

Antibody Reduces Allergic Reactions to Multiple Foods in NIH Clinical Trial

Drug can help protect kids with multiple food allergies during accidental exposure.

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A 16-week course of a monoclonal antibody, omalizumab, increased the amount of peanut, tree nuts, egg, milk and wheat that multi-food allergic children as young as 1 year could consume without an allergic reaction in a late-stage clinical trial.

Nearly 67% of participants who completed the antibody treatment could consume a single dose of 600 milligrams (mg) or more of peanut protein, equivalent to 2.5 peanuts, without a moderate or severe allergic reaction, in contrast with less than 7% of participants who received placebo. The treatment yielded similar outcomes for egg, milk, wheat, cashew, walnut and hazelnut at a threshold dose of 1,000 mg protein or more. This suggests the antibody therapy has the potential to protect children and adolescents if they accidentally eat a food to which they are allergic despite efforts to avoid it, according to the investigators. The findings were [presented](#) today [February 25] at the American Academy of Allergy, Asthma & Immunology Annual Meeting in Washington, D.C., and [published in The New England Journal of Medicine](#).

“People with food allergies and their caregivers need to maintain constant vigilance to avoid foods that could cause a potentially life-threatening allergic reaction. This is extremely stressful, especially for parents of young children,” said Jeanne Marrazzo, MD, MPH, director of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health and the trial’s regulatory sponsor. “Although food avoidance remains critical, the findings reported today show that a medicine can help reduce the risk of allergic reactions to common foods and may provide protection from accidental exposure emergencies.”

NIAID funds the ongoing trial with additional support from and collaboration with Genentech, a member of the Roche Group, and Novartis Pharmaceuticals Corporation. The two companies collaborate to develop and promote omalizumab, marketed as Xolair, and are supplying it for the trial. The National Center for Advancing Translational Sciences, also part of NIH, supports some of the staff, space and services used to conduct the trial.

An estimated 7.6% of children in the United State — roughly 5.5 million kids — have food allergies. On February 16, 2024, the Food and Drug Administration approved omalizumab for the reduction of allergic reactions, including anaphylaxis, that may occur with an accidental exposure to one or

more foods in adults and children aged 1 year and older with food allergy. The FDA approval was based on data from a planned interim analysis of the Phase 3 NIAID trial. People taking omalizumab still need to avoid foods they are allergic to. Omalizumab is not approved for the emergency treatment of allergic reactions, including anaphylaxis.

Previously, the only available treatment for food allergy was oral immunotherapy, or OIT, which involves daily ingestion of a specific food allergen in gradually increasing doses up to a maintenance amount.

The multi-stage trial is called Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults, or OUtMATCH. The first stage of the study was designed to see if taking omalizumab increased the threshold for the amount of food that caused allergic reactions, thereby reducing the likelihood of reactions to small amounts of food allergens during accidental exposure.

Omalizumab works by binding to the allergy-causing antibody called immunoglobulin E in the blood and preventing it from arming key immune cells responsible for allergic reactions. This renders these cells much less sensitive to stimulation by any allergen.

The NIAID-funded Consortium for Food Allergy Research (CoFAR) is conducting OUtMATCH at 10 locations across the United States. The CoFAR has enrolled 177 children and adolescents ages 1 to 17 years and three adults ages 18 to 55 years, all with confirmed allergy to peanut and at least two other common foods among milk, egg, cashew, wheat, hazelnut or walnut.

In the first stage of the trial, people who reacted to small amounts of food allergens during oral food challenges were assigned at random to receive injections of either omalizumab or placebo. Neither the participants nor the investigators knew which food was used in a challenge nor who was in which group. After 16 to 20 weeks of injections, the participants were challenged again in a carefully controlled setting to see if they could tolerate a greater amount of food than they did at the outset. The goal was to find out if omalizumab injections led to a statistically significant increase in the proportion of participants who could consume roughly the equivalent of 2.5 peanuts without a moderate or severe allergic reaction, up from less than half a peanut at the outset, and similarly greater quantities of milk, egg or cashew among people allergic to those foods.

Investigators found that omalizumab was superior to placebo in increasing the reaction threshold for peanut, milk, egg and cashew — as well as wheat, walnut and hazelnut — to levels that likely would protect against allergic reactions upon accidental exposure. Seventy-nine of 118 omalizumab-treated children and adolescents, or 66.9%, could consume at least a single dose of 600 mg or more of peanut protein without a moderate or severe allergic reaction during the post-treatment challenge, in contrast with four out of 59 children and adolescents, or 6.8%, who received placebo. The researchers observed similar results for milk, egg, cashew, wheat, walnut and hazelnut at a threshold dose of 1,000 mg protein or more.

Many omalizumab-treated participants ate more than 600 mg of peanut protein without a

moderate or severe allergic reaction. Sixty-seven percent consumed a cumulative dose of 1,044 mg of peanut protein, or about four peanuts, and 44% ate a cumulative dose of 6,044 mg of peanut protein, or about 25 peanuts. In addition, substantial proportions of treated participants consumed a cumulative dose of 1,044 mg of more than one food without a moderate or severe allergic reaction. 69% ate this amount of two foods, and 47%, three foods.

The first 60 participants who completed the first stage entered a 24-week open-label extension of omalizumab injections followed by additional oral food challenges. Most participants who had received omalizumab in the first stage maintained or increased the amount of food protein they could consume without an allergic reaction during the extension.

Robert Wood, MD, and Sharon Chinthrajah, MD are leading the trial. Dr. Wood is the Julie and Neil Reinhard Professor of Pediatric Allergy and Immunology and director of the Pediatric Clinical Research Unit at the Johns Hopkins University School of Medicine. Dr. Chinthrajah is an associate professor of medicine and of pediatric allergy and clinical immunology at Stanford University School of Medicine.

Further information about the ongoing OUTMATCH trial is available at [ClinicalTrials.gov](https://clinicaltrials.gov/study/NCT03881696) under study identifier [NCT03881696](https://clinicaltrials.gov/study/NCT03881696). The outcomes of later stages of the trial will be published in the future.

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