Clinical trials of antithrombotics for thrombosis prevention in elective hip replacement

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1 direct factor Xa inhibitors

Trial	Treatments	Patients	Trials design and methods
apixaban vs enoxaparin			
ADVANCE 3 , 2010 [NCT00423319] n=2708/2699 follow-up: 35 days (+60)	apixaban 2.5mg twice daily for 35 days versus enoxaparin 40mg once daily for 35 days	patients undergoing elective total hip replacement surgery	Parallel groups double blind 21 countries
rivaroxaban vs enoxaparin			
RECORD 1 , 2008 [NCT00329628] n=2266/2275 follow-up: 36 days (range 30-42)	rivaroxaban 10mg once daily for 35 days versus enoxaparin 40mg subcutaneous once daily for 31-39 days	patients undergoing total hip arthroplasty	Parallel groups double blind 27 countries worldwide
edoxaban vs enoxaparin (short duration)			
STARS J-V [NCT01181167] n=255/248 follow-up:	edoxaban 30 mg once daily for 11 to 14 days versus subcutaneous enoxaparin 2,000 IU, equivalent to 20 mg, twice daily (BID) for 11 to 14 days	total hip arthroplasty	Parallel groups double-blind japan
rivaroxaban vs enoxaparin (short duration)			
ODIXa-HIP 10mg , 2006 n=142/157 follow-up: 5-9 days	rivaroxaban 10mg daily for 59 days versus once-daily subcutaneous enoxaparin dose of 40 mg for 59 days	patients undergoing elective total hip replacement	Parallel groups double blind Europe, Israel
rivaroxaban (long duration) vs enoxaparin (short duration)			
RECORD 2 , 2008 [NCT00332020] n=1252/1257 follow-up: 30-42 days	extended thromboprophylaxis with rivaroxaban 10mg once daily for 31-39 days versus enoxaparin 40mg subcutaneous once daily for 10-14 days	patients undergoing elective total hip replacement	Parallel groups double blind 21 countries worldwide

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RECORD 2, 2008:

Kakkar AK, Brenner B, Dahl OE, Eriksson BI, Mouret P, Muntz J, Soglian AG, Pap AF, Misselwitz F, Haas S Extended duration rivaroxaban versus short-term enoxaparin for the prevention of venous thromboembolism after total hip arthroplasty: a double-blind, randomised controlled trial. Lancet 2008 Jun 24;: [18582928]

2 Low molecular weight heparin

Trial	Treatments	Patients	Trials design and methods
semuloparin vs enoxaparin			
SAVE-HIP1 , 2012 [NCT00697099] n=1161/1165 follow-up:	Semuloparin 20 mg once-daily versus Enoxaparin 40 mg once-daily	-	
enoxaparin vs no treatment			
Warwick , 1995 n=78/78 follow-up: 8-10 days	enoxaparin 4000x1 + elastic stockings versus no treatment + elastic stockings	Elective hip	open
nadroparin vs no treatment			
Yoo , 1997 n=50/50 follow-up: 10 days	nadroparin 41/kgx1 days 1-3, 62/kg x1 days 4-11+elastic stockings versus no treatment	Elective hip	open
dalteparin vs placebo			
Torholm , 1991 n=58/54 follow-up: 9 days	dalteparin 5000x1 versus Placebo	Elective hip	double blind
enoxaparin vs placebo			
Kalodiki , 1996 n=13/14 follow-up: discharge (8-12 days)	enoxaparin 4000x1 versus Placebo	Elective hip	double blind
Samama , 1997 n=85/85 follow-up: 8-12 days	enoxaparin 4000x1+elastic stockings versus Placebo+elastic stockings	Elective hip	double blind

continued...

Trial	Treatments	Patients	Trials design and methods
Turpie , 1986 n=50/50 follow-up: 14 days or discharge	Enoxaparin 3000 x2 versus Placebo	Elective hip	double blind
tinzaparin vs placebo			
Lassen , 1991 n=105/105 follow-up: 8-10 days	tinzaparin 50/kg x1 +elastic stockings versus Placebo+elastic stockings	Elective hip	double blind
dalteparin vs Dextran			
Matzsch , 1991 n=120/123	dalteparin versus Dextran	Elective hip	
Eriksson , 1988 n=50/50	dalteparin versus Dextran	Elective hip	
Matzsch , 1988 n=48/52	dalteparin versus Dextran	Elective hip	
enoxaparin vs Dextran			
DES Group , 1991 n=120/126	Enoxaparin versus Dextran	Elective hip	
certoparine + DHE vs Unfractionated heparin			
Haas , 1987 n=80/80	Sandoz +0.5mg DHE versus Unfractionated heparin	Elective hip	
Lassen , 1988 n=118/122 follow-up: 6 days	certoparin 3000+0.5mg DHE, x1 versus Placebo	Elective hip	double blind
dalteparin vs Unfractionated heparin			
Binsack , 1986 n=48/47	dalteparin versus Unfractionated heparin	Elective hip	
Barre , 1987 n=40/40	dalteparin versus Unfractionated heparin	Elective hip	
Dechavanne , 1989 n=82/40	dalteparin versus Unfractionated heparin	Elective hip	
Eriksson , 1989 n=67/69	dalteparin versus Unfractionated heparin	Elective hip	

continued...

