

Clinical trials of rivaroxaban

TrialResults-center www.trialresultscenter.org

1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs aspirin			
COMPASS (rivaroxaban alone) , 2017 [NCT01776424] n=27400 follow-up:	Rivaroxaban 2.5 mg twice daily alone versus aspirin 100 mg once daily	Patients With Coronary or Peripheral Artery Disease	
rivaroxaban + aspirin vs aspirin			
COMPASS (rivaroxaban + aspirin) , 2017 [NCT01776424] n=9152/9126 follow-up: 23 months	rivaroxaban (2.5 mg twice daily) plus aspirin (100 mg once daily) versus aspirin 100 mg once daily	Patients With Coronary or Peripheral Artery Disease	Parallel groups double-blind
rivaroxaban vs placebo			
COMMANDER HF ongoing [NCT01877915] n=5000 follow-up:	Rivaroxaban 2.5 mg versus placebo	Subjects With Heart Failure and Significant Coronary Artery Disease Following an Episode of Decompensated Heart Failure	

More details and results :

- anticoagulant for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q481>
- direct oral anticoagulant (DAO) for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q706>
- direct factor Xa inhibitors for cardiovascular prevention in secondary prevention at <http://www.trialresultscenter.org/go-Q707>
- anticoagulant for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q709>

References

COMPASS (rivaroxaban alone), 2017:

COMPASS (rivaroxaban + aspirin), 2017:

Eikelboom JW, Connolly SJ, Bosch J, Dagenais GR, Hart RG, Shestakovska O, Diaz R, Alings M, Lonn EM, Anand SS, Widimsky P, Hori M, Avezum A, Piegas LS, Branch KRH, Probstfield J, Bhatt DL, Zhu J, Liang Y, Maggioni AP, Lopez-Jaramillo P, O'Donnell M, Kakka Rivaroxaban with or without Aspirin in Stable Cardiovascular Disease. N Engl J Med 2017;377:1319-1330 [28844192]

COMMANDER HF, :

ongoing trial NCT01877915

2 heart failure

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs placebo			
COMMANDER HF <i>ongoing</i> [NCT01877915] n=5000 follow-up:	Rivaroxaban 2.5 mg versus placebo	Subjects With Heart Failure and Significant Coronary Artery Disease Following an Episode of Decompensated Heart Failure	

More details and results :

- antithrombotics for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q73>

References

COMMANDER HF, :

ongoing trial NCT01877915

3 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs warfarin			
ROCKET (2nd prevention subgroup) , 2011 n=3892/3875 follow-up:	rivaroxaban versus warfarin INR 2-3	patients with a prior stroke or transient ischemic attack	Parallel groups double-blind
rivaroxaban vs warfarin standard dose			

continued...

Trial	Treatments	Patients	Trials design and methods
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 <i>ongoing</i> [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/go-Q57>
- direct factor Xa inhibitors for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q373>
- direct oral anticoagulant (DAO) for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q391>
- antithrombotics for atrial fibrillation in secondary prevention of thromboembolic events at <http://www.trialresultscenter.org/go-Q392>

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References

ROCKET (2nd prevention 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

Patel MR, Mahaffey KW, Garg J, Pan G, Singer DE, Hacke W, Breithardt G, Halperin JL, Hankey GJ, Piccini JP, Becker RC, Nessel CC, Paolini JF, Berkowitz SD, Fox KA, Califf RM Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. N Engl J Med 2011 Aug 10;: [21830957] 10.1056/NEJMoa1009638

ROCKET J, :

ongoing trial NCT00494871

4 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
rivaroxaban 2.5mg vs placebo			

continued...

Trial	Treatments	Patients	Trials design and methods
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

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More details and results :

- antithrombotics for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q24>
- anticoagulant for acute coronary syndrome in All ACS (including AMI) at <http://www.trialresultscenter.org/go-Q167>
- direct factor Xa inhibitors for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q345>
- antithrombotics for acute coronary syndrome in patients with a recent ACS at <http://www.trialresultscenter.org/go-Q387>
- direct oral anticoagulant (DAO) for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q480>

References

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

Mega JL, Braunwald E, Mohanavelu S, Burton P, Poulter R, Misselwitz F, Hricak V, Barnathan ES, Bordes P, Witkowski A, Markov V, Oppenheimer L, Gibson CM
Rivaroxaban versus placebo in patients with acute coronary syndromes (ATLAS ACS-TIMI 46): a randomised, double-blind, phase II trial. Lancet 2009 Jul 4;374:29-38
[19539361]

