



RE-LY® Study

(Randomized Evaluation of Long Term Anticoagulant TherapY)

A global, multi-centre, non-inferiority, randomised trial comparing two blinded doses of dabigatran etexilate with open label warfarin in patients with non-valvular atrial fibrillation for the prevention of stroke and systemic embolism.

Duration

The median treatment duration is two years with a minimum of 1 year follow-up.

Trial information

The phase III - study of stroke prevention in atrial fibrillation, called RE-LY® is under the umbrella of the so-called RE-VOLUTION® trial programme.

The RE-LY® trial is comparing two blinded doses of oral dabigatran etexilate with the current standard therapy, warfarin (target INR 2.0-3.0) in patients with non-valvular atrial fibrillation who are at moderate to high risk of stroke.

Results expected

in 2009

Clinical outcome

Primary outcomes:

- Efficacy: Composite of stroke (including hemorrhagic) and systemic embolism
- Safety: Bleeding events during treatment

Study design

Prospective, On-label, Blinded Endpoint (PROBE) design aiming to prove non-inferiority of dabigatran etexilate versus warfarin.

Lead investigators

The trial is led by:

Dr Salim Yusuf, Professor of Epidemiology and Cardiology, Population Health Research Institute McMaster University, Hamilton, Canada

Dr Lars Wallentin, Professor of Cardiology and Director of the Uppsala University, Sweden

Dr Michael Ezekowitz, Vice President and Professor, Lankenau Institute for Medical Research, Wynnewood, PA, USA

Dr Stuart Connolly, Professor of Medicine and Director, Division of Cardiology at McMaster University, Hamilton, Canada

Study centres

18,113 patients in more than 900 study centres in 44 countries enrolled between December 2005 and December 2007.

- Europe: 24 countries
- Asia: 10 countries
- South America: 5 countries
- North America: 2 countries
- Africa & Middle East: 2 countries
- Australia: 1 country