

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

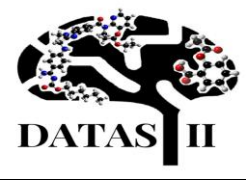
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DATAS II Rationale and Hypothesis

- 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



Key Exclusion Criteria:

1. DWI volume <25 ml
2. No OAC indication
3. No revascularization procedure planned

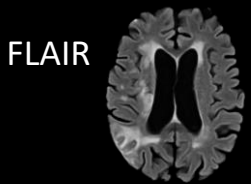
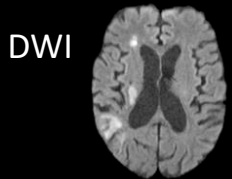
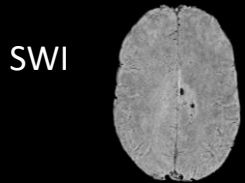
300 Patients, NIHSS 0-9, MRI, Randomized <72 h from Onset

Dabigatran 150/110 mg BID x 30 days

ASA 81 mg OD x 30 days

Day 30: MRI and clinical assessment

Day 30: MRI and clinical assessment



Hemorrhagic Transformation
(Primary Endpoint)

Recurrent Infarction

Day 90: Clinical Assessment

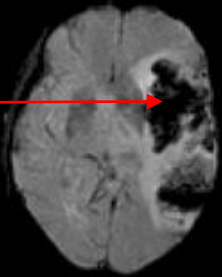
Day 90: Clinical Assessment

Primary Outcome (Safety)

Symptomatic HT:

1. >30% of the infarcted area on DWI (PH2)
2. ≥ 4 point increase NIHSS
3. <5 weeks of treatment initiation

PH2
(SWI MRI)



On Treatment	Dabigatran (151)	ASA (150)	Relative Risk (95% CI)
Symptomatic Hemorrhagic Transformation	0	0	N/A
Parenchymal Hemorrhage	0	0	N/A

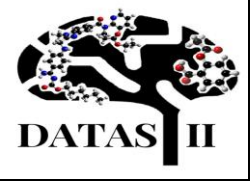
Dabigatran did not increase the rate of symptomatic Hemorrhagic Transformation relative to ASA.

Secondary Endpoints

On Treatment	Dabigatran (141)	ASA (142)	Relative Risk (95% CI)
Asymptomatic MRI Hemorrhagic Infarction (%)	11 (7.8%)	5 (3.5%)	2.22 (0.79, 6.21)

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

Intention To Treat	Dabigatran (142)	ASA (142)	Relative Risk (95% CI)
Recurrent Infarct on Day 30 MRI n (Proportion)	9 (6.3%)	14 (9.9%)	0.64 (0.29, 1.44)



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

