

## AuSCR Research Task Group approved projects

<b>Title</b>	<b>An investigator-initiated and conducted, prospective, multicentre, randomised outcome-blinded study of antiplatelet monotherapy in patients with a history of stroke due to intracerebral haemorrhage (ASPIRING)</b>
<b>Principle investigators</b>	Professor Graeme J. Hankey, Professor Craig S. Anderson, Professor Rustam Al-Shahi Salman
<b>Institute</b>	University of Western Australia
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<b>Submission date</b>	20 July 2021
<b>AuSCR role</b>	Recruitment
<b>Approved</b>	25 August 2021
<b>Status</b>	In progress
<b>Summary</b>	<p><b>Background/Rationale</b></p> <ul style="list-style-type: none"> <li>· Spontaneous (non-traumatic) intracerebral haemorrhage (ICH) accounts for about one quarter of all strokes.</li> <li>· ICH is most commonly caused by cerebral small vessel disease, which predisposes survivors to a risk of major ischaemic vascular events as high as, or higher than, the risk of recurrent ICH.</li> <li>· The RESTART reported in 2019 that, among 537 ICH survivors, starting oral antiplatelet therapy was associated with less recurrent ICH (adjusted hazard ratio [HR] 0.51, 95%CI 0.25-1.03) and similar numbers of major occlusive vascular events (HT 1.02 ; 0.65–1.60), compared to avoiding antiplatelet therapy over two years follow-up.</li> </ul> <p><b>Aims/Hypothesis</b></p> <ul style="list-style-type: none"> <li>· To determine if antiplatelet monotherapy is of overall net benefit in reducing the incidence of serious vascular events compared to avoiding antiplatelet therapy for adults with a history of spontaneous ICH.</li> </ul> <p><b>Methods</b></p> <ul style="list-style-type: none"> <li>· Design: Randomised, open-label, blinded outcome (PROBE), parallel-group clinical trial</li> <li>· Participants: History of symptomatic “primary” intracerebral haemorrhage (ICH) – at any time in the past, no structural cause – just presumed cerebral small vessel disease (e.g. hypertensive, or cerebral amyloid angiopathy)</li> <li>· Intervention: Start open-label antiplatelet monotherapy (aspirin or clopidogrel – clinician choice) OR Avoid antiplatelet therapy (no placebo is involved).</li> <li>· Follow-up: At time of discharge (or 1 month, whichever is earliest) by randomising or hospital doctor/study nurse. At 3, 6, 12, 18, 24, 30, 36, 42 months (<math>\pm 14</math> days) after randomisation by trial coordinating centre (Perth, WA), by phone/face time/skype (or post or face-to-face visit).</li> <li>· Primary Outcome: Any serious vascular event (stroke, myocardial infarction, or vascular death).</li> <li>· Timeline: June 2021-Dec 2025</li> </ul> <p>We seek access to the AuSCR dataset to determine the feasibility of remote recruitment and participation of patients who were registered with ICH.</p>