

Clinical trials of dabigatran 150mg

TrialResults-center www.trialresultscenter.org

1 atrial fibrillation

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

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/NEJMoa0905561

2 thrombosis prevention

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 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 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

More details and results :

- 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>
- anticoagulant for thrombosis prevention in orthopedic surgery at <http://www.trialresultscenter.org/go-Q184>
- direct antithrombins for thrombosis prevention in all type of patients at <http://www.trialresultscenter.org/go-Q369>
- 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>

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-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-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](#)

Entry terms: dabigatran, Pradaxa, Pradax