

Clinical trials of dabigatran

TrialResults-center www.trialresultscenter.org

1 post myocardial infarction

Trial	Treatments	Patients	Trials design and methods
dabigatran vs placebo			
REDEEM , 2009 <i>unpublished</i> [NCT00621855] n=1501/373 follow-up: 6 months	dabigatran 4 dosages (50mg twice daily, 75mg twice daily, 110mg twice daily, 150mg twice daily) versus placebo	patients with recent acute coronary syndromes (ST- or non-ST-elevation myocardial infarction)	Parallel groups double blind

More details and results :

- antithrombotics for post myocardial infarction in all type of patients at <http://www.trialresultscenter.org/go-Q364>

References

REDEEM, 2009:

unpublished

Oldgren J, Budaj A, Granger CB, Khder Y, Roberts J, Siegbahn A, Tijssen JG, Van de Werf F, Wallentin L Dabigatran vs. placebo in patients with acute coronary syndromes on dual antiplatelet therapy: a randomized, double-blind, phase II trial. Eur Heart J 2011 Nov;32:2781-9 [[21551462](#)]

2 atrial fibrillation

Trial	Treatments	Patients	Trials design and methods
dabigatran 100mg vs warfarin			
RE-LY 110mg (2nd prevention subgroup) , 2010 n=NA follow-up: 2 y	dabigatran 110mg daily versus warfarin	patients with a prior stroke or transient ischemic attack	Parallel groups open
dabigatran 150mg vs warfarin			

continued...

Trial	Treatments	Patients	Trials design and methods
RE-LY 150mg (2nd prevention subgroup) n=NA follow-up: 2 y	dabigatran 150mg daily versus warfarin	patients with a prior stroke or transient ischemic attack	Parallel groups open
dabigatran vs warfarin standard dose			
phase 2 dabigatran <i>unpublished</i> [NCT01136408] n=NA follow-up:	Dabigatran 110, 220, 300 mg twice daily versus warfarin	patients with non-valvular atrial fibrillation (paroxysmal, persistent or permanent)	Parallel groups open Japan
dabigatran 110mg vs warfarin standard dose			
RE-LY (110mg) , 2009 [NCT00262600] n=6015/6022 follow-up: 2 y (median)	dabigatran 110 mg twice a day versus warfarin adjusted dose to a 2-3 INR	Patients With Non-Valvular Atrial Fibrillation	Parallel groups open (blind assessment) 44 countries
dabigatran 150mg vs warfarin standard dose			
PETRO (150mg) , 2007 n=166/70 follow-up: 12 weeks	dabigatran 150 mg twice daily (alone or combined with 81- or 325-mg aspirin) versus warfarin administered to achieve an international normalized ratio of 2 to 3 for	patients with AF at high risk for thromboembolic events	Factorial plan double blind Denmark, The netherlands, Sweden, US
RE-LY (150mg) , 2009 [NCT00262600] n=6076/6022 follow-up: 2 y (median)	dabigatran 150 mg twice a day versus warfarin adjusted-dose to a 2.0 to 3.0 INR	Patients With Non-Valvular Atrial Fibrillation	Parallel groups open (blind assessment) 44 countries

More details and results :

- antithrombotics for atrial fibrillation in primary prevention of thromboembolic events at <http://www.trialresultscenter.org/go-Q57>
- direct antithrombins for atrial fibrillation in all type of patients at <http://www.trialresultscenter.org/go-Q368>
- 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>

References

RE-LY 110mg (2nd prevention subgroup) , 2010:

1.Diener HC, Connolly S, Ezekowitz MD, et al. Dabigatran compared to warfarin in patients with atrial fibrillation and prior TIA or stroke: Results of RE-LY American Stroke Association International Stroke Conference 2010; February 26, 2010; San Antonio, TX. Abstract 195

RE-LY 150mg (2nd prevention subgroup) , :

1.Diener HC, Connolly S, Ezekowitz MD, et al. Dabigatran compared to warfarin in patients with atrial fibrillation and prior TIA or stroke: Results of RE-LY American Stroke Association International Stroke Conference 2010; February 26, 2010; San Antonio, TX. Abstract 195

phase 2 dabigatran, 0:

unpublished

RE-LY (110mg), 2009:

