

# Clinical trials of pentasaccharide for DVT prophylaxis in orthopedic surgery

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## 1 synthetic oligosaccharide

| Trial   | Treatments  | Patients   | Trials design and methods                                 |
|---|---|--|---|
| <b>fondaparinux vs placebo</b>  |   |  |   |
| <b>DRI4757</b><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                  |
| <b>fondaparinux vs enoxaparin</b>   |   |  |   |
| <b>L8541</b><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                  |
| <b>L8635</b><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       |
| <b>PENTAMAKS (Bauer) , 2001</b><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          |
| <b>PENTHIFRA (Eriksson) , 2001</b><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           |
| <b>EPHESUS (Lassen) , 2002</b><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  |
| <b>PENTATHLON (Turpie) , 2002</b><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 |
| <b>Turpie , 2001</b><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, Australia  |

continued...

| Trial   | Treatments   | Patients  | Trials design and methods                       |
|---|--|---|---|
| <b>SR123781A vs enoxaparin</b>  |  |   |   |
| <b>DRIVE , 2008</b><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 |
| <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                 |

## References

**DRI4757, 0:**

**L8541, 0:**

**L8635, 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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