

# Clinical trials of direct antithrombins for DVT prophylaxis in orthopedic surgery

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## 1 oral direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
<b>ximelagatran vs Dalteparin</b>			
<b>METHRO I , 2002</b> n=103 follow-up: 69 days	Melagatran 14 mg s.c. immediately before surgery, melagatran at 20.00 hours, then ximelagatran 624 mg orally b.d. for 69 days versus Dalteparin 5000 IU o.d., started evening before surgery for 69 days	adults undergoing hip or knee replacement	parallel group open Swedish
<b>METHRO II , 2002</b> n=1495/381 follow-up: 710 days	Melagatran 13 mg s.c. immediately before surgery, melagatran same day, then ximelagatran 824 mg orally b.d. for 710 days versus Dalteparin 5000 IU o.d., started evening before surgery for 710 days	undergoing hip or knee replacement	Parallel groups double-blind
<b>ximelagatran vs Enoxaparin</b>			
<b>Platinum (Colwell) , 2003</b> n=906/910 follow-up: 712 days	Ximelagatran 24 mg orally b.d., starting at least 12 h after surgery for 712 days versus Enoxaparin 30 mg s.c. b.d., starting at least 12 h after surgery for 712 days	adults undergoing hip replacement	parallel group double-blind USA, Canada, Israel, Mexico, Argentina, South Africa
<b>METHRO III , 2002</b> n=2788 follow-up: 811 days	Melagatran 3 mg s.c. 412h after surgery, then ximelagatran 24 mg orally b.d. for 710 days versus Enoxaparin 40 mg s.c. o.d. 12 h before surgery for 710 days	hip or knee replacement	double-blind Europe, South Africa
<b>Phase II (Heit) , 2001</b> n=600 follow-up: 612 days	Ximelagatran 8, 12, 18 or 24 mg orally b.d., at least 12 h after surgery for 612 days versus Enoxaparin 30 mg s.c. b.d., starting at least 12 h after surgery for 612 days	adults (age > 18 years and weight at least 40 kg) undergoing knee replacements	parallel group double-blind North American
<b>EXPRESS , 2003</b> n=2835 follow-up: 811 days	Melagatran 2 mg s.c. up to 30 min before surgery, then melagatran 3 mg at least 8 h after surgery, then ximelagatran 24 mg orally b.d. for 811 days versus Enoxaparin 40 mg s.c. o.d., starting 12 h before surgery for 811 days	hip or knee replacement	parallel group double-blind Europe

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