Dabigatran Etexilate for Secondary Stroke Prevention in Patients With Embolic Stroke of Undetermined Source (RE-SPECT ESUS)

**Sponsor:**
Boehringer Ingelheim

**Purpose**
This trial will enroll approximately 6,000 patients with recent embolic stroke of unknown source (ESUS). Patients will be randomized to dabigatran or acetylsalicylic acid (ASA) (1:1 ratio) and have visits every three months. The study doctor may prescribe blinded concomitant ASA for pts with coronary artery disease but this is not mandatory. All Adverse Events (AEs), Serious Adverse Events (SAEs), outcome events will be recorded. The trial will conclude when the required number of stroke events are positively adjudicated which is estimated to take 3 years (including 2.5 years of enrollment).

**Official Title:** Randomized, Double-blind, Evaluation in Secondary Stroke Prevention Comparing the Efficacy and Safety of the Oral Thrombin Inhibitor Dabigatran Etexilate (110 mg or 150 mg, Oral b.i.d.) Versus Acetylsalicylic Acid (100 mg Oral q.d.) in Patients With Embolic Stroke of Undetermined Source (RESPECT ESUS)

**Primary Outcome Measures:**
Time to first recurrent stroke (ischemic, hemorrhagic, or unspecified) [ Time Frame: up to 36 months ]

**Eligibility**
Ages Eligible for Study: 18 Years to 150 Years (Adult, Senior)

**Inclusion criteria:**
Ischemic stroke with a brain lesion visualized by neuroimaging (either brain Computed Tomography (CT) or Magnetic Resonance Image (MRI)). The visualized stroke is a non-lacunar infarct, e.g. involving the cortex or >1.5 cm (>2.0 cm if measured on MRI diffusion-weighted images) in largest diameter if exclusively subcortical. Visualization by CT usually requires delayed imaging >24-48 hours after stroke onset.
The index stroke must have occurred either up to 3 months before randomization (Modified Rankin Scale (mRS) ≤ 3 at randomization) or up to 6 months before randomization (mRS ≤ 3 at randomization) in selected patients that are ≥ 60 years plus at least one additional risk factor for recurrent stroke.

Arterial imaging or cervical plus TCD ultrasonography does not show extra-cranial or intracranial atherosclerosis with ≥ 50% luminal stenosis in artery supplying the area of acute ischemia.

As evidenced by cardiac monitoring for ≥ 20 hours with automated rhythm detection, there is absence of AF > 6 minutes in duration (within a 20 hour period, either as single episode or cumulative time of multiple episodes).

Further inclusion criteria apply.

**Exclusion criteria:**

Modified Rankin Scale of ≥ 4 at time of randomization or inability to swallow medications.

Major risk cardioembolic source of embolism such as: a) intracardiac thrombus as evidenced by transthoracic or transesophageal echocardiography, b) paroxysmal, persistent or permanent AF, c) atrial flutter, d) prosthetic cardiac valve (mitral or aortic, bioprosthetic or mechanical), e) atrial myxoma, f) other cardiac tumors, g) moderate or severe mitral stenosis, h) recent (< 4 weeks) myocardial infarction, i) valvular vegetations, or j) infective endocarditis.

Any indication that requires treatment with an anticoagulant as per Investigator’s judgment.

History of atrial fibrillation (unless it was due to reversible causes such as hyperthyroidism or binge drinking, and has been permanently resolved).

Other specific stroke etiology (i.e. cerebral arteritis or arterial dissection, migraine with aura/vasospasm, drug abuse).

Renal impairment with estimated creatinine clearance (as calculated by Cockcroft-Gault equation) < 30 mL/min at screening, or where Investigator expects creatinine clearance is likely to drop below 30 mL/min during the course of the study.

Further exclusion criteria apply.