ATLAS ACS 2 - TIMI 51 (2.5mg), 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

ATLAS ACS-TIMI 46 (5mg), 2009:

Mega JL, Braunwald E, Mohanavelu S, Burton P, Poulter R, Misselwitz F, Hricak V, Barnathan ES, Bordes P, Witkowski A, Markov V, Oppenheimer L, Gibson CM Rivaroxaban versus placebo in patients with acute coronary syndromes (ATLAS ACS-TIMI 46): a randomised, double-blind, phase II trial. Lancet 2009 Jul 4;374:29-38 [19539361]

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

5 thrombosis prevention

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs placebo			
MARINER <i>ongoing</i> [NCT02111564] n=NA follow-up:	rivaroxaban thromboprophylaxis using rivaroxaban, begun at hospital discharge and continued for 45 days, versus placebo	high-risk medical patients	
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
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)			

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Trial	Treatments	Patients	Trials design and methods
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 :

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- antithrombotics for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q37>
- antithrombotics for thrombosis prevention in elective major knee surgery at <http://www.trialresultscenter.org/go-Q38>
- antithrombotics for thrombosis prevention in elective hip replacement at <http://www.trialresultscenter.org/go-Q39>
- antithrombotics for thrombosis prevention in medical patients at <http://www.trialresultscenter.org/go-Q87>
- anticoagulant for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q184>
- direct factor Xa inhibitors for thrombosis prevention in all type of patients at <http://www.trialresultscenter.org/go-Q371>
- direct oral anticoagulant (DAO) for thrombosis prevention in all type of patients at <http://www.trialresultscenter.org/go-Q393>
- direct oral anticoagulant (DAO) for thrombosis prevention in elective major knee surgery at <http://www.trialresultscenter.org/go-Q394>
- direct oral anticoagulant (DAO) for thrombosis prevention in elective hip replacement at <http://www.trialresultscenter.org/go-Q395>
- direct oral anticoagulant (DAO) for thrombosis prevention in orthopaedic surgery at <http://www.trialresultscenter.org/go-Q475>
- direct oral anticoagulant (DAO) for thrombosis prevention in medical patients at <http://www.trialresultscenter.org/go-Q485>

References

MARINER, :

ongoing trial NCT02111564

Raskob GE, Spyropoulos AC, Zrubek J, Ageno W, Albers G, Elliott CG, Halperin J, Haskell L, Hiatt WR, Maynard GA, Peters G, Spiro T, Steg PG, Suh EY, Weitz JI The MARINER trial of rivaroxaban after hospital discharge for medical patients at high risk of VTE. Design, rationale, and clinical implications. *Thromb Haemost* 2016;115:1240-8 [[26842902](#)]

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](#)

RECORD 3, 2008:

Lassen MR, Ageno W, Borris LC, Lieberman JR, Rosencher N, Bandel TJ, Misselwitz F, Turpie AG Rivaroxaban versus enoxaparin for thromboprophylaxis after total knee arthroplasty. *N Engl J Med* 2008 Jun 26;358:2776-86 [[18579812](#)]

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](#)]

Eriksson BI, Borris LC, Dahl OE, Haas S, Huisman MV, Kakkar AK, Muehlhofer E, Dierig C, Misselwitz F, Klebo P A once-daily, oral, direct Factor Xa inhibitor, rivaroxaban (BAY 59-7939), for thromboprophylaxis after total hip replacement. *Circulation* 2006 Nov 28;114:2374-81 [[17116766](#)]

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](#)]

ODIXa-KNEE, 2005:

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:

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](#)

6 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
rivaroxaban 10mg vs aspirin			

continued...

Trial	Treatments	Patients	Trials design and methods
EINSTEIN CHOICE (10mg) , 2017 [NCT02064439] n=1127/1131 follow-up:	Rivaroxaban 10 mg once daily for 12 months versus ASA (Acetylsalicylic Acid) 100 mg once daily for 12 months	Patients with confirmed symptomatic DVT (Deep Vein Thrombosis) or PE (Pulmonary embolism) who completed 6 or 12 months of treatment of anticoagulation	
rivaroxaban vs discontinuation			
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 20mg vs placebo			
EINSTEIN EXT , 2010 n=602/595 follow-up:	rivaroxaban alone (20 mg once daily)for an additional 6 or 12 months versus placebo	patients who had completed 6 to 12 months of treatment for venous thromboembolism	
rivaroxaban 20mg vs aspirin			
EINSTEIN CHOICE (20mg) , 2017 [NCT02064439] n=1107/1131 follow-up:	Rivaroxaban 20 mg once daily for 12 months versus ASA (Acetylsalicylic Acid) 100 mg once daily for 12 months	Patients with confirmed symptomatic DVT (Deep Vein Thrombosis) or PE (Pulmonary embolism) who completed 6 or 12 months of treatment of anticoagulation	
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)