Ezekowitz MD, Connolly S, Parekh A, Reilly PA, Varrone J, Wang S, Oldgren J, Themeles E, Wallentin L, Yusuf S Am Heart J 2009;157:805-10, 810.e1-2 [19376304]

Connolly SJ, Ezekowitz MD, Yusuf S, Eikelboom J, Oldgren J, Parekh A, Pogue J, Reilly PA, Themeles E, Varrone J, Wang S, Alings M, Xavier D, Zhu J, Diaz R, Lewis BS, Darius H, Diener HC, Joyner CD, Wallentin L Dabigatran versus Warfarin in Patients with Atrial Fibrillation. N Engl J Med 2009 Aug 30; [19717844] 10.1056/NEJM0a0905561

PETRO (150mg), 2007:

Ezekowitz MD, Reilly PA, Nehmiz G, Simmers TA, Nagarakanti R, Parcham-Azad K, Pedersen KE, Lionetti DA, Stangier J, Wallentin L Dabigatran with or without concomitant aspirin compared with warfarin alone in patients with nonvalvular atrial fibrillation (PETRO Study). Am J Cardiol 2007;100:1419-26 [17950801]

RE-LY (150mg), 2009:

Ezekowitz MD, Connolly S, Parekh A, Reilly PA, Varrone J, Wang S, Oldgren J, Themeles E, Wallentin L, Yusuf S Rationale and design of RE-LY: randomized evaluation of long-term anticoagulant therapy, warfarin, compared with dabigatran. Am Heart J 2009;157:805-10, 810.e1-2 [19376304]

Connolly SJ, Ezekowitz MD, Yusuf S, Eikelboom J, Oldgren J, Parekh A, Pogue J, Reilly PA, Themeles E, Varrone J, Wang S, Alings M, Xavier D, Zhu J, Diaz R, Lewis BS, Darius H, Diener HC, Joyner CD, Wallentin L Dabigatran versus warfarin in patients with atrial fibrillation. N Engl J Med 2009 Sep 17;361:1139-51 [19717844] 10.1056/NEJM0a0905561

3 acute coronary syndrome

Trial	Treatments	Patients	Trials design and methods
dabigatran vs placebo			
REDEEM , 2009 <i>unpublished</i> [NCT00621855] n=1501/373 follow-up: 6 months	dabigatran 4 dosages (50mg twice daily, 75mg twice daily, 110mg twice daily, 150mg twice daily) versus placebo	patients with recent acute coronary syndromes (ST- or non-ST-elevation myocardial infarction)	Parallel groups double blind

More details and results :

- 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>

- direct oral anticoagulant (DAO) for acute coronary syndrome in all type of patients at <http://www.trialresultscenter.org/go-Q480>

References

REDEEM, 2009:

unpublished

Oldgren J, Budaj A, Granger CB, Khder Y, Roberts J, Siegbahn A, Tijssen JG, Van de Werf F, Wallentin L Dabigatran vs. placebo in patients with acute coronary syndromes on dual antiplatelet therapy: a randomized, double-blind, phase II trial. Eur Heart J 2011 Nov;32:2781-9 [21551462]

4 DVT prophylaxis

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

continued...

Trial	Treatments	Patients	Trials design and methods
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

CT

More details and results :

- antithrombotics for DVT prophylaxis in orthopedic surgery at <http://www.trialresultscenter.org/go-Q37>
- antithrombotics for DVT prophylaxis in elective major knee surgery at <http://www.trialresultscenter.org/go-Q38>
- antithrombotics for DVT prophylaxis in elective hip replacement at <http://www.trialresultscenter.org/go-Q39>
- anticoagulant for DVT prophylaxis in orthopedic surgery at <http://www.trialresultscenter.org/go-Q184>
- direct antithrombins for DVT prophylaxis in all type of patients at <http://www.trialresultscenter.org/go-Q369>
- direct oral anticoagulant (DAO) for DVT prophylaxis in all type of patients at <http://www.trialresultscenter.org/go-Q393>
- direct oral anticoagulant (DAO) for DVT prophylaxis in elective major knee surgery at <http://www.trialresultscenter.org/go-Q394>
- direct oral anticoagulant (DAO) for DVT prophylaxis in elective hip replacement at <http://www.trialresultscenter.org/go-Q395>
- direct oral anticoagulant (DAO) for DVT prophylaxis in orthopaedic surgery at <http://www.trialresultscenter.org/go-Q475>