Trial	Treatments	Patients	Trials design and methods
Haas , 1985 n=65/65	dalteparin versus Unfractionated heparin	Elective hip	
enoxaparin vs Unfractionated heparin			
Levine , 1991 n=333/332	Enoxaparin versus Unfractionated heparin	Elective hip	
Planes , 1988 n=124/113	Enoxaparin versus Unfractionated heparin	Elective hip	
fluxum vs Unfractionated heparin			
Chiapuzzo , 1988 n=70/70	Fluxum versus Unfractionated heparin	Elective hip	
Pini , 1989 n=25/24	Fluxum versus Unfractionated heparin	Hip	
nadroparin vs Unfractionated heparin			
Leyvraz , 1991 n=203/206 follow-up:	Fraxiparin versus Unfractionated heparin	Elective hip	

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3 oral direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
dabigatran 150mg vs enoxaparin			
RE-NOVATE (150mg) , 2007 [NCT00168818] n=1174/1162 follow-up: 28-35 days, median 33d	dabigatran etexilate 150 mg q.d. 28-35 days versus Enoxaparin 40 mg q.d. for 28-25 days	Total hip replacement	double blind Europe, Australia, South Africa
dabigatran 220mg vs enoxaparin			
RE-NOVATE 2 *unpublished* [NCT00657150] n=1010/1003 follow-up: 28-35 days (mean 32d)	dabigatran 220mg once daily for 28-35 Days versus enoxaparin 40mg subcutaneous once daily for 28-35 Days	patients undergoing total hip-replacement surgery	Parallel groups double-blind
RE-NOVATE (220mg) , 2007 [NCT00168818] n=1157/1162 follow-up: 28-35 days, median 33d	dabigatran etexilate 220 mg q.d. for 28-35 days versus Enoxaparin 40 mg q.d. for 23-35 days	Total hip replacement	Parallel groups double blind Europe, Australia, South Africa
ximelagatran vs Enoxaparin			
Platinum (Colwell) , 2003 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
METHRO III , 2002 n=2788 follow-up: 811 days	Melagatran 3 mg s.c. 412h after surgery, then ximelagatran24 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
EXPRESS , 2003 n=2835 follow-up: 811 days	Melagatran 2 mg s.c. up to 30 min before surgery, then melagatran 3 mg at least 8 hafter 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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RE-NOVATE 2, 0:

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4 platelet aggregation inhibitors

Trial	Treatments	Patients	Trials design and methods
Aspirin vs no treatment			
Rocha , 1986 n=60/30 follow-up: 1 weeks	Aspirin 250mg or 1000mg daily versus control (combination of heparin plus dihydroergotamine)	total hip replacement	Parallel groups open
Aspirin vs placebo			
Stockholm-I , 1975 n=26/25 follow-up: 2 weeks	Aspirin 2000mg daily versus placebo	elective surgery of the hip	double blind
Harris-I , 1977 n=58/59 follow-up: 1 weeks	Aspirin 1200mg daily versus placebo	patients over 40 years of age, who had undergone total hip replacement	Parallel groups double-blind
Sautter , 1983 n=68/77 follow-up: 3 weeks	Aspirin 900mg daily + sulfinpyrazone versus placebo	patient with total hip replacement	Parallel groups
Hydroxychloroquine vs placebo			
Cooke , 1977 n=25/25 follow-up: 2 weeks	Hydroxychloroquine versus placebo	elective surgery on the hip	Parallel groups double-blind
Hume-A , 1977 n=20/20 follow-up: 2 weeks	Hydroxychloroquine versus placebo	total hip replacement	
Stockholm-II , 1981 n=18/17 follow-up: 2 weeks	Hydroxychloroquine versus placebo	total hip replacement	

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5 recombinant hirudin

Trial	Treatments	Patients	Trials design and methods
desirudin vs enoxaparin			
Ericksson , 1997 n=NA follow-up:	desirudin 15mg SC twice daily for 8-12 days versus enoxaparin 40mg once daily for 8-12 days	Patients who undergo total hip replacement	Parallel groups double blind Europe
desirudin vs UFH			
REVASC , 1997 n=225/220 follow-up:	desirudin 15mg twice daily versus unfractionated heparin 5000 IU three times a day	patients having a primary elective total hip replacement	Parallel groups

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Trial	Treatments	Patients	Trials design and methods
Eriksson , 1996 n=1119 follow-up:	recombinant hirudin, desirudin (CGP 39393) 10, 15, or 20 mg twice daily started just before surgery and continued for 8-11 days versus unfractionated heparin 5000 IU three times daily started just before surgery and continued for 8-11 days	patients undergoing elective hip surgery	Parallel groups double blind Europe

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6 synthetic oligosaccharide

Trial	Treatments	Patients	Trials design and methods
fondaparinux vs control			
NCT00320398 *ongoing* [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
fondaparinux vs enoxaparin			
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
SR123781A vs enoxaparin			

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Trial	Treatments	Patients	Trials design and methods
DRIVE , 2008	SR123781A for 5-10 days, doses ranging from	patients undergoing total hip replacement	Parallel groups
[NCT00338897]	0.25 to 4.0 mg daily for 10 days	surgery	double blind
n=854/169	versus		12 countries
follow-up: 5-10 days	enoxaparin 40 mg		

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7 About TrialResults-center.org

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