

Clinical trials of apixaban

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1 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
apixaban vs aspirin			
AVERROES , 2011 [NCT00496769] n=2808/2791 follow-up: maximum 21 months	apixaban 5 mg (or 2.5 mg) twice daily versus aspirin 81-324 md daily	patients with atrial fibrillation who have failed or are unsuitable for vitamin K antagonist treatment	Parallel groups double blind 36 countries
apixaban vs warfarin standard dose			
ARISTOTLE , 2011 [NCT00412984] n=9120/9081 follow-up: 1.8 yrs (median)	apixaban 5mg twice daily versus warfarin adjusted for an INR between 2 and 3	subjects with atrial fibrillation and risk factors for stroke	Parallel groups double blind 39 countries
phase 2 apixaban unpublished [NCT00787150] n=222 follow-up: 12 weeks	apixaban 5 or 2.5 mg twice daily versus warfarin	patient with non valvular AF	Parallel groups double blind

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 patients ineligible for warfarin at <http://www.trialresultscenter.org/godirect.asp?q=565>

References

AVERROES, 2011:

Eikelboom JW, O'Donnell M, Yusuf S, Diaz R, Flaker G, Hart R, Hohnloser S, Joyner C, Lawrence J, Pais P, Pogue J, Synhorst D, Connolly SJ Rationale and design of AVERROES: apixaban versus acetylsalicylic acid to prevent stroke in atrial fibrillation patients who have failed or are unsuitable for vitamin K antagonist treatment. Am Heart J 2010;159:348-353.e1 [20211294] 10.1016/j.ahj.2009.08.026

Connolly SJ, Eikelboom J, Joyner C, Diener HC, Hart R, Golitsyn S, Flaker G, Avezum A, Hohnloser SH, Diaz R, Talajic M, Zhu J, Pais P, Budaj A, Parkhomenko A, Jansky P, Commerford P, Tan RS, Sim KH, Lewis BS, Van Mieghem W, Lip GY, Kim JH, Lanus-Zanetti F Apixaban in Patients with Atrial Fibrillation. N Engl J Med 2011 Feb 10;: [21309657] 10.1056/NEJMoa1007432

ARISTOTLE, 2011:

Lopes RD, Alexander JH, Al-Khatib SM, Ansell J, Diaz R, Easton JD, Gersh BJ, Granger CB, Hanna M, Horowitz J, Hylek EM, McMurray JJ, Verheugt FW, Wallentin L Apixaban for reduction in stroke and other Thromboembolic events in atrial fibrillation (ARISTOTLE) trial: design and rationale. Am Heart J 2010;159:331-9 [20211292] 10.1016/j.ahj.2009.07.035

Granger CB, Alexander JH, McMurray JJ, Lopes RD, Hylek EM, Hanna M, Al-Khalidi HR, Ansell J, Atar D, Avezum A, Bahit MC, Diaz R, Easton JD, Ezekowitz JA, Flaker G, Garcia D, Ghalibaf M, Gersh BJ, Golitsyn S, Goto S, Hermosillo AG, Hohnloser SH, Horowitz J Apixaban versus Warfarin in Patients with Atrial Fibrillation. N Engl J Med 2011 Aug 27;: [21870978] 10.1056/NEJMoa1107039

phase 2 apixaban, 0:

unpublished

2 acute coronary syndrome

2

Trial	Treatments	Patients	Trials design and methods
apixaban vs placebo			
APPRAISE 2 , 2011 [NCT00831441] n=3705/3687 follow-up: 8 months	apixaban 5mg twice daily versus placebo	patients with a recent acute coronary syndrome and at least two additional risk factors for recurrent ischemic events	Parallel groups double blind 39 countries
APPRAISE-1 (10mg od) , 2009 [NCT00313300] n=318/611 follow-up: 6 months	apixaban 10 mg once daily versus placebo	patients with a recent ST-elevation or nonST-elevation acute coronary syndrome(<7 days)	Parallel groups double blind Europe, Middle East, North America
APPRAISE-1 (2.5 mg bid) , 2009 [NCT00313300] n=NA follow-up: 6 months	Apixaban 2.5mg twice daily versus placebo	patients with a recent ST-elevation or nonST-elevation acute coronary syndrome(<7 days)	double blind Europe, Middle East, North America

continued...

