Clinical trials of rivaroxaban

TrialResults-center www.trialresultscenter.org

1 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs warfarin			
ROCKET (subgroup) , 2011 n=3892/3875 follow-up:	rivaroxaban versus warfarin INR 2-3	-	Parallel groups double-blind
rivaroxaban vs warfarin standard dose			
ROCKET-AF , 2010 [NCT00403767] n=7131/7133 follow-up: median 1.94 y	Rivaroxaban 20mg p.o. once daily versus Warfarin p.o. once daily titrated to a target INR of 2.5 (range 2.0 to 3.0, inclusive)	Subjects With Non-Valvular Atrial Fibrillation	Parallel groups double blind 45 countries
ROCKET J *ongoing* [NCT00494871] n=NA follow-up:	Rivaroxaban versus warfarin	-	parallel groups double-blind Japan

More details and results :

- antithrombotics for atrial fibrillation in primary prevention of thromboembolic events at http://www.trialresultscenter.org/godirect.asp?q=57
- direct factor Xa inhibitors for atrial fibrillation in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=373
- new oral anticoagulants for atrial fibrillation in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=391
- antithrombotics for atrial fibrillation in secondary prevention of thromboembolic events at http://www.trialresultscenter.org/godirect.asp?q=392

References

ROCKET (subgroup), 2011:
ROCKET-AF, 2010:

Rivaroxaban-once daily, oral, direct factor Xa inhibition compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation: rationale and design of the ROCKET AF study. Am Heart J 2010;159:340-347.e1 [20211293] 10.1016/j.ahj.2009.11.025

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ROCKET J, :

ongoing trial NCT00494871

2 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
rivaroxaban 2.5mg vs placebo			
ATLAS ACS-TIMI 46 (2.5mg) , 2009 [NCT00402597] n=152/1160 follow-up: 6 months	rivaroxaban 2.5 mg twice daily versus placebo	recent ACS patients treated with aspirin alone (n=761) or aspirin plus clopidogrel (n=2730)	double blind 27 countries
ATLAS ACS 2 - TIMI 51 (2.5mg) , 2011 [NCT00809965] n=5174/5176 follow-up: 13 months	rivaroxaban 2.5 mg twice daily in addition to standard care versus placebo	patients with a recent ACS	Parallel groups double blind 44 countries
rivaroxaban 5mg vs placebo			
ATLAS ACS-TIMI 46 (5mg) , 2009 [NCT00402597] n=519/1160 follow-up: 6 months	rivaroxaban 5 mg twice daily versus placebo	recent ACS patients treated with aspirin alone (n=761) or aspirin plus clopidogrel (n=2730)	Parallel groups double blind 27 countries
ATLAS ACS 2 - TIMI 51 (5mg) , 2011 [NCT00809965] n=5176/5176 follow-up: 13 months	rivaroxaban 5 mg twice daily in addition to standard care versus placebo	patients with a recent ACS	double blind 44 countries

More details and results :

- antithrombotics for acute coronary syndrome in all type of patient at http://www.trialresultscenter.org/godirect.asp?q=24
- anticoagulant for acute coronary syndrome in All ACS (including AMI) at http://www.trialresultscenter.org/godirect.asp?q=167

- direct factor Xa inhibitors for acute coronary syndrome in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=345
- antithrombotics for acute coronary syndrome in patients with a recent ACS at http://www.trialresultscenter.org/godirect.asp?q=387
- new oral anticoagulants for acute coronary syndrome in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=480

References

ATLAS ACS-TIMI 46 (2.5mg), 2009:

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ATLAS ACS 2 - TIMI 51 (2.5mg), 2011:

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ATLAS ACS 2 - TIMI 51 (5mg), 2011:

Mega JL, Braunwald E, Wiviott SD, Bassand JP, Bhatt DL, Bode C, Burton P, Cohen M, Cook-Bruns N, Fox KA, Goto S, Murphy SA, Plotnikov AN, Schneider D, Sun X, Verheugt FW, Gibson CM Rivaroxaban in Patients with a Recent Acute Coronary Syndrome. N Engl J Med 2011 Nov 13;: [22077192] 10.1056/NEJMoa1112277

3 DVT prophylaxis

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs enoxaparin			
MAGELLAN , 2011 *unpublished* [NCT00571649] n=4050/4051 follow-up: 35 days	rivaroxaban 10 mg once daily for 35 days versus subcutaneous enoxaparin 40 mg once daily for 10 days	patients hospitalized for acute medical illness	Parallel groups double-blind

continued...

