Drug increases speed, safety of treatment for multiple food allergies

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In a randomized, controlled phase-2 clinical trial, an asthma medication increased the speed and safety of a protocol used to treat children for several food allergies at once, according to a study by researchers at the Stanford University School of Medicine.

The study will be published online Dec. 11 in *The Lancet Gastroenterology & Hepatology*.

About 30 percent of people who have food allergies are allergic to more than one food. Doctors tell them never to eat foods that trigger their allergies—the consequences can be deadly—but this requires constant vigilance.

"Patients find it very hard to live with multiple food allergies," said the study's senior author, Sharon Chinthrajah, MD, director of the Clinical Translational Research Unit at the Sean N. Parker Center for Allergy and Asthma Research at Stanford University. "It puts a huge social and economic burden on families." The trial was conducted at the Parker Center.

The new trial examined oral immunotherapy, an allergy treatment in which patients are dosed daily with tiny amounts of the foods that cause their allergic reactions. Over time, the dose is gradually increased until the patient can tolerate normal quantities of the food. In the trial, the oral treatment was combined with omalizumab, an antibody medication that ramps down the allergic response.

The new trial used a placebo-controlled, randomized design to determine whether omalizumab made it safer and faster for children to receive oral

immunotherapy to desensitize them to multiple foods simultaneously. At the end of the nine-month trial, 83 percent of children who had received omalizumab could tolerate at least 2 grams of two different food allergens, whereas only 33 percent receiving placebo reached the same level of tolerance.

'Excited to see the clinical efficacy'

"We were excited to see the clinical efficacy of this combination approach using omalizumab and multiple foods," said Chinthrajah, who is also a clinical assistant professor of medicine and of pediatrics at Stanford. "This could be a very promising way to decrease the burden of living with food allergies."

"The study showed significant efficacy and safety improvements in multi-allergic patients treated with omalizumab and food immunotherapy," said co-author Kari Nadeau, MD, PhD, director of the Parker Center and professor of medicine and of pediatrics. "Multi-allergic patients are at much higher risk for anaphylactic reactions since they are allergic to more foods, and omalizumab can help change the course of therapy by making it safer and faster."

The study included 48 children ages 4-15. Thirty-six children were randomly assigned to receive omalizumab, and 12 children to receive placebo, during oral immunotherapy. The drug or placebo was given for eight weeks before oral immunotherapy began, and also for the first eight weeks of oral immunotherapy. Immunotherapy continued without the medication or placebo for the next 20 weeks. The oral immunotherapy was tailored to patients' individual allergies, with each child being treated for two to five of their food allergens. The foods included in the study were almond, cashew, egg, hazelnut, milk, peanut, sesame, soy, walnut and wheat, all of which are common causes of food allergies.

Children taking omalizumab were desensitized significantly faster than those dosed with placebo. They also had fewer gastrointestinal side effects during therapy, such as nausea and abdominal pain, and fewer respiratory side effects, such as shortness of breath. Twenty-two percent of oral immunotherapy doses in omalizumab patients and 54 percent of doses for placebo patients caused gastrointestinal side effects, while 0 and 1 percent of doses caused respiratory side effects in the omalizumab and placebo groups, respectively. None of the patients in the study experienced serious side effects, such as anaphylactic shock.

To maintain success of treatment for their food allergies, patients continued to eat each food daily after the study was completed. The trial found that after the nine-month immunotherapy procedure, patients continued to be able to eat the foods safely. Larger and longer clinical trials are needed to understand how tolerance develops after someone stops eating the food every day and what makes the benefits of treatment last, the researchers said. The Parker Center is now engaged in such studies.

The successful therapy made a big difference in the lives of children who participated in the trial, Chinthrajah said.

"Patients and families say they're so grateful," she said. "They can broaden their food variety and participate in more social activities without fear of a bad allergic reaction. Kids say things like 'I no longer sit at the allergen-free table at lunch; I can sit with my usual friends.' These tiny things that others take for granted can open their social world."

The team's work is an example of Stanford Medicine's focus on precision health, the goal of which is to anticipate and prevent disease in the healthy and precisely diagnose and treat disease in the ill.

More information: Sandra Andorf et al, Anti-IgE treatment with oral immunotherapy in multifood allergic participants: a double-blind, randomised, controlled trial, *The Lancet Gastroenterology & Hepatology* (2017). DOI: 10.1016/S2468-1253(17)30392-8 , dx.doi.org/10.1016/S2468-1253(17)30392-8