Trial	Treatments	Patients	Trials design and methods
APPRAISE japan ongoing [NCT00852397] n=NA follow-up:	2 doses of apixaban (2.5 mg BID and 5.0 mg BID) for 24 weeks in combination with standard therapy (aspirin and /or additional antiplatelet therapy) versus placebo	patients with recent (<=7 days) acute coronary syndrome	double-blind Japan

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>

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APPRAISE 2, 2011:

Alexander JH, Lopes RD, James S, Kilaru R, He Y, Mohan P, Bhatt DL, Goodman S, Verheugt FW, Flather M, Huber K, Liaw D, Husted SE, Lopez-Sendon J, De Caterina R, Jansky P, Darius H, Vinereanu D, Cornel JH, Cools F, Atar D, Leiva-Pons JL, Keltai M, Ogawa H Apixaban with Antiplatelet Therapy after Acute Coronary Syndrome. N Engl J Med 2011 Jul 24;: [21780946] [10.1056/NEJMoa1105819](https://doi.org/10.1056/NEJMoa1105819)

APPRAISE-1 (10mg od), 2009:

Apixaban, an Oral, Direct, Selective Factor Xa Inhibitor, in Combination With Antiplatelet Therapy After Acute Coronary Syndrome. Results of the Apixaban for Prevention of Acute Ischemic and Safety Events (APPRAISE) Trial. Circulation 2009;: [19470889]

APPRAISE-1 (2.5 mg bid), 2009:

Circulation 2009;: [19470889]

APPRAISE japan, :

ongoing trial NCT00852397

3 DVT prophylaxis

Trial	Treatments	Patients	Trials design and methods
apixaban vs placebo			
CV185-027 <i>ongoing</i> [NCT00320255] n=NA follow-up:	-	Patients undergoing treatment for advanced cancer	Parallel groups double blind
apixaban vs enoxaparin			
ADOPT , 2011 [NCT00457002] n=3255/3273 follow-up: 30 days	apixaban 2.5mg twice daily, 30 days versus enoxaparin 40mg once daily 6-14 days	acutely ill patients who had congestive heart failure or respiratory failure or other medical disorders and at least one additional risk factor for venous thromboembolism and who were hospitalized with an expected stay of at least 3 days	Parallel groups double blind
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
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
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

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>
- antithrombotics for DVT prophylaxis in patients with cancer at <http://www.trialresultscenter.org/godirect.asp?q=386>
- 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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CV185-027, :

ongoing trial NCT00320255

ADOPT, 2011:

Goldhaber SZ, Leizorovicz A, Kakkar AK, Haas SK, Merli G, Knabb RM, Weitz JI Apixaban versus Enoxaparin for Thromboprophylaxis in Medically Ill Patients. N Engl J Med 2011 Nov 13;: [22077144] [10.1056/NEJMoa1110899](https://doi.org/10.1056/NEJMoa1110899)

ADVANCE 3, 2010:

Lassen MR, Gallus A, Raskob GE, Pineo G, Chen D, Ramirez LM Apixaban versus Enoxaparin for Thromboprophylaxis after Hip Replacement. N Engl J Med 2010;363:2487-2498 [21175312] [10.1056/NEJMoa1006885](https://doi.org/10.1056/NEJMoa1006885)

ADVANCE 2, 2010:

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APROPOS 2.5mg, 2007:

Lassen MR, Davidson BL, Gallus A, Pineo G, Ansell J, Deitchman D The efficacy and safety of apixaban, an oral, direct factor Xa inhibitor, as thromboprophylaxis in patients following total knee replacement. J Thromb Haemost 2007 Dec;5:2368-75 [17868430]

ADVANCE-1, 2008:

Lassen MR, Raskob GE, Gallus A, Pineo G, Chen D, Portman RJ Apixaban or enoxaparin for thromboprophylaxis after knee replacement. N Engl J Med 2009;361:594-604 [19657123]