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Trial	Treatments	Patients	Trials design and methods
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/go-Q101>
- antithrombotics for venous thrombosis in secondary prevention of VTE at <http://www.trialresultscenter.org/go-Q149>
- direct oral anticoagulant (DAO) for venous thrombosis in all types of patients at <http://www.trialresultscenter.org/go-Q505>
- antithrombotics for venous thrombosis in secondary prevention - 2 at <http://www.trialresultscenter.org/go-Q682>

References

EINSTEIN CHOICE (10mg), 2017:

Weitz JI, Lensing AWA, Prins MH, Bauersachs R, Beyer-Westendorf J, Bounameaux H, Brighton TA, Cohen AT, Davidson BL, Decousus H, Freitas MCS, Holberg Rivaroxaban or Aspirin for Extended Treatment of Venous Thromboembolism. N. Engl. J. Med. 2017; 376:1211-1222 [28316279] 10.1056/NEJMoa1700518

EINSTEIN-extension, 2009:

Biller H R. Once daily oral rivaroxaban versus placebo in the long term treatment of recurrent symptomatic venous thromboembolism. The Einstein-extension study. ASH, 8 dcembre 2009

Oral Rivaroxaban for Symptomatic Venous Thromboembolism. N Engl J Med 2010 Dec 3;: [21128814] 10.1056/NEJMoa1007903

EISNTEIN EXT, 2010:

Bauersachs R, Berkowitz SD, Brenner B, Buller HR, Decousus H, Gallus AS, Lensing AW, Misselwitz F, Prins MH, Raskob GE, Segers A, Verhamme P, Wells P, Agnelli G, Bounameaux H, Cohen A, Davidson BL, Piovella F, Schellong S Oral rivaroxaban for symptomatic venous thromboembolism. N Engl J Med 2010;363:2499-510 [21128814] 10.1056/NEJMoa1007903

EINSTEIN CHOICE (20mg), 2017:

Weitz JI, Lensing AWA, Prins MH, Bauersachs R, Beyer-Westendorf J, Bounameaux H, Brighton TA, Cohen AT, Davidson BL, Decousus H, Freitas MCS, Holberg Rivaroxaban or Aspirin for Extended Treatment of Venous Thromboembolism. N. Engl. J. Med. 2017; 376:1211-1222 [28316279] 10.1056/NEJMoa1700518

Einstein-DVT Dose-Ranging Study, 2008:

Buller HR, Lensing AW, Prins MH, Agnelli G, Cohen A, Gallus AS, Misselwitz F, Raskob G, Schellong S, Segers A A dose-ranging study evaluating once-daily oral administration of the factor Xa inhibitor rivaroxaban in the treatment of patients with acute symptomatic deep vein thrombosis: the Einstein-DVT Dose-Ranging Study. Blood 2008;112:2242-7 [18621928]

Einstein-DVT Evaluation, 2010:

Oral Rivaroxaban for Symptomatic Venous Thromboembolism. N Engl J Med 2010 Dec 3;: [21128814] [10.1056/NEJMoa1007903](https://doi.org/10.1056/NEJMoa1007903)

Einstein-PE Evaluation, 2012:

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

7 peripheral vascular diseases

Trial	Treatments	Patients	Trials design and methods
rivaroxaban vs placebo			
VOYAGER PAD <i>ongoing</i> [NCT02504216] n=6500 follow-up:	Rivaroxaban 2.5 mg orally twice daily (5 mg cumulative daily dose) versus Placebo	Patients With Symptomatic Peripheral Artery Disease Undergoing Lower Extremity Revascularization Procedures	

More details and results :

- antithrombotics for peripheral vascular diseases in after revascularisation at <http://www.trialresultscenter.org/go-Q661>
- anticoagulant for peripheral vascular diseases in after revascularisation at <http://www.trialresultscenter.org/go-Q662>

References

VOYAGER PAD, :

ongoing trial NCT02504216

8 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/go-Q102>

References

Einstein-PE Evaluation, 2012:

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

Entry terms: Xarelto, BAY 59-7939,