

Transcript Details

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www.reachmd.com
info@reachmd.com
(866) 423-7849

Is Peanut Oral Immunotherapy a Safe & Effective Treatment?

Announcer: This audio abstract is a special edition of Cracking the Code on Peanut Allergies brought to you through an independent educational grant from Aimmune Therapeutics.

Dr. Vickery: With the prevalence of peanut allergy among children on the rise, it's no wonder that researchers are continuously trying to find new ways to combat this health threat. While previous studies have identified oral immunotherapy as a potential treatment, most practice guidelines have been slow to adopt this strategy due to the trials' small sample sizes and differing methods. But a recent study sought to change that, and even has the potential to alter the way we treat peanut allergies moving forward.

I'm Dr. Brian Vickery, Associate Professor of Pediatrics at Emory University and Director of the Food Allergy Center of Children's Healthcare of Atlanta. I'm also the lead author of a recent study published in the New England Journal of Medicine, titled "AR101 Oral Immunotherapy for Peanut Allergy." This international, randomized, phase 3 trial evaluated the efficacy and safety of AR101, a new oral biologic drug that delivers a target daily maintenance dose of 300 mg of peanut protein with a characterized protein profile.

To better understand how healthcare professionals can help patients who are at risk for unpredictable and occasionally life-threatening allergic reactions, we screened participants between 4 to 55 years of age with peanut allergy for dose-limiting allergic symptoms at a challenge dose of 100 mg or less of peanut protein. Participants with an allergic response were randomly assigned, in a 3:1 ratio, to receive either AR101 or placebo in an escalating-dose program. Participants who completed the 24-week maintenance regimen underwent a food challenge at trial exit. The primary efficacy end point was the proportion of participants who could ingest a challenge dose of 600 mg (the equivalent of 2 peanut kernels) or more without dose-limiting symptoms.

Of the 551 participants, 496 were 4 to 17 years of age, and of these, 67.2% who received active treatment were able to ingest a dose of 600 mg or more of peanut protein without dose-limiting symptoms at the exit food challenge. During this challenge, the maximum severity of symptoms was moderate in 25% of the participants in the active group and 59% of those in the placebo group and severe in 5% and 11%, respectively. Adverse events during the intervention period affected more than 95% of the participants. 34.7% in the active group had mild events, as compared with 50% of those in the placebo group; 59.7% and 44.4% of the participants, respectively, had events that were graded as moderate, and 4.3% and 0.8% had events that were graded as severe. Efficacy was not shown in the participants 18 years of age or older.

In conclusion, evidence from PALISADE, an international, phase 3 trial of peanut oral immunotherapy that was conducted to a regulatory standard, showed that AR101 was an immunomodulatory treatment that resulted in desensitization in children and adolescents who were highly allergic to peanuts.

Announcer:

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Aimmune is a clinical-stage biopharmaceutical company developing desensitization treatments to help protect people with food allergies from the potentially life-threatening consequences of accidental exposure. For more information, visit www.aimmune.com.