

Clinical trials of anticoagulant for DVT prophylaxis in orthopedic surgery

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1 antivitamins K

| Trial | Treatments | Patients | Trials design and methods |
|---|---|-------------|---------------------------|
| vs no treatment | | | |
| Borsgtrom , 1965 n=29/29 follow-up: 65279;34 weeks | 65279;Dicoumarol versus 65279;No treatment | HFS | Open |
| Phenindione vs no treatment | | | |
| Eskeland , 1966 n=100/100 follow-up: 3 months | Phenindione versus No treatment | HFS | Open |
| Hamilton , 1970 n=38/38 follow-up: 310 months | Phenindione versus No treatment | HFS | Open |
| Warfarin vs no treatment | | | |
| Pinto , 1970 n=25/25 follow-up: >3 weeks | Warfarin versus No treatment | Hip surgery | Open |
| Hume , 1973 n=17/19 follow-up: Discharge | Warfarin versus No treatment | THR | Open |
| Morris , 1976 n=80/80 follow-up: 3 months | Warfarin versus No treatment | HFS | Open |
| Powers , 1989 n=65/63 follow-up: 3 months | Warfarin versus No treatment | HFS | Open |
| Warfarin vs placebo | | | |
| Myrhe , 1969 n=50/55 follow-up: 3 weeks | Wwarfarin versus Placebo | HFS | double blind |
| Warfarin vs Ardeparin | | | |
| RD Heparin , 1994 n=403/770 follow-up: 3 months | Warfarin versus Ardeparin 50 anti-Xa IU /kg or 90 anti-Xa IU /kg x1 | THR or TKR | Open |
| Heit , 1997 n=279/554 follow-up: Days 514 | Warfarin versus Ardeparin 25, 35, 50 anti-Xa U /kg x2 | TKR | double blind |
| Warfarin vs Aspirin | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|-------------------------------|----------------------------------|
| Lotke , 1997 n=146/166 follow-up: 6 months | Warfarin versus Aspirin 325 mg x2 | THR or TKR (stratified) | Open |
| Powers , 1989 n=65/66 follow-up: 3 months | Warfarin versus Aspirin 650 mg x2 | HFS | Open |
| Warfarin vs Dalteparin | | | |
| Francis , 1997 n=292/288 follow-up: Day 7 2 | Warfarin versus Dalteparin 5000 anti-Xa IU x1 | THR | Open |
| Hull , 2000 n=489/983 follow-up: Day 6 2 | Warfarin versus Dalteparin 5000 anti-Xa IU x1 | THR | double blind |
| Warfarin vs Danaparoid | | | |
| Gerhart , 1991 n=131/132 follow-up: 9 days | Warfarin versus Danaparoid 750 U x2 | HFS | Open |
| van Comp , 1998 n=247/241 follow-up: 3 months | Warfarin versus Danaparoid 750 U x2 | THR | Open |
| Warfarin vs Dextran | | | |
| Harris , 1972 n=114/113 follow-up: NA | Warfarin versus Dextran 40 | THR | Open |
| Barber , 1977 n=58/51 follow-up: 1114 days | Warfarin versus Dextran 70 | THR | Open |
| Francis , 1983 n=57/43 follow-up: 57 days | Warfarin versus Dextran 40 | THR or TKR (stratified)65279; | Open |
| Myrhe , 1969 n=50/55 follow-up: 3 weeks | Warfarin versus Dextran 70 | HFS | double blind |
| Warfarin vs Enoxaparin | | | |
| Leclerc , 1996 n=334/336 follow-up: 6 months | Warfarin versus Enoxaparin 30 mg x2 | TKR | double blind |
| Colwell , 1999 n=1495/1516 follow-up: 3 months | Warfarin versus Enoxaparin 30 mg x2 | THR | Open |
| Fitzgerald , 2001 n=176/173 follow-up: 3 weeks | Warfarin versus Enoxaparin 30 mg x2 | TKR | Open |
| Warfarin vs Intermittent pneumatic compression | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|--|-------------------------------|----------------------------------|
| Francis , 1992 n=103/98 follow-up: 68 days | Warfarin versus IPC | THR | Open |
| Paiement , 1987 n=80/83 follow-up: 12 days | Warfarin versus IPC | THR | Open |
| Bailey , 1991 n=45/50 follow-up: 57 days | Warfarin versus IPC | THR | Open |
| Kaempffe , 1991 n=52/48 follow-up: At least 2 months | Warfarin versus IPC | THR or TKR (stratified) | Open |
| Warfarin vs Logiparin | | | |
| Hull , 1993 n=721/715 follow-up: 65279;Day 14 or discharge | Warfarin versus Logiparin 75 anti-Xa IU /kg x1 | 65279;THR or TKR (stratified) | double blind |
| Acenocoumarol vs Nadroparin | | | |
| Hamulyak , 1994 n=342/330 follow-up: Day 10 2 | Acenocoumarol versus Nadroparin 60 anti-Xa IU /kg x1 | THR or TKR (stratified) | single blind |
| Acenocoumarol vs Reviparin | | | |
| Samama , 2001 n=645/644 follow-up: 6 weeks | Acenocoumarol versus Reviparin 4200 anti-Xa IU x1 | THR | Open |
| Warfarin vs Sudoxicam | | | |
| Hume , 1973 n=52/51 follow-up: Discharge | Warfarin versus Sudoxicam | THR | single blind |
| Acenocoumarol vs unfractionated heparin | | | |
| van Geloven , 1977 n=11/11 follow-up: NA | Acenocoumarol versus UFH 4000 x2 | THR | double blind |
| Warfarin vs unfractionated heparin | | | |
| Hume , 1973 n=17/18 follow-up: Discharge | Warfarin versus UFH 5000 x3 | THR | Open |
| Barber , 1977 n=58/19 follow-up: 1114 days | Warfarin versus UFH 5000 x2 | THR | Open |

