The Dabigatran following Acute Transient ischemic Attack and minor Stroke trial: Final Results


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DATAS II Rationale and Hypothesis

- Recurrent Stroke Rates are highest in the first 30 days after a TIA/minor stroke
- Many recurrent strokes are secondary to etiologies that are optimally prevented with anticoagulants, rather than antiplatelets
- The reduced risk of early recurrent stroke associated with older anticoagulants is offset by an increased risk of hemorrhagic transformation

Hypothesis: Symptomatic Hemorrhagic Transformation rates in acute stroke/TIA treated with dabigatran and ASA patients are not significantly different.
DATAS II Protocol

300 Patients, NIHSS 0-9, MRI, Randomized <72 h from Onset

- Dabigatran 150/110 mg BID x 30 days
  - Day 30: MRI and clinical assessment
    - SWI
      - Hemorrhagic Transformation (Primary Endpoint)
      - Day 90: Clinical Assessment
- ASA 81 mg OD x 30 days
  - Day 30: MRI and clinical assessment
    - DWI
    - FLAIR
      - Recurrent Infarction
      - Day 90: Clinical Assessment

Key Exclusion Criteria:
1. DWI volume <25 ml
2. No OAC indication
3. No revascularization procedure planned
**Primary Outcome (Safety)**

Dabigatran did not increase the rate of symptomatic Hemorrhagic Transformation relative to ASA.

<table>
<thead>
<tr>
<th>Symptomatic HT:</th>
<th>1. &gt;30% of the infarcted area on DWI (PH2)</th>
<th>2. ≥4 point increase NIHSS</th>
<th>3. &lt;5 weeks of treatment initiation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>On Treatment</strong></td>
<td>Dabigatran (151)</td>
<td>ASA (150)</td>
<td>Relative Risk (95% CI)</td>
</tr>
<tr>
<td>Symptomatic Hemorrhagic Transformation</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Parenchymal Hemorrhage</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Symptomatic HT:**
1. >30% of the infarcted area on DWI (PH2)
2. ≥4 point increase NIHSS
3. <5 weeks of treatment initiation
### Secondary Endpoints

#### On Treatment

<table>
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<tr>
<th></th>
<th>Dabigatran (141)</th>
<th>ASA (142)</th>
<th>Relative Risk (95% CI)</th>
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<tr>
<td>Asymptomatic MRI Hemorrhagic Infarction (%)</td>
<td>11 (7.8%)</td>
<td>5 (3.5%)</td>
<td>2.22 (0.79, 6.21)</td>
</tr>
</tbody>
</table>

**Dabigatran did not increase the rate of asymptomatic Hemorrhagic Transformation relative to ASA.**

#### Intention To Treat

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<td>Recurrent Infarct on Day 30 MRI n (Proportion)</td>
<td>9 (6.3%)</td>
<td>14 (9.9%)</td>
<td>0.64 (0.29, 1.44)</td>
</tr>
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</table>
Conclusions

1. Dabigatran and ASA have similar safety profiles when administered to acute minor ischemic stroke patients

2. The hypothesis that dabigatran can reduce early recurrent ischemic stroke needs to be tested in a larger efficacy trial