Clinical trials of pentasaccharide for thrombosis prevention in orthopedic surgery

TrialResults-center www.trialresultscenter.org

1 synthetic oligosaccharide

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs placebo			
DRI4757 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
fondaparinux vs enoxaparin			
L8541 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
L8635 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
PENTAMAKS (Bauer) , 2001 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
PENTHIFRA (Eriksson) , 2001 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
EPHESUS (Lassen) , 2002 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
PENTATHLON (Turpie) , 2002 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
Turpie , 2001 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, Autralia

continued...

Trial	Treatments	Patients	Trials design and methods
SR123781A vs enoxaparin			
DRIVE , 2008 [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
extended prophylaxis vs standard prophylaxis			
PENTHIFRAPLUS (Eriksson) , 2003 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

References

DRI4757, 0:

L8541, 0:

L8635, 0:

PENTAMAKS (Bauer), 2001:

Bauer KA, Eriksson BI, Lassen MR, Turpie AG Fondaparinux compared with enoxaparin for the prevention of venous thromboembolism after elective major knee surgery. N Engl J Med 2001 Nov 1;345:1305-10 [11794149]

PENTHIFRA (Eriksson), 2001:

Eriksson BI, Bauer KA, Lassen MR, Turpie AG Fondaparinux compared with enoxaparin for the prevention of venous thromboembolism after hip-fracture surgery. N Engl J Med 2001 Nov 1;345:1298-304 [11794148]

EPHESUS (Lassen), 2002:

Lassen MR, Bauer KA, Eriksson BI, Turpie AG Postoperative fondaparinux versus preoperative enoxaparin for prevention of venous thromboembolism in elective hip-replacement surgery: a randomised double-blind comparison. Lancet 2002 May 18;359:1715-20 [12049858]

PENTATHLON (Turpie), 2002:

Turpie AG, Bauer KA, Eriksson BI, Lassen MR Postoperative fondaparinux versus postoperative enoxaparin for prevention of venous thromboembolism after elective hip-replacement surgery: a randomised double-blind trial. Lancet 2002 May 18;359:1721-6 [12049860]

Turpie, 2001:

Turpie AG, Gallus AS, Hoek JA A synthetic pentasaccharide for the prevention of deep-vein thrombosis after total hip replacement. N Engl J Med 2001;344:619-25 [11228275]

DRIVE, 2008:

Lassen MR, Dahl O, Mismetti P, Zielske D, Turpie AG SR123781A: a new once-daily synthetic oligosaccharide anticoagulant for thromboprophylaxis after total hip replacement surgery: the DRIVE (Dose Ranging Study in Elective Total Hip Replacement Surgery) study. J Am Coll Cardiol 2008 Apr 15;51:1498-504 [18402906]

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]

2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

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.

TrialResults-center is non-profit and self-funded.