Study shows no benefit from widely used antioxidant in treating deadly lung disease

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(Medical Xpress)—A common antioxidant had no effect on lung function compared to a placebo in patients with a chronic, progressive respiratory disease, according to research led by Weill Cornell Medical College and the IPF Clinical Research Network. The findings on N-acetylcysteine (NAC), released today by the *New England Journal of Medicine*, are likely to prompt physicians to reconsider the best way to treat idiopathic pulmonary fibrosis (IPF), an incurable disease that often kills patients within a few years of their diagnosis.

There was no evidence that NAC slowed the progression of IPF or improved lung function, as measured by forced vital capacity, compared to placebo," said lead author Dr. Fernando Martinez, executive vice chair of medicine at Weill Cornell Medical College and NewYork-Presbyterian Hospital/Weill Cornell Medical Center. "Further research is needed to evaluate current and future treatment approaches for this devastating disease.

The senior author of the research is Dr. Ganesh Raghu, a professor of medicine at the University of Washington's Division of Pulmonary and Critical Care Medicine and director of the UW Medicine Center for Interstitial Lung Disease in Seattle. Dr. Raghu presented the findings today at the American Thoracic Society annual meeting in San Diego. Investigators there plan to discuss the implications of the research for patients' future treatment.

IPF is characterized by thickening and scarring of the lungs. The

scarring typically starts at the edges of the lungs and progresses toward the center, making it increasingly difficult to breathe. Over time, the lungs lose their ability to take in and transfer oxygen, depriving vital organs of necessary oxygen. IPF affects an estimated 100,000 people in the United States, and about 34,000 Americans are diagnosed with the disease each year. It affects more men than women and mostly occurs between the ages of 50 and 70. The cause of IPF is unknown, and it kills up to 60 percent of patients.

Patients who are currently taking NAC alone or in combination with other medications should see their physician to discuss treatment options and whether the results of this study apply to them,Dr. Raghu said.

The 264-patient study, called PANTHER-IPF, began in December 2009 as a randomized, double-blind trial to assess whether the combination of the drugs NAC, prednisone and azathioprine could slow disease progression and improve lung function in patients with mild to moderate IPF. Previously published guidelines on the management of IPF sponsored by the joint American Thoracic and European Respiratory Societies (AJRCCM 2000) had recommended treatment with prednisone, a corticosteroid, plus azathioprine, an immunosuppressant, for patients with IPF. The recommendations were based on the consensus of an expert panel and not on information from a randomized clinical trial. In PANTHER-IPF, patients were assigned to one of three study arms, where they received either the three-treatment combination or a placebo substitute; NAC alone; or placebo.

The National Heart, Lung, and Blood Institute, which funded the study, stopped the triple-therapy arm in October 2011 because of safety concerns. The study resumed in January 2012 comparing NAC alone against a placebo.

The investigators are reporting on that phase now. They found no

significant difference between the treatment groups in reduction in lung function impairment over 60 weeks, as measured by a person's capacity to exhale with force after inhaling as deeply as possible—a measurement known as forced vital capacity. In addition, a subgroup analysis showed no difference between patients who took NAC alone before the original trial stopped and those who took NAC in the revised, two-arm trial. Overall, NAC was associated with more cardiac events and fewer gastrointestinal events compared to placebo.

The study underscores the difficulty in predicting treatment outcomes in IPF," said Dr. Martinez, who also is an adjunct professor in the Department of Internal Medicine, Division of Pulmonary and Critical Care Medicine at the University of Michigan Medical Center. "Accordingly, we need to design clinical studies that better predict how individual IPF patients—not study populations—will respond to treatment. I believe we'll achieve better outcomes by tailoring the right treatment to the right patient."

Provided by Cornell University

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