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ASPIRIN AS EFFECTIVE AS TICLOPIDINE IN AFRICAN AMERICAN ANTIPLATELET STROKE PREVENTION STUDY

Results from the African American Antiplatelet Stroke Prevention Study (AAASPS), a large multicenter trial of 1,809 African American stroke patients from over 60 sites in the United States, show that aspirin is as effective as ticlopidine for prevention of a second stroke in this population. The study, sponsored by the National Institute of Neurological Disorders and Stroke (NINDS) is published in the June 11, 2003, issue of the "Journal of the American Medical Association". Originally scheduled to run until October 2003, the AAASPS was stopped in July 2002, after analyses suggested that there was less than a 1% chance that ticlopidine would be shown to be superior to aspirin if the study were carried to completion.

Looking at the results of previous trials of ticlopidine, a type of clot inhibitor, investigators thought that there was a strong possibility that this agent would be safer and more effective than aspirin in African Americans with a history of stroke. The NINDS funded the AAASPS in order to study this possibility.

"The study shows that aspirin is probably a better choice than ticlopidine for recurrent stroke prevention in African Americans. For those who can tolerate it, aspirin is readily available, inexpensive, and easy to administer. Ticlopidine, on the other hand, is more expensive, more difficult to use, and has the potential for serious side effects," said John R. Marler, M.D., Associate Director for Clinical Trials research at the NINDS.

African Americans are at about twice the risk of experiencing a stroke or dying from a stroke, compared to whites, and have a higher prevalence of stroke and cardiovascular disease risk factors such as hypertension, diabetes mellitus, obesity, and cigarette smoking.

The FDA approved ticlopidine, for clinical use in the early 1990s to reduce the risk of fatal or non-fatal stroke in patients with stroke risk factors and in patients who had a completed thrombotic stroke. In North America, ticlopidine was tested in two large trials, the Ticlopidine Aspirin Stroke Study (TASS) and the Canadian American Ticlopidine Study (CATS). A sub-analysis from TASS suggested that ticlopidine might produce fewer side effects and be particularly effective for stroke reduction among non-whites, mostly African Americans. Ticlopidine can cause rash and diarrhea but carries a lower risk of gastrointestinal bleeding and irritation than aspirin. Other adverse effects attributed to ticlopidine include serious blood conditions such as neutropenia and thrombocytopenia.

AAASPS study subjects were enrolled between one week and 90 days after the occurrence of an ischemic stroke. Volunteers were assigned daily doses of either 650 mg of aspirin or 500 mg of ticlopidine. They were examined every 2 weeks during the first 3 months of the study as well as at 6, 10, 12, 16, 20, and 24 months for the occurrence of adverse events. Complete blood and platelet counts were monitored every 2 weeks in the first 3 study months, as well as at 12 months, 24 months, any time a study subject withdrew from the trial, or at any time a local investigator believed these blood tests were indicated. Telephone contacts were made each month that an enrollee was not scheduled for an examination.

Historically, African Americans have been underrepresented in clinical trials including stroke prevention studies. AAASPS investigators built control mechanisms into the study to effectively maintain and assure patient safety, and they worked closely with the African American community during the pre-trial planning phases and during the conduct of the study. An African American Community Advisory Board and other community organizations played an active role in advising the AAASPS investigators on key issues relating to minority participation in clinical trials and the use of specific educational materials.

"We are encouraged to have such a large number of African Americans in a clinical trial on stroke. This study showed that with careful planning and sensitivity to community concerns we were able to recruit a large number of African Americans and safely follow them through an important clinical trial initiative such as AAASPS," said Audrey S. Penn, M.D., Acting Director of the NINDS.

The study was led by Philip B. Gorelick, M.D., M.P.H., of the Center for Stroke Research at Rush Medical College in Chicago, IL.

All remaining study subjects have the option of staying in the study until patient follow-up is completed to assure that all patients receive stroke prevention care. During this transition period, all of the study volunteers may opt for stroke prevention therapy prescribed by their community physician and best community practice or continue on in AAASPS in an open-label aspirin arm of the study.

The NINDS is part of the National Institutes of Health, a component of the Department of Health and Human Services. NINDS is the primary supporter of brain research in the country.

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