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2 direct factor Xa inhibitors

9

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---|
| edoxaban vs placebo | | | |
| DU176b-04 <i>ongoing</i> [NCT01203072] n=NA follow-up: | edoxaban 5, 15, 30, 60 mg once daily for 2 weeks versus placebo | elective total knee arthroplasty | parallel groups double-blind Japan |
| 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 |
| edoxaban vs enoxaparin | | | |
| DU176b-B-J302 <i>ongoing</i> [NCT01181102] n=NA follow-up: | edoxaban 30mg once daily versus enoxaparin sodium (enoxaparin sodium 20mg(=2000IU)/0.2ml twice daily, subcutaneous injection) | elective total knee arthroplasty | parallel groups double-blind Japan |
| DU176b-B-J303 <i>ongoing</i> [NCT01181141] n=NA follow-up: | edoxaban 30mg once daily versus Enoxaparin sodium 20mg(=2000IU)/0.2ml twice daily, subcutaneous injection | elective hip fracture surgery | open Japan |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|--|--|---|
| DU176b-B-J304 <i>ongoing</i> [NCT01181167] n=NA follow-up: | edoxaban 30mg once daily versus (enoxaparin sodium 20mg(=2000IU)/0.2ml twice daily, subcutaneous injection | elective total hip arthroplasty | parallel groups double-blind Japan |
| 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 |
| apixaban vs enoxaparin (europe regimen) | | | |
| ADVANCE 2 , 2010 [NCT00452530] n=1528/1529 follow-up: 12 days | apixaban 2.5mg twice daily during 12 days versus enoxaparin 40mg once daily 12 days | patients undergoing elective unilateral or bilateral total knee replacement | Parallel groups double blind 27 countries |
| rivaroxaban vs enoxaparin (europe regimen) | | | |
| RECORD 3 , 2008 [NCT00361894] n=1254/1277 follow-up: 13-17 days | rivaroxaban 10 mg once daily for 10- 14 days versus enoxaparin 40 mg subcutaneous once daily for 10-14 days | patients undergoing total knee arthroplasty | Parallel groups double blind 19 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 |
| apixaban vs enoxaparin (US regimen) | | | |
| APROPOS 2.5mg , 2007 [NCT00097357] n=153/152 follow-up: 12 days | apixaban 2.5mg BID for 12 days versus enoxaparin 30mg twice daily for 12 days | patients undergoing elective total knee replacement surgery | Parallel groups double blind |

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| Trial | Treatments | Patients | Trials design and methods |
|--|--|---|--|
| ADVANCE-1 , 2008 [NCT00371683] n=1599/1596 follow-up: 10-14 days | apixaban 2.5 mg orally twice daily for 10 to 14 days versus enoxaparin 30mg subcutaneously every 12 hours for 10-14 days | patients undergoing knee-replacement surgery | Parallel groups double blind 14 countries |
| rivaroxaban vs enoxaparin (US regimen) | | | |
| ODIXa-KNEE , 2005 n=102/105 follow-up: 5-9 days | BAY 59-7939 5mg b.i.d. for 59 days versus enoxaparin 30 mg b.i.d. for 59 days | patients undergoing elective total knee replacement | Parallel groups double blind North America |
| RECORD 4 , 2009 [NCT00362232] n=1584/1564 follow-up: 40 days | rivaroxaban 10mg once daily for 10 to 14 days versus enoxaparin 30 mg twice daily by subcutaneous injection for 10-14 days | patients who had undergone total-knee-replacement surgery | Parallel groups double blind 12 countries |

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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 |
| dabigatran 150mg vs enoxaparin (europe regimen) | | | |
| RE-MODEL (150mg) , 2007 n=708/699 follow-up: 6-10 days, mean 8 days | dabigatran etexilate 150 mg q.d. for 6-10 days versus Enoxaparin 40 mg q.d. for 6-10 days | Total knee replacement | Parallel groups double blind Europe, Australia, South Africa |
| dabigatran 220mg vs enoxaparin (europe regimen) | | | |
| RE-MODEL (220mg) , 2007 n=694/699 follow-up: 6-10 days, mean 8 days | dabigatran etexilate 220 mg q.d. 6-10 days versus Enoxaparin 40 mg q.d. for 6-10 days | patients undergoing total knee replacement | double blind Europe, Australia, South Africa |
| dabigatran 150mg vs enoxaparin (US regimen) | | | |

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| Trial | Treatments | Patients | Trials design and methods |
|--|---|------------------------|---|
| RE-MOBILIZE (150mg) , 2008 n=877/876 follow-up: 12-15 days, median 14d | dabigatran etexilate 150 mg q.d. for 12-15 days versus enoxaparin 30 mg SC BID after surgery for 12-15 days | Total knee replacement | double blind US, Canada, Mexico, UK |
| dabigatran 220mg vs enoxaparin (US regimen) | | | |
| RE-MOBILIZE (220mg) , 2008 n=862/876 follow-up: 12-15 days, median 14d | dabigatran etexilate 220 mg for 12-15 days versus Enoxaparin 30mg SC BID after surgery for 12-15 days | Total knee replacement | Parallel groups double blind US, Canada, Mexico, UK |

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RE-NOVATE 2, 0:

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4 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.