

Clinical trials of anticoagulant for thrombosis prevention 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			

continued...

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

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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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DU176b-B-J304, 0:

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STARS J-V, 0:

ODIXa-HIP 10mg, 2006:

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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 (150mg), 2007:

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RE-NOVATE 2, 0:

RE-NOVATE (220mg), 2007:

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RE-MODEL (150mg), 2007:

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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.