4 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
extended apixaban vs placebo			
AMPLIFY-EXT , 2012 [NCT00633893] n=2430 follow-up: 12 mo	Extended Treatment with apixaban 5 or 2.5 mg twice daily 12 months versus placebo	patients who have completed their intended treatment for deep vein thrombosis or pulmonary embolism	Parallel groups double blind
apixaban (without LMWH) vs LMWH/VKA			
AMPLIFY , 2013 [NCT00643201] n=2691/2704 follow-up: 6 mo	apixaban 10 mg twice daily for 7 days then 5 mg, twice daily, 6 months versus conventional therapy: enoxaparin 1mg/kg twice daily until INR \geq 2 then warfarin for an INR between 2-4, once daily, 6 months	patients with deep vein thrombosis or pulmonary embolism	Parallel groups double blind
Botticelli DVT , 2008 [NCT00252005] n=358/118 follow-up:	apixaban 5 mg twice-daily, 10 mg twice-daily, or 20 mg once-daily for 84-91 days versus low molecular weight heparin followed by vitamin K antagonists	patients with symptomatic deep vein thrombosis	Parallel groups open

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

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AMPLIFY-EXT, 2012:

Agnelli G, Buller HR, Cohen A, Curto M, Gallus AS, Johnson M, Porcari A, Raskob GE, Weitz JI Apixaban for Extended Treatment of Venous Thromboembolism. N Engl J Med 2012 Dec 8;: [23216615] [10.1056/NEJMoa1207541](https://doi.org/10.1056/NEJMoa1207541)

AMPLIFY, 2013:

Agnelli G, Buller HR, Cohen A, Curto M, Gallus AS, Johnson M, Masiukiewicz U, Pak R, Thompson J, Raskob GE, Weitz JI Oral Apixaban for the Treatment of Acute Venous Thromboembolism. N Engl J Med 2013 Jul 1;: [23808982] [10.1056/NEJMoa1302507](https://doi.org/10.1056/NEJMoa1302507)

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Buller H, Deitchman D, Prins M, Segers A Efficacy and safety of the oral direct factor Xa inhibitor apixaban for symptomatic deep vein thrombosis. The Botticelli DVT dose-ranging study. J Thromb Haemost 2008 Aug;6:1313-8 [[18541000](https://doi.org/10.1111/j.1538-7836.2008.01854.x)]

5 pulmonary embolism

Trial	Treatments	Patients	Trials design and methods
extended apixaban vs placebo			
AMPLIFY-EXT , 2012 [NCT00633893] n=2430 follow-up: 12 mo	Extended Treatment with apixaban 5 or 2.5 mg twice daily 12 months versus placebo	patients who have completed their intended treatment for deep vein thrombosis or pulmonary embolism	Parallel groups double blind
apixaban (without LMWH) vs LMWH/VKA			
AMPLIFY , 2013 [NCT00643201] n=2691/2704 follow-up: 6 mo	apixaban 10 mg twice daily for 7 days then 5 mg, twice daily, 6 months versus conventional therapy: enoxaparin 1mg/kg twice daily until INR \geq 2 then warfarin for an INR between 2-4, once daikly, 6 months	patients with deep vein thrombosis or pulmonary embolism	Parallel groups double blind

More details and results :

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

References

AMPLIFY-EXT, 2012:

Agnelli G, Buller HR, Cohen A, Curto M, Gallus AS, Johnson M, Porcari A, Raskob GE, Weitz JI Apixaban for Extended Treatment of Venous Thromboembolism. N Engl J Med 2012 Dec 8;: [23216615] [10.1056/NEJMoa1207541](https://doi.org/10.1056/NEJMoa1207541)

AMPLIFY, 2013:

Agnelli G, Buller HR, Cohen A, Curto M, Gallus AS, Johnson M, Masiukiewicz U, Pak R, Thompson J, Raskob GE, Weitz JI Oral Apixaban for the Treatment of Acute Venous Thromboembolism. N Engl J Med 2013 Jul 1;: [23808982] [10.1056/NEJMoa1302507](https://doi.org/10.1056/NEJMoa1302507)

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