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CTP10

## Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) Study

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Atherosclerotic stenosis of the major intracranial arteries causes 56,000 strokes per year in the USA, costing the country at least \$840,000,000 annually. There have been no prospective trials evaluating optimal medical therapy for this disease. The main objective of this clinical trial is to compare warfarin (INR 2-3) with aspirin (1300 mg/day) for preventing stroke (ischemic and hemorrhagic) and vascular death in patients with symptomatic stenosis of a major intracranial artery. Study Design: Prospective, randomized, double-blind, multi-center trial. The sample size required will be 403 patients per group (based on stroke and vascular death rates of 33% / 3 years in the aspirin group vs. 22% / 3 years in the warfarin group, an alpha of 0.05, beta of 0.20, a 30% withdrawal of therapy rate, and a 5% drop out rate). Conduct of Trial: Patients with transient ischemic attack (TIA) or minor stroke caused by angiographically proven stenosis ( $>$  or  $=$  50%) of a major intracranial artery (internal carotid, middle cerebral, vertebral or basilar artery) will be randomized to warfarin or aspirin. The dose of warfarin will be adjusted to maintain the INR between 2-3 based on monthly blood tests. Patients will be contacted monthly by phone and examined every four months (mean follow-up of 3 years) to determine whether any endpoints have occurred. The primary analysis will compare the rates of stroke (ischemic and hemorrhagic) and vascular death in the two treatment groups. Secondary analyses will compare the two treatment groups with respect to rates of 1) all vascular deaths and disabling stroke (ischemic and hemorrhagic), 2) all stroke (ischemic and hemorrhagic), 3) fatal and nonfatal ischemic stroke, 4) all ischemic stroke, myocardial infarction and vascular death, 5) all major systemic and any intracranial hemorrhage, 6) all ischemic stroke in the territory of the stenotic intracranial artery. Conclusion: This study will 1) determine whether warfarin or aspirin is superior for treating patients with symptomatic intracranial arterial stenosis, and 2) identify patients whose rate of ischemic stroke in the territory of the stenotic intracranial artery on best medical therapy is sufficiently high (i.e.  $>$  6% per year) to justify a subsequent trial comparing intracranial angioplasty with best medical therapy in these patients. This trial has enrolled 504 patients to date and is actively recruiting eligible patients. For more information please check our website at: [www.sph.emory.edu/WASID/](http://www.sph.emory.edu/WASID/)