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Early Oral Peanut Immunotherapy Successful in Preschoolers

Kate Johnson | February 24, 2015

HOUSTON — For preschool children with a known or highly suspected peanut allergy, early oral immunotherapy can lead to a safer level of peanut tolerance, known as "sustained unresponsiveness," according to a new study presented here at American Academy of Allergy, Asthma & Immunology (AAAAI) 2015.

"We believe that the findings support our hypothesis that early-intervention oral immunotherapy is an effective strategy to overcome some of the limitations of the therapy in older subjects and, ultimately, to improve outcomes for individuals with peanut allergy," said Brian Vickery, MD, from the University of North Carolina at Chapel Hill.

The Determining the Efficacy and Value of Immunotherapy on the Likelihood of Peanut Tolerance study, known as DEVIL, is the first to assess oral immunotherapy intervention in children 9 to 36 months of age, he told *Medscape Medical News*.

Dr Vickery presented preliminary results from the DEVIL study at the AAAAI 2013 meeting.

Peanut allergy shows up early and tends to "take hold" during the first years of life, before "establishing itself as permanent," he explained during a news conference at this year's meeting. The researchers began to wonder whether, instead of just watching these children get worse, oral immunotherapy might be effective, he explained.

The DEVIL Study

The 40 children enrolled in the study experienced an allergic reaction to peanut in the previous 6 months or were determined to be very likely to have a reaction because they had a peanut-specific immunoglobulin (Ig)E level above 5 kUA/L.

After an oral food challenge confirmed peanut allergy, the children were randomized to either low-dose (300 mg/day) or high-dose (3000 mg/day) oral immunotherapy with peanut protein for a minimum of 12 months.

"Our hypothesis was that by intervening early, we might be able to correct the immune response with a lower dose," said Dr Vickery.

The primary end point was sustained unresponsiveness, defined as no allergic reaction to 5 g of peanut ingested 1 month after stopping oral immunotherapy.

Of the 40 children enrolled, three were disqualified before starting the therapy and five withdrew, leaving 32 available for evaluation. Of the 30 who have completed the study, 29 achieved sustained unresponsiveness. Two children have not yet completed the study.

"This means the per protocol success rate is 97%," said Dr Vickery. "This is a very high response rate, and helps support the idea that early intervention may be more useful and at least as safe as it is in older children, if not actually a bit more safe."

He acknowledged, however, that the study's main limitation is the lack of a control group.

The study has not yet been unblinded to show the differences between the high- and low-dose groups. But overall, median peanut-specific IgE levels were lower at the end of the study than at baseline (1.8 vs 13.6 kUa/L), Dr Vickery reported.

Roughly 80% of the study participants experienced adverse events possibly related to immunotherapy, although all were mild or moderate, he said.

"We do see what we consider to be a favorable safety signal," he added.

Study participants who achieved sustained unresponsiveness are now encouraged to include unrestricted peanut in their diets on at least 5 of 7 days. "Making sure there's a stable incorporation of the previously allergenic food in the diet is probably critical to the long-term outlook," Dr Vickery explained.

His group is now conducting a multicenter, randomized, placebo-controlled trial of early-intervention oral immunotherapy for peanut allergy.

"This is very encouraging," despite there being no control group, said Hugh Sampson, MD, from the Icahn School of Medicine at Mount Sinai in New York City, who was not involved in the study. "A lot of us have felt that the younger you start, the better the response is going to be. I think this study really gives credence to that."

"The development of an active therapy for peanut allergy is such a critical unmet need," said session moderator Amy Scurlock, MD, from Arkansas Children's Hospital in Little Rock.

"I think this work represents refinement and advancement by looking into these younger ages, where you'd theoretically have potentially more immune plasticity or you may be able to modify other factors, such as the microbiome," she told *Medscape Medical News*. "It's exciting that we might be able to harness that potential."

There might be some logistical hurdles to overcome in terms of administering oral immunotherapy to toddlers, and some anxiety involved in treating such young children, said Dr Scurlock, but there is also a particular comfort in treating this age group.

"When you start to send your kid to school, camp, and sleepovers, anything that gives them some protection is really important," she added.

Dr Vickery and Dr Scurlock have disclosed no relevant financial relationships.

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