

Clinical trials of direct oral anticoagulant (DAO) for thrombosis prevention in all type of patients

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1 direct factor Xa inhibitors

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
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)			

continued...

Trial	Treatments	Patients	Trials design and methods
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
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-J303, 0:

DU176b-B-J304, 0:

RECORD 1, 2008:

Eriksson BI, Borris LC, Friedman RJ, Haas S, Huisman MV, Kakkar AK, Bandel TJ, Beckmann H, Muehlhofer E, Misselwitz F, Geerts W Rivaroxaban versus enoxaparin for thromboprophylaxis after hip arthroplasty N Engl J Med 2008;358:2765-75 [[18579811](#)] [10.1056/NEJMoa0800374](#)

ADVANCE 2, 2010:

Lassen MR, Raskob GE, Gallus A, Pineo G, Chen D, Hornick P Apixaban versus enoxaparin for thromboprophylaxis after knee replacement (ADVANCE-2): a randomised double-blind trial. Lancet 2010 Mar 6;375:807-15 [[20206776](#)] [10.1016/S0140-6736\(09\)62125-5](#)

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STARS J-V, 0:

ODIXa-HIP 10mg, 2006:

Eriksson BI, Borris L, Dahl OE, Haas S, Huisman MV, Kakkar AK, Misselwitz F, Klebo P Oral, direct Factor Xa inhibition with BAY 59-7939 for the prevention of venous thromboembolism after total hip replacement. J Thromb Haemost 2006 Jan;4:121-8 [[16409461](#)]

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Turpie AG, Fisher WD, Bauer KA, Kwong LM, Irwin MW, Klebo P, Misselwitz F, Gent M BAY 59-7939: an oral, direct factor Xa inhibitor for the prevention of venous thromboembolism in patients after total knee replacement. A phase II dose-ranging study. J Thromb Haemost 2005 Nov;3:2479-86 [[16241946](#)]

RECORD 4, 2009:

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2 oral direct thrombin inhibitor

Trial	Treatments	Patients	Trials design and methods
dabigatran 150mg vs enoxaparin			

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Trial	Treatments	Patients	Trials design and methods
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)			
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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3 About TrialResults-center.org

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