Needed: 4 to 55 Year Olds with Multiple Food Allergies

Why are we doing this research?

Cincinnati Children's is conducting a research study, sometimes known as a clinical trial or clinical study, to learn more about children and adults who have multiple food allergies, including peanut, milk, egg, wheat, soy, sesame seed, fish, shellfish and/or certain tree nuts (almond, cashew, walnut, hazelnut, pecan).

We also want to see if a drug, called omalizumab, will help those children and adults be able to safely ingest foods they are allergic to.

Omalizumab is considered an investigational drug because the U.S. Food and Drug Administration has not yet approved it for the treatment of food allergies in both children and adults. It is approved by the FDA for the treatment of asthma in children and adults, age 12 and above.

Who can participate?

Children, teens and adults, 4 to 55 years old, who have 2 or more food allergies, may be eligible to participate. Food allergies include peanut, milk, egg, wheat, soy, sesame seed, fish, shellfish, and/or certain tree nuts (almond, cashew, walnut, hazelnut, pecan).

Individuals with an oat allergy, moderate or severe persistent asthma, eosinophilic disorders will not be able to participate. Participants must be able to avoid anti-histamines for up to 5 days prior to some study visits.

What will happen in the study?

If you (if you are 18) or your child qualifies for this research study, and you choose to participate, you will be in this study for about 38 weeks.

Before choosing to participate, you and/or your child can ask study staff as many questions as you need to, in order to understand the procedures and the precautions we use during the study visits.

The following tests and procedures will happen to you or your child during the screening, baseline and/or study visits:

- Medical history regarding food allergies, other allergies and general health
- Physical exam
- Vital sign measurements (heart rate, respiratory rate, temperature and blood pressure)
- Breathing test
- Skin prick test on the back (to see what foods you or your child are allergic to)
- Information on how you or your child copes with food allergy
- Urine pregnancy test (for female participants of childbearing potential)
- Blood tests
- Food challenge (explained below)
- Rapid oral desensitization (explained below)
- Electronic dose diary (to document that you or your child has taken the study drug and if any symptoms have occurred at home)
- Food elimination diet

If you or your child qualifies after initial tests, study staff will schedule a time to administer a food challenge. The food challenge will confirm whether or not you/your child has a food allergy to peanut, certain tree nuts, milk, egg, wheat, soy, sesame seed, fish and/or shellfish. You/your child will have a separate food challenge for each food allergen (from 2 to 5 food allergens) as well as a placebo food challenge.

During each food challenge, you or your child will eat a food you are allergic to or placebo. This means that study staff will give you/your child 7 different doses (allergen flour or placebo) at timed intervals. After the last dose, study staff will monitor you/your child for at least 2 hours.

Neither the study clinicians, the research team (with the exception of the nutritionists) nor you or your child will know if you are receiving the allergen protein or placebo (this is called double-blinded). You/your child will be informed at the end of all of the food challenges as to which food was given at each food challenge.

You or your child must be allergic to at least 2 foods during the food challenge to continue on in the study. If you/your child have a reaction to the placebo challenge, you will not be able to continue in the study.

If you or your child are able to continue, you will receive the first injection (shot) of the study drug omalizumab. You/your child will then receive the omalizumab shot every 2 to 4 weeks for the next 16 weeks.

After 8 weeks of receiving omalizumab injections, you or your child will be have a study visit where you will be introduced to your allergens in a process called rapid oral desensitization. This consists of eating up to 6 doses of the food allergens at timed intervals. After the last dose, you/your child will be monitored for at least 2 hours.

You or your child will not be eligible to continue if you do not tolerate 5mg total protein of your allergens.

If eligible to continue, study staff will give you or your child food allergen protein powders to take at home on a daily basis. You/your child will record what you take at home, along with any symptoms that occur after each dose, in an electronic diary each day.

Over the next 20 weeks, you or your child will visit the clinic every 2 weeks. At each clinic visit, you/your child will be given increased doses of the protein powders, under observation by a study doctor and nurse. The study doctor will monitor symptoms throughout the study, and may possibly adjust doses if necessary.

If you or your child can tolerate 2,000mg of each allergen by week 28 of the study, you will have individual food challenges for each food allergen at your next visit (week 30). If you/your child react to more than 1 food allergen during the food challenges, you will have no additional study visits.

If you or your child tolerate 2 or more allergens at the week 30 food challenges, you will be randomized (like flipping a coin) into 1 of 3 different groups: to continue to receive the same dosing of your allergen; receive 300mg of allergen; OR receive a placebo (oat).

You or your child will remain in 1 of these 3 categories for the next 6 weeks. At week 36, your/your child will undergo another set of food challenges. These challenges are the last visits of the study.

You or your child will be followed closely throughout this study for the development of symptoms, including hives, worsening of eczema or wheezing

Participants and parents or guardians interested in having their child participate will be given a consent form that thoroughly explains all of the details of the study. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered.

What are the good things that can happen from this research?

You or your child may or may not receive a direct medical benefit from being in this study.

You or your child may benefit by being followed for your health status or by a decrease in sensitivity to peanut, certain tree nuts (almond, cashew, walnut, hazelnut), milk, egg, wheat, soy sesame seed, cod salmon and/or shrimp.

The information gained from this study may help researchers in the advancement and understanding of food allergy and help in the development of new approaches for its treatment or prevention.

What are the bad things that can happen from this research?
There are risks, discomforts and inconveniences associated with any research study. Everyone taking part in the study will be observed by the study doctor and staff for any side effects.

Possible risks or discomforts will be discussed with participants, parents or guardians interested in learning more about the study.

Will you/your child be paid to be in this research study?
Participants may receive $20 to $40 per visit for their time and travel.

Who should I contact for more information?
Lisa Thornbury Clark
513-803-3663
foodstudies@cchmc.org
Cincinnati Children's Hospital Medical Center
Division of Allergy and Immunology
3333 Burnet Avenue
Cincinnati, OH 45229-3039

Study Doctor:
Amal Assa'ad, MD
Division of Allergy and Immunology
Cincinnati Children's Hospital Medical Center