Clinical Trials Update

Trial Suggests Starting Peanut Oral Immunotherapy Early
Most young children allergic to peanuts were desensitized after oral immunotherapy in a trial conducted at US academic medical centers, and 1 in 5 were in remission 6 months after the treatments concluded. The oral immunotherapy was most beneficial for the youngest children with lower peanut-specific antibodies at baseline.

The trial’s 146 participants, who were aged 12 months to about 48 months, were randomly assigned to receive a daily dose of peanut protein powder or oat flour placebo over 134 weeks. The children were considered desensitized if they could consume 5000-mg peanut protein powder, or about 16 peanuts, without significant symptoms at the end of the treatment phase. To test remission, the food challenge was repeated 26 weeks after treatment ended.

Researchers reported in The Lancet that 71% of children achieved desensitization and 21% achieved remission in the immunotherapy group, while in the placebo group only 2% achieved desensitization and the same percent achieved remission. Of the 93 children who completed the study protocol, including the 26-week posttreatment period, 29% of the immunotherapy group and 4% of the placebo group achieved remission. Most adverse reactions were mild to moderate.

In the immunotherapy group, 71% of participants who were younger than 24 months when the study began achieved remission compared with 19% of those aged 36 months or older.

The US Food and Drug Administration approved a peanut oral immunotherapy for children aged 4 to 17 years in 2020.

Postantibiotic Microbiome Therapeutic Reduces C difficile Recurrence
A phase 3 trial suggests that a microbiome therapeutic can restore gastrointestinal flora after antibiotic treatment for Clostridioides difficile, inhibiting the bacterium’s spore germination and reducing recurrence.

The multicenter trial tested SER-109, an investigational, oral, live microbiome therapeutic containing purified Firmicutes bacterial spores, which play a major role in a healthy microbiome. The study involved 182 patients in the US and Canada who had 3 or more episodes of C difficile infection in a year. Participants were randomly assigned to a 3-day course of SER-109 or placebo administered in 4 daily capsules after completing