Trial	Treatments	Patients	Trials design and methods
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
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
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
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

More details and results :

- antithrombotics for DVT prophylaxis in orthopedic surgery at http://www.trialresultscenter.org/godirect.asp?q=37
- antithrombotics for DVT prophylaxis in elective major knee surgery at http://www.trialresultscenter.org/godirect.asp?q=38
- antithrombotics for DVT prophylaxis in elective hip replacement at http://www.trialresultscenter.org/godirect.asp?q=39

- antithrombotics for DVT prophylaxis in medical patients at http://www.trialresultscenter.org/godirect.asp?q=87
- anticoagulant for DVT prophylaxis in orthopedic surgery at http://www.trialresultscenter.org/godirect.asp?q=184
- direct factor Xa inhibitors for DVT prophylaxis in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=371
- new oral anticoagulants for DVT prophylaxis in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=393
- new oral anticoagulants for DVT prophylaxis in elective major knee surgery at http://www.trialresultscenter.org/godirect.asp?q=394
- new oral anticoagulants for DVT prophylaxis in elective hip replacement at http://www.trialresultscenter.org/godirect.asp?q=395
- new oral anticoagulants for DVT prophylaxis in orthopaedic surgery at http://www.trialresultscenter.org/godirect.asp?q=475
- new oral anticoagulants for DVT prophylaxis in medical patients at http://www.trialresultscenter.org/godirect.asp?q=485

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MAGELLAN, 2011:

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RECORD 3, 2008:

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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]

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RECORD 4, 2009:

Turpie AG, Lassen MR, Davidson BL, Bauer KA, Gent M, Kwong LM, Cushner FD, Lotke PA, Berkowitz SD, Bandel TJ, Benson A, Misselwitz F, Fisher WD Rivaroxaban versus enoxaparin for thromboprophylaxis after total knee arthroplasty (RECORD4): a randomised trial. Lancet 2009 May 16;373:1673-80 [19411100] 10.1016/S0140-6736(09)60734-0

4 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
extended rivaroxaban vs placebo			
EINSTEIN-extension , 2009 [NCT00439725] n=602/595 follow-up:	rivaroxaban 20 mg once-daily for an additional 6 or 12 months versus placebo	patients who had completed six to 12 months of anticoagulant treatment for an acute episode of VTE	Parallel groups double blind 28 countries
rivaroxaban (without LMWH) vs LMWH/VKA			
Einstein-DVT Dose-Ranging Study , 2008 n=NA follow-up:	rivaroxaban 20, 30, or 40 mg once daily versus low-molecular-weight heparin followed by vitamin K antagonists	patients with deep vein thrombosis	open
Einstein-DVT Evaluation , 2010 [NCT00440193] n=1731/1718 follow-up:	rivaroxaban 15 mg twice daily for 3 weeks, then 20 mg daily versus enoxaparin 1 mg/kg twice daily >=5 days, then warfarin with target INR between 2-3	Patients with Confirmed Acute Symptomatic Deep-Vein Thrombosis without Pulmonary Embolism	Parallel groups open (assessor-blind)
Einstein-PE Evaluation , 2012 [NCT00439777] n=2419/2413 follow-up: 9.8 months	rivaroxaban (15 mg twice daily for 3 weeks, followed by 20 mg once daily) for 3, 6, or 12 months versus standard therapy with enoxaparin followed by an adjusted-dose vitamin K antagonist	patients who had acute symptomatic pulmonary embolism with or without deep-vein thrombosis	Parallel groups open 38 countries

More details and results :

- antithrombotics for venous thrombosis in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=101
- antithrombotics for venous thrombosis in secondary prevention of VTE at http://www.trialresultscenter.org/godirect.asp?q=149
- direct factor Xa inhibitors for venous thrombosis in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=372

- new oral anticoagulants for venous thrombosis in all types of patients at http://www.trialresultscenter.org/godirect.asp?q=505

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Einstein-DVT Evaluation, 2010:

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Einstein-PE Evaluation, 2012:

Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism. N Engl J Med 2012 Mar 26;: [22449293] 10.1056/NEJMoa1113572

5 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
rivaroxaban (without LMWH) vs LMWH/VKA			
Einstein-PE Evaluation , 2012 [NCT00439777] n=2419/2413 follow-up: 9.8 months	rivaroxaban (15 mg twice daily for 3 weeks, followed by 20 mg once daily) for 3, 6, or 12 months versus standard therapy with enoxaparin followed by an adjusted-dose vitamin K antagonist	patients who had acute symptomatic pulmonary embolism with or without deep-vein thrombosis	Parallel groups open 38 countries

More details and results :

- antithrombotics for pulmonary embolism in all type of patients at http://www.trialresultscenter.org/godirect.asp?q=102

References

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Oral Rivaroxaban for the Treatment of Symptomatic Pulmonary Embolism. N Engl J Med 2012 Mar 26;: [22449293] 10.1056/NEJMoa1113572

Entry terms: Xarelto, BAY 59-7939,