PROTECT (fundaparinux) *ongoing*<br>[NCT00881088]<br>n=NA<br>follow-up: | fondaparinux 2,5 mg daily group during immobilization<br>versus<br>no treatment | Patients with a nonsurgical fracture of the lower extremity immobilised in a below-knee plaster cast | Parallel groups<br>single blind |
| **fondaparinux vs placebo** | | | |
| DRI4757<br>n=345/87<br>follow-up: 14 days | fondaparinux subcutaneously at 0.75, 1.5, 2.5, and 3.0 mg for at least 10 calendar days, (with a maximum of 14 days)<br>versus<br>placebo | Japanese patients undergoing elective total knee replacement surgery | Parallel groups<br>double blind<br>Japan |
| **fondaparinux vs placebo (on top intermittent pneumatic comp.)** | | | |
| APOLLO (Turpie) , 2007<br>n=650/659<br>follow-up: 10 days | fondaparinux 2.5 mg s.c. for 5-9 days, starting 6-8 h postoperatively + intermittent pneumatic compression<br>versus<br>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<br>double blind<br>US |
| **fondaparinux vs enoxaparin** | | | |
| L8541<br>n=119/118<br>follow-up: 9 days (49d) | fondaparinux 2.5mg subcutaneous once-daily for 7+/-2 days<br>versus<br>enoxaparin 40mg s.c. once-daily | chinese patients undergoing major orthopaedic surgery of the lower limbs | Parallel groups<br>single-blind<br>China |
| L8635<br>n=28/23<br>follow-up: 10 days | Fondaparinux 2.5mg once daily subcutaneously for 7 days<br>versus<br>enoxaparin 40mg once daily SC for 7 days | Taiwanese patients undergoing elective knee replacement | Parallel groups<br>open, blind assessment<br>Taiwan |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| PENTAMAKS (Bauer) , 2001<br>n=517/517<br>follow-up: 11 days | fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery<br>versus<br>enoxaparin 30mg twice daily (North america recommendation) | elective major knee surgery | Parallel groups<br>double blind<br>North america |
| PENTHIFRA (Eriksson) , 2001<br>n=831/840<br>follow-up: 11 days | fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery<br>versus<br>enoxaprin 40mg once daily | hip fracture surgery | Parallel groups<br>double blind<br>21 countries |
| EPHESUS (Lassen) , 2002<br>n=1155/1154<br>follow-up: 11 days (6 weeks) | fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery<br>versus<br>enoxaprin 40mg once daily | elective hip replacement surgery | Parallel groups<br>double blind<br>16 European countries |
| PENTATHLON (Turpie) , 2002<br>n=1138/1137<br>follow-up: 11 days | fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery<br>versus<br>enoxaparin 30mg twice daily (North america recommendation) | elective hip replacement surgery | Parallel groups<br>double blind<br>USA, Canada, Australia |
| PEGASUS , 2005<br>n=1465/1462<br>follow-up: 10 days (30 days) | once-daily subcutaneous injections of fondaparinux 25 mg started 6 h after surgery for 59 days<br>versus<br>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<br>double blind<br>22 countries |
| Turpie , 2001<br>n=673/260<br>follow-up: >15 days | pentasaccharide Org31540/SR90107A subcutaneous once daily at doses 0.75 mg, 1.5 mg, 3.0 mg, 6.0 mg, and 8.0 mg<br>versus<br>enoxaparin 30mg once daily subcutaneous | patients undergoing total hip replacement | Parallel groups<br>double blind<br>US, Canada, Autralia |
| **SR123781A vs enoxaparin** | | | |
| DRIVE , 2008<br>[NCT00338897]<br>n=854/169<br>follow-up: 5-10 days | SR123781A for 5-10 days, doses ranging from 0.25 to 4.0 mg daily for 10 days<br>versus<br>enoxaparin 40 mg | patients undergoing total hip replacement surgery | Parallel groups<br>double blind<br>12 countries |
| **extended prophylaxis vs standard prophylaxis** | | | |
| PENTHIFRAPLUS (Eriksson) , 2003<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 |

## References

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**NCT00320398, 0:**
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**DRI4757, 0:**

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**L8541, 0:**

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# 2 About TrialResults-center.org

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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.

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