References

RE-NOVATE (150mg), 2007:

Eriksson BI, Dahl OE, Rosencher N, Kurth AA, van Dijk CN, Frostick SP, Prins MH, Hettiarachchi R, Hantel S, Schnee J, Bller HR Dabigatran etexilate versus enoxaparin for prevention of venous thromboembolism after total hip replacement: a randomised, double-blind, non-inferiority trial. Lancet 2007;370:949-56 [17869635]

RE-NOVATE 2, 0:

unpublished

RE-NOVATE (220mg), 2007:

Eriksson BI, Dahl OE, Rosencher N, Kurth AA, van Dijk CN, Frostick SP, Prins MH, Hettiarachchi R, Hantel S, Schnee J, Bller HR Dabigatran etexilate versus enoxaparin for prevention of venous thromboembolism after total hip replacement: a randomised, double-blind, non-inferiority trial. Lancet 2007;370:949-56 [17869635]

RE-MODEL (150mg), 2007:

Eriksson BI, Dahl OE, Rosencher N, Kurth AA, van Dijk CN, Frostick SP, Klebo P, Christiansen AV, Hantel S, Hettiarachchi R, Schnee J, Bller HR Oral dabigatran etexilate vs. subcutaneous enoxaparin for the prevention of venous thromboembolism after total knee replacement: the RE-MODEL randomized trial. J Thromb Haemost 2007;5:2178-85 [17764540] 10.1111/j.1538-7836.2007.02748.x

RE-MODEL (220mg), 2007:

Eriksson BI, Dahl OE, Rosencher N, Kurth AA, van Dijk CN, Frostick SP, Klebo P, Christiansen AV, Hantel S, Hettiarachchi R, Schnee J, Bller HR Oral dabigatran etexilate vs. subcutaneous enoxaparin for the prevention of venous thromboembolism after total knee replacement: the RE-MODEL randomized trial. J Thromb Haemost 2007 Nov;5:2178-85 [17764540]

RE-MOBILIZE (150mg), 2008:

Ginsberg JS, Davidson BL, Comp PC, Francis CW, Friedman RJ, Huo MH, Lieberman JR, Muntz JE, Raskob GE, Clements ML, Hantel S, Schnee JM, Caprini JA Oral thrombin inhibitor dabigatran etexilate vs North American enoxaparin regimen for prevention of venous thromboembolism after knee arthroplasty surgery. J Arthroplasty 2009;24:1-9 [18534438] 10.1016/j.arth.2008.01.132

RE-MOBILIZE (220mg), 2008:

The Oral Thrombin Inhibitor Dabigatran Etexilate vs the North American Enoxaparin Regimen for the Prevention of Venous Thromboembolism after Knee Arthroplasty Surgery. J Arthroplasty 2008;: [18534438]

5 venous thrombosis

Trial	Treatments	Patients	Trials design and methods
dabigatran vs warfarin			
RE-MEDY , 2011 [NCT00329238] n=1430/1426 follow-up: 6 to 36 months	dabigatran 150 mg twice daily for an additional period of 6 to 36 months versus warfarin (to maintain an international normalized ratio of 2.0 to 3.0) for an additional period of 6 to 36 months	Secondary prevention of VTE in patients with VTE who had initially received 3 to 12 months of anticoagulant therapy	Parallel groups double-blind

continued...

Trial	Treatments	Patients	Trials design and methods
REMEDY , 2013 n=1430/1426 follow-up:	-	-	
dabigatran vs discontinuation			
RE-SONATE , 2011 [NCT00558259] n=681/662 follow-up:	dabigatran 150 mg twice daily for an additional period of 6 months versus placebo	Secondary prevention of VTE in patients with VTE who had completed 6-18 months of anticoagulant therapy	Parallel groups double-blind
dabigatran vs placebo			
RESONATE , 2013 n=681/662 follow-up:	dabigatran at a dose of 150 mg twice daily versus placebo	-	
heparin/dabigatran vs heparin/VKA			
RE-COVER , 2009 [NCT00291330] n=1274/1265 follow-up: 6 months	dabigatran 150 mg twice daily in a fixed-dose versus warfarin dose-adjusted to an INR between 2.0 and 3.0	patients with acute venous thromboembolism , treated with low molecular weight or unfractionated heparin for 5 to 11 days	Parallel groups double blind
RE-COVER II , 2011 <i>unpublished</i> [NCT00680186] n=1294/1295 follow-up: 6 months	dabigatran, 150 mg twice daily, for 6 months versus warfarin, dose-adjusted to an INR of 2.0 and 3.0, for 6 months	patients with acute VTE, treated with low molecular weight or unfractionated heparin for 5 to 11 days	Parallel groups double-blind 31 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

RE-MEDY, 2011:

Schulman S, Kearon C, Kakkar AK, Schellong S, Eriksson H, Baanstra D, Kvamme AM, Friedman J, Mismetti P, Goldhaber SZ Extended use of dabigatran, warfarin, or placebo in venous thromboembolism. N Engl J Med 2013 Feb 21;368:709-18 [23425163] 10.1056/NEJMoa1113697

REMEDY, 2013:

Schulman S, Kearon C, Kakkar AK, Schellong S, Eriksson H, Baanstra D, Kvamme AM, Friedman J, Mismetti P, Goldhaber SZ Extended use of dabigatran, warfarin, or placebo in venous thromboembolism. N Engl J Med 2013 Feb 21;368:709-18 [23425163]

RE-SONATE, 2011:

RESONATE, 2013:

Schulman S, Kearon C, Kakkar AK, Schellong S, Eriksson H, Baanstra D, Kvamme AM, Friedman J, Mismetti P, Goldhaber SZ Extended use of dabigatran, warfarin, or placebo in venous thromboembolism. N Engl J Med 2013;368:709-18 [23425163] 10.1056/NEJMoa1113697

RE-COVER, 2009:

Schulman S, Eriksson H, Goldhaber SZ, et al. Dabigatran etexilate versus warfarin in the treatment of venous thromboembolism. Oral presentation, ASH Annual Meeting 2009, Abstract number 19394, 6 December 2009

Schulman S, Kearon C, Kakkar AK, Mismetti P, Schellong S, Eriksson H, Baanstra D, Schnee J, Goldhaber SZ Dabigatran versus warfarin in the treatment of acute venous thromboembolism. N Engl J Med 2009 Dec 10;361:2342-52 [19966341] 10.1056/NEJMoa0906598

RE-COVER II, 2011:

unpublished

Schulman S, Kakkar AK, Goldhaber SZ, Schellong S, Eriksson H, Mismetti P, Christiansen AV, Friedman J, Le Maulf F, Peter N, Kearon C Treatment of acute venous thromboembolism with dabigatran or warfarin and pooled analysis. Circulation 2014 Feb 18;129:764-72 [24344086]

6 post acute coronary syndromes

8

Trial	Treatments	Patients	Trials design and methods
dabigatran vs placebo			
REDEEM , 2009 <i>unpublished</i> [NCT00621855] n=1501/373 follow-up: 6 months	dabigatran 4 dosages (50mg twice daily, 75mg twice daily, 110mg twice daily, 150mg twice daily) versus placebo	patients with recent acute coronary syndromes (ST- or non-ST-elevation myocardial infarction)	Parallel groups double blind

More details and results :

- antithrombotics for post acute coronary syndromes in all type of patients at <http://www.trialresultscenter.org/go-Q363>

References

REDEEM, 2009:

unpublished

Oldgren J, Budaj A, Granger CB, Khder Y, Roberts J, Siegbahn A, Tijssen JG, Van de Werf F, Wallentin L Dabigatran vs. placebo in patients with acute coronary syndromes on dual antiplatelet therapy: a randomized, double-blind, phase II trial. Eur Heart J 2011 Nov;32:2781-9 [21551462]

Entry terms: Pradaxa, Pradax