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Heart drugs ineffective in treating pulmonary arterial hypertension

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Despite their beneficial effects in treating heart disease, neither aspirin nor simvastatin appear to offer benefit to patients suffering from pulmonary artery hypertension (PAH), according to a National Institutes of Health (NIH)-funded study conducted at four U.S. medical centers. This was the first NIH-funded randomized clinical trial (RCT) in PAH.

The results of the study will be presented at the ATS 2011 International Conference in Denver.

PAH is a progressive, incurable disease characterized by increased blood pressure in the arteries of the lungs, which causes shortness of breath, dizziness and fatigue, and can lead to heart failure and death. PAH can occur on its own or be associated with other conditions, such as connective tissue diseases and congenital heart disease.

Although both aspirin and simvastatin are effective in many types of cardiovascular disease, these drugs have not been well-studied in the treatment of PAH, said Steven Kawut, MD, MS lead author and associate professor of medicine and epidemiology at the University of Pennsylvania School of Medicine. The study was designed to determine if the drugs could be effective in the treatment of patients with PAH.

"Surprisingly, we found no evidence that aspirin or simvastatin had beneficial clinical effects in this population, and the study was terminated early by the National Heart Lung and Blood Institute upon the recommendation of the Data and Safety Monitoring Board

(DSMB)," said Dr. Kawut, who is also director of the university's Pulmonary Vascular Disease Program. "The results of this study do not support the routine treatment of PAH with these medications."

Researchers enrolled 65 patients in this placebo-controlled trial and randomized them into four groups: one in which patients received aspirin, one in which patients received simvastatin, one in which patients received both drugs, and one in which patients received neither drug. The main outcome, six-minute walk distance (6MWD) (a measure of how far a person can walk in six minutes), tended to be lower in the group taking simvastatin at six months. Based on these early results, the DSMB recommended stopping the study since there was a low probability of demonstrating a beneficial effect of simvastatin even if the study enrolled the planned number of subjects (92). There was no significant difference in the 6MWD between the group taking aspirin and the group taking placebo.

"Multiple animal studies have suggested that simvastatin would be effective in PAH, and aspirin has biologic effects which would be expected to benefit PAH patients," Dr. Kawut said. "This study demonstrates that federally-funded, investigator-initiated RCTs in PAH and other pulmonary vascular diseases are feasible. The findings show the importance of subjecting traditional cardiovascular therapies and drugs which appear effective in the laboratory to placebo-controlled RCTs in humans before recommending their use."

"Aspirin and simvastatin may be prescribed for usual clinical indications in patients with PAH, but should not be administered specifically to treat PAH," he added.

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