

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:

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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 | | | |
| Leyvrax , 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 <i>unpublished</i> [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 (220mg), 2007:

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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 + sulfipyrazone 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

6 synthetic oligosaccharide

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| fondaparinux vs control | | | |
| NCT00320398 <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 |
| 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 | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|--|---|---|
| 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 |

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7 About TrialResults-center.org

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