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WARCEF (Warfarin vs Aspirin in Reduced Cardiac Ejection Fraction) Study

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Heart failure is one of the most important public health problems in cardiovascular medicine. There are 4.7 million Americans with heart failure and 400,000 new cases each year with 250,000 deaths and 90,000 strokes per year attributable to heart failure. Cardiac Ejection Fraction (EF) is a good index of left ventricular dysfunction and low EF ($\leq 30\%$) is a risk factor for stroke in patients with cardiac failure. WARCEF-CLIN and WARCEF-STAT are two separate but highly coordinated units which together constitute WARCEF, a NINDS-funded two-arm (1:1) double blind, randomized, multicenter clinical trial (target enrollment 2860 patients at 70 clinical sites) designed to test the primary null hypothesis of no difference between warfarin (INR 2.5-3) and aspirin (325 mg) in 3-5 year survival for the composite endpoint death or recurrent stroke or intracerebral hemorrhage among patients with low EF. Secondary hypotheses are to be tested for subgroups of women and African Americans, and for the endpoint of stroke alone. Patients with low EF by quantitative assessment or with a wall motion index ≤ 1 by echocardiography will be randomized to warfarin or aspirin. The dose of warfarin will be adjusted to keep the INR between 2.5 to 3 with a target INR of 2.75, using a double blind algorithm to fabricate INRs for patients on active aspirin as is being used successfully in an ongoing warfarin-aspirin study (WARSS). Patients will be contacted monthly by phone and examined every four months over a mean follow up of 3 years to determine whether any endpoints have occurred. The study will define optimal antithrombotic therapy for patients with cardiac failure and patients with low EF. With the rapidly increasing numbers of elderly patients with cardiac failure, the study has important public health implications. Our long-term goals are to study antithrombotic therapy in cardiac disease giving rise to stroke. The study started recruiting patients on October 8, 2002.