

Clinical trial to evaluate experimental treatment in people allergic to multiple foods

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Common food allergens include peanut, cow's milk and wheat. Credit: NIAID

Though food allergy affects more than 4.8 million children in the United

States, no approved preventative treatments currently exist. While experimental desensitization strategies are available in research settings, people with food allergies must avoid known allergens and are advised to carry injectable epinephrine to prevent potentially life-threatening allergic reactions caused by accidental exposures. To help alleviate this risk, a new study to evaluate an experimental treatment for food allergy launched today. The study is supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health; Genentech, a member of the Roche Group; and Novartis Pharmaceuticals Corporation.

The study is called Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen Oral Immunotherapy in Food Allergic Children and Adults, or OUtMATCH. It will test the ability of biweekly or monthly injections of [omalizumab](#)—alone or together with multi-allergen oral immunotherapy (OIT)—to increase a person's ability to tolerate foods to which they are allergic. Multi-allergen OIT involves consuming small, gradually increasing amounts of several allergens in a controlled setting to build the body's tolerance to those food allergens. Investigators will assess whether the [experimental treatment](#) regimens help prevent allergic reactions to small amounts of food that may be consumed unintentionally, thereby mitigating the danger of life-threatening emergencies among people with multiple food allergies.

The NIAID-supported Consortium of Food Allergy Research, or CoFAR, will conduct OUtMATCH at 10 clinical sites throughout the United States. The study aims to enroll 225 participants ages 2 to less than 56 years with allergy to peanut and at least two other foods, such as cow's milk, egg white, wheat, cashew, hazelnut or walnut. Rho Federal Systems Division, Inc., will serve as the Statistical and Clinical Coordinating Center.

"For children and adults with food allergy, accidentally eating a common

food can trigger alarming and sometimes deadly reactions," said Anthony S. Fauci, M.D., NIAID Director. "While rescue medications like epinephrine save lives, our goal is to develop an intervention that can prevent emergencies by decreasing the immune system's sensitivity to the allergenic food or foods in question."

Data from earlier studies suggested that omalizumab may help prevent allergic reactions to small amounts of food allergens, like those that may be consumed accidentally. Also, NIAID-supported studies indicated that omalizumab, given for a few weeks at the beginning of OIT, may help prevent OIT-induced allergic reactions, which are common. In 2017, [a small study](#) of 48 people found that 83% of participants could consume two grams of two food allergens after receiving omalizumab injections and OIT. In contrast, only 33% of participants in that study who received OIT and a placebo injection could consume the same amount.

Omalizumab (trade name Xolair) is a manufactured antibody that reduces immunoglobulin E (IgE). IgE is a class of human antibodies that trigger reactions to allergens, including certain foods. These reactions can progress to dangerous airway constriction and a sudden drop in blood pressure—symptoms of a life-threatening reaction known as anaphylaxis. Last year, the FDA granted Breakthrough Therapy Designation for omalizumab for the prevention of severe allergic reactions following accidental exposure to one or more foods in people with allergies.

"We are launching the OUtMATCH study to learn whether omalizumab can decrease or prevent [allergic reactions](#) to peanut and other food allergens," said R. Sharon Chinthrajah, M.D., clinical associate professor at Stanford University and OUtMATCH study co-chair. "We want to know if this drug can intercept the allergic antibody that starts the allergic response—essentially blocking the messenger before the signal is delivered in the majority of food-allergic individuals, as we have

shown in pilot studies."

OUtMATCH will take place in three separate stages, with each participant enrolling for about 4 years and 8 months. During the first stage, each participant will be randomized to receive biweekly or monthly injections of omalizumab or a placebo injection. After 16 weeks of treatment, each participant will complete a double-blind, placebo-controlled food challenge for each of three food allergens selected for that participant. The food challenge will be performed in a controlled clinic setting, with researchers present while the participant eats small, increasing amounts of a food allergen or a placebo ingredient. Researchers will then closely watch the participant for signs of an allergic reaction and provide treatment if needed.

Sixty participants who take part in the first stage will then enter the OUtMATCH Open Label Extension, during which they will receive 24 weeks of biweekly or monthly omalizumab before completing additional food challenges. This extension will allow investigators to assess whether omalizumab remains beneficial when given for a prolonged period. The remaining participants will enter the second stage of the trial in which all participants will begin the stage by receiving 8 weeks of biweekly or monthly omalizumab. Then, one group will be randomized to receive 52 weeks of multi-allergen OIT; these participants will begin multi-allergen OIT with 8 weeks of omalizumab followed by placebo injections for the remaining 44 weeks. The other group will receive 52 weeks of placebo OIT—in which participants receive oat flour instead of the three selected allergens—while taking omalizumab.

Participants who complete the Open Label Extension or stage two will then enter the third stage of the trial, in which investigators will create individualized, flexible treatment plans for each participant and provide long-term follow-up. Depending on the results of their food challenges in the Open Label Extension or the second stage, participants may be

advised to begin introducing the three selected allergens into their diet, may be given more OIT, or may be asked to continue avoiding the food [allergen](#) if they are unable to tolerate it. The goal of this stage of the trial is to determine whether treatment with omalizumab alone or in conjunction with OIT can induce long-term desensitization for food allergens without the need for continuous omalizumab injections.

"Many people with food allergy must avoid [food](#) allergens throughout their lives and carry epinephrine on them wherever they go just in case they are accidentally exposed," said Robert A. Wood, M.D., professor of pediatrics at the Johns Hopkins University School of Medicine and OUtMATCH study chair. "We hope that OUtMATCH can help us learn how to instead provide some protection from [food allergy](#) emergencies."

Provided by NIH/National Institute of Allergy and Infectious Diseases

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