



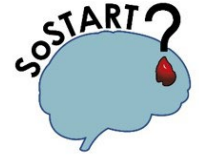
Edinburgh Stroke Trials

Effects of long-term oral anticoagulation for atrial fibrillation after spontaneous intracranial haemorrhage: the Start or STop Anticoagulants Randomised Trial (SoSTART)

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Start or STop Anticoagulants Randomised Trial: 67 UK hospitals



Intracranial haemorrhage, atrial fibrillation, and CHA₂DS₂-VASc score ≥ 2

Pre-randomisation: brain MRI (optional sub-study)

Randomisation (central)

1:1

101 started oral anticoagulation (OAC)*

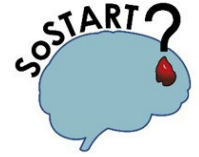
102 avoided oral anticoagulation (OAC)

Follow-up for ≥ 1 year (local hospital discharge, central annual questionnaires)

* Direct / non-vitamin K OAC (NOAC/DOAC) or warfarin

NCT03153150

Effects of oral anticoagulation (OAC) over median 1.2 years



	Start OAC (n=101)	Avoid OAC (n=102)	Adjusted HR (95%CI)	p value
Primary outcome – OAC was not non-inferior				
Recurrent symptomatic intracranial haemorrhage	8	4	2.42 (0.72–8.09)	0.152
Secondary outcomes – OAC might be superior				
Any symptomatic major vascular event	12	24	0.51 (0.26–1.03)	0.060
Any stroke	11	22	0.53 (0.25–1.09)	0.084
Any stroke or vascular death	12	23	0.55 (0.27–1.10)	0.090



Conclusions

- We did not find evidence that starting OAC was non-inferior to avoiding OAC for AF after intracranial haemorrhage
 - Small pilot trial, primary outcome event rates lower than expected, UK only
- Starting OAC might be superior to avoiding OAC for preventing symptomatic major vascular events
 - Consistent with known benefits
- Fatal vs. non-fatal event trade-offs
- Main phase trials appear feasible
- These results can inform recruitment discussions
- Maximise recruitment to ongoing trials. IPDMA planned*

* www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021246133