Three Peanut Immunotherapy Studies Under Way

Categories: The Children's Hospital of Philadelphia

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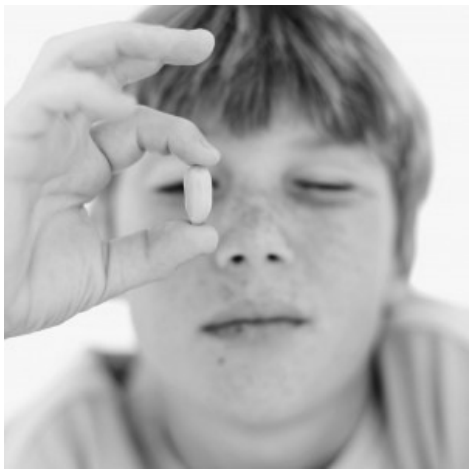

Strict avoidance of peanuts and the constant fear of accidental exposure cause tremendous stress for children with peanut allergy and their families. As little as 1/44,000 of a peanut kernel can trigger a reaction for severely allergic individuals.

Three studies under way at The Children's Hospital of Philadelphia are looking at potential ways to desensitize children so that they can develop a level of tolerance to peanut protein that would provide some clinical protection against accidental exposure.

"Accidental ingestions are unfortunately common, with up to 50 percent of food-allergic patients having at least one allergic reaction over a two-year period," said Jonathan Spergel, MD, PhD, chief of CHOP's allergy section and co-director of the Center of Pediatric Eosinophilic Disorders.

About 6 percent to 8 percent of children under the age of 3 years have food allergies. Although most children "outgrow" their sensitivity, allergy to peanuts and tree nuts may be lifelong and carry a risk of fatal food-induced anaphylaxis.

A peanut-free diet is the only treatment for children with peanut allergy, so CHOP researchers have been investigating alternative approaches such as oral immunotherapy (OIT), which is a gradual increase in peanut ingestion.

Various proof-of-concept clinical trials have shown that OIT is a slow and safe way to increase tolerance to peanuts, but OIT has not yet been approved by the U.S. Food and Drug Administration. Dr. Spergel's research team recently received an award from Allergen Research Corp. to conduct a phase 2 study that will put OIT on the licensure pathway.

If the investigators can demonstrate that peanut OIT is effective and safe in desensitizing peanut allergic study participants, "you'll have evidence supporting a method that may effectively treat 70 to 80 percent of people with peanut allergies," Dr. Spergel said. "This will be a major therapy."

Enrollment for the randomized, double-blinded, placebo-controlled study has begun and will include 55 participants from ages 4 to 26 with a history of allergy to peanuts or peanut-containing foods at eight sites in the United States. They initially will receive extremely low doses of characterized peanut allergen, a pharmaceutical-grade formulated peanut protein, followed by an up-dosing regimen every two weeks for six to nine months. The aim is for study participants to build up their tolerance to at least 250 mg of peanut protein, which would afford protection to one peanut.

Dr. Spergel is also principal investigator for CHOP's arm of the PRROTECT study, a phase 2, randomized, double-blind, placebo-controlled trial that will determine if pretreatment with anti-IgE mAb (omalizumab/Xolair) will allow for faster and safer OIT desensitization. Anti-IgE mAb is an injectable prescription medicine used for patients with moderate to severe persistent allergic asthma. It works by blocking IgE which binds to allergens causing allergic reactions.

While OIT has been shown to be effective for about 80 percent of children with peanut allergy, most experience some type of reaction, such as itchy mouth or hives, and one in five children will require epinephrine, according to Dr. Spergel.

"Using Xolair as pretreatment with oral immunotherapy, we hope to see very little reaction," he said.

CHOP and Food Allergy Research Education (FARE) are funding the PRROTECT study, which is a joint project with Boston Children's Hospital, Stanford

University, and Lurie Children's Hospital.

A third study is taking a different approach to peanut immunotherapy that uses a patch to deliver precise quantities of peanut proteins on the upper layers of skin.

"The method of epicutaneous (EPIT) delivery has some potential advantages including fewer side effects seen in earlier human study and possible increased tolerance, which has been seen in murine models," Dr. Spergel said. "EPIT also may be more palatable to patients due to the method of delivery."

The VIPES (Viaskin® Peanut's Efficacy and Safety) study, funded by DBV Technologies, is a 12-month randomized, double-blind, placebo-controlled study of participants ages 6 to 55 with a history of immediate hypersensitive reaction to peanuts. Initiated in 2012, VIPES is the first and only global trial ever in desensitization of peanut-allergic children and adults, and it is by far the largest involving 22 investigators and 221 participants in Europe and North America. This study is finished recruiting and will have preliminary results in late 2014.

Participants who completed the VIPES study were invited to participate in a follow-up extension study (OLFUS-VIPES) to address the crucial question of tolerance post treatment. Subjects enrolled in this study will receive an additional 24 months of Viaskin® Peanut treatment followed by a two-month period without treatment. Before launching VIPES, a study of 100 children and adults with peanut allergy (including anaphylaxis) showed very good safety.

A true partnership among researchers, physicians, nurses, and families allows CHOP's study teams to work on these peanut immunotherapy studies simultaneously, according to Dr. Spergel.

"There is no approved treatment of peanut allergy, and by doing these three studies, we are looking at which approach is the safest and most effective," he said. "We will understand which one will be best."

Tags: epicutaneous immunotherapy, food allergies, oral immunotherapy, peanut immunotherapy

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