

Omalizumab Relieves Seasonal Asthma Attacks in Youth

Improves Symptom Control, Prevents Seasonal Attacks

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DENVER — A drug that targets the antibody immunoglobulin E (IgE), a key player in asthma, nearly eliminated seasonal increases in asthma attacks and decreased asthma symptoms among young people living in inner city environments, according to research done at National Jewish Health and other institutions in the NIH-funded Inner City Asthma Consortium.

The findings appear in the March 17 issue of the *New England Journal of Medicine*.

This study shows that adding omalizumab to NIH-guidelines based treatment improves asthma control and dramatically reduces severe asthma exacerbations and hospitalizations for inner city children and adolescents, who suffer a disproportionate burden of disease,” said investigator Andy Liu, MD, Associate Professor of Pediatrics at National Jewish Health.

In the United States, asthma affects approximately 18 million adults and 7 million children under the age of 18. Symptoms include wheezing, coughing, chest tightness and shortness of breath, any of which can be provoked by viral infections, allergens and air pollution. The number of asthma attacks rises in the spring and fall seasons when more allergens are in the air and the occurrence of respiratory viruses increases.

The study, funded specifically by the National Institute of Allergy and Infectious Disease, enrolled 419 children and youths, ages 6 to 20 years old, diagnosed with moderate to severe allergic asthma lasting more than one year. The children came from Boston, Chicago, Cleveland, Dallas, Denver, New York City, Tucson, Ariz. and Washington, D.C. Nearly all were minorities, including African-Americans (60 percent) and Hispanics (37 percent).

The primary goal of the study was to determine if adding omalizumab to NIH guidelines-based asthma therapy reduced the number of days that participants experienced any asthma-related symptoms. Another aim was to find out if the addition of omalizumab could also reduce the number of severe asthma attacks.

Omalizumab is a humanized monoclonal antibody, a pure form of a single protein, custom-made for use in humans, which binds to and blocks the activity of IgE, an important molecule in allergy. When allergens bind to IgE on the surface of certain immune cells, these cells release substances that cause allergic reactions. In the airways of asthma patients, these substances can trigger the muscles to contract, trapping air inside the lungs and causing difficulty breathing. Omalizumab is approved in the United States for patients ages 12 and older with moderate to severe persistent allergic asthma.

In addition to standard therapy, half of the participants were assigned at random to receive omalizumab, and the other half a placebo. Drug or placebo was delivered via an injection under the skin every two to four weeks over the 60-week period of study.

As the trial proceeded, participants returned to the clinic every three months for evaluation of their symptoms. As needed, their non-trial medications were adjusted according to the NIH asthma treatment guidelines.

At the end of the study, the investigators found that, overall, children and adolescents who received omalizumab had a 25 percent reduction in days with symptoms and a 30 percent reduction in asthma attacks compared with those who received placebo. Those who received omalizumab also had a 75 percent reduction in hospitalizations. Importantly, the spring and fall increases in asthma attacks that were seen in the participants receiving placebo were almost eliminated in those participants receiving omalizumab.

“The spike in asthma attacks in the fall, which is associated with colds and other viral airway infections, disappeared in the kids in the omalizumab group,” said William Busse, M.D., the principal investigator of ICAC and professor of

medicine at the University of Wisconsin-Madison. “Because the drug specifically targets IgE, which is the antibody responsible for allergies, our observations show the possible interplay between allergies, respiratory viruses and IgE in provoking asthma attacks.”

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Omalizumab Prevents Seasonal Peak in Hospitalizations

Children and adolescents who responded the best to omalizumab had positive skin tests for cockroach allergy and high levels of cockroach allergen in their homes. In previous work by NIAID-supported researchers, the combination of cockroach allergy and exposure to cockroaches was found to be an important cause of asthma-related illness and hospitalization.

The NIH Guidelines for the Diagnosis and Management of Asthma can be [viewed or downloaded](#).

National Jewish Health is known worldwide for treatment of patients with respiratory, cardiac, immune and related disorders, and for groundbreaking medical research. Founded in 1899 as a nonprofit hospital, National Jewish Health remains the only facility in the world dedicated exclusively to these disorders. Since 1998, *U.S. News & World Report* has ranked National Jewish the #1 respiratory hospital in the nation.

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports research—at NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at www.niaid.nih.gov.

The National Institutes of Health (NIH)—*The Nation's Medical Research Agency*—includes 27 Institutes and Centers and is a component of the U. S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments and cures for both common and rare diseases. For more information about NIH and its programs, visit <http://www.nih.gov>.

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National Jewish Health is the leading respiratory hospital in the nation. Founded 124 years ago as a nonprofit hospital, National Jewish Health today is the only facility in the world dedicated exclusively to groundbreaking medical research and treatment of patients with respiratory, cardiac, immune and related disorders. Patients and families come to National Jewish Health from around the world to receive cutting-edge, comprehensive, coordinated care. To learn more, visit the media resources page.

Media Contacts

Our team is available to arrange interviews, discuss events and story ideas.

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