

# Clinical trials of pentasaccharide for DVT prophylaxis in all type of patients

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## 1 synthetic oligosaccharide

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

continued...

<b>Trial</b>	<b>Treatments</b>	<b>Patients</b>	<b>Trials design and methods</b>
<b>PENTAMAKS (Bauer) , 2001</b> n=517/517 follow-up: 11 days	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaparin 30mg twice daily (North america recommendation)	elective major knee surgery	Parallel groups double blind North america
<b>PENTHIFRA (Eriksson) , 2001</b> n=831/840 follow-up: 11 days	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaprin 40mg once daily	hip fracture surgery	Parallel groups double blind 21 countries
<b>EPHESUS (Lassen) , 2002</b> n=1155/1154 follow-up: 11 days (6 weeks)	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaprin 40mg once daily	elective hip replacement surgery	Parallel groups double blind 16 European countries
<b>PENTATHLON (Turpie) , 2002</b> n=1138/1137 follow-up: 11 days	fondaparinux 2.5-mg once-daily subcutaneous, starting 6 hours after surgery versus enoxaparin 30mg twice daily (North america recommendation)	elective hip replacement surgery	Parallel groups double blind USA, Canada, Australia
<b>PEGASUS , 2005</b> 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
<b>Turpie , 2001</b> n=673/260 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 versus enoxaparin 30mg once daily subcutaneous	patients undergoing total hip replacement	Parallel groups double blind US, Canada, Australia
<b>SR123781A vs enoxaparin</b>			
<b>DRIVE , 2008</b> [NCT00338897] n=854/169 follow-up: 5-10 days	SR123781A for 5-10 days, doses ranging from 0.25 to 4.0 mg daily for 10 days versus enoxaparin 40 mg	patients undergoing total hip replacement surgery	Parallel groups double blind 12 countries
<b>extended prophylaxis vs standard prophylaxis</b>			
<b>PENTHIFRAPLUS (Eriksson) , 2003</b> n=656 follow-up: 19-23 days	25-31 days of fondaparinux 2.5-mg once-daily versus 6-8 days of fondaparinux 2.5-mg once-daily	patients undergoing hip fracture surgery	Parallel groups double blind

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NCT00320398, 0:

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