Lip (phase 2 AZD0837) 2009

NCT00684307

1 Treatments

**Studied treatment**  AZD0837 for 3-9 months

**Control treatment**  dose-adjusted Vitamin-K antagonists (VKA) (aiming for an international normalized ratio (INR) 2.0 to 3.0)

**Concomitant treatments**  -

**subgroup test**  b

**time within the therapeutic range (%)**  -

2 Patients

**Patients**  patients with non-valvular atrial fibrillation (AF) with one or more additional risk factors for stroke

**Inclusion criteria**  1) Nonvalvular AF (NVAF) verified by at least two ECGs in the last year separated by at least one week.; 2) Previous cerebral ischemic attack (stroke or TIA, >30 days prior to randomization); 3) Previous systemic embolism.; 4) Symptomatic congestive heart failure (CHF); 5) Impaired left ventricular systolic function; 6) Diabetes mellitus; 7) Hypertension requiring anti-hypertensive treatment.;

**Exclusion criteria**  1) AF secondary to reversible disorders, eg hyperthyroidism, drugs and pulmonary embolism; 2) Known contraindication to VKA treatment; 3) Presence of a valvular heart disease, mechanical heart valves, active endocarditis, left ventricular aneurysm or thrombus, atrial myxoma or any condition other than AF requiring chronic anticoagulation treatment; 4) Conditions associated with increased risk of major bleeding for example: history of intracranial bleeding, history of bleeding gastrointestinal disorder or major surgical procedure or trauma two weeks prior to randomization;

**CHADS2 Score (mean)**  -

**CHADS2 Score = 2 (%)**  -

**CHADS2 Score = 3 (%)**  -

3 Methods

**Blinding**  double blind

**Design**  Parallel groups

**Centers**  -
Geographical area  -

Sizes  636/318

4 Results

<table>
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<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
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</thead>
<tbody>
<tr>
<td>coronary events</td>
<td>-/636</td>
<td>-/318</td>
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<td>-</td>
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<td>major and clinically relevant non-major bleeding</td>
<td>-/636</td>
<td>-/318</td>
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5 References