

Clinical trials of dabigatran 150mg

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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) , :

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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]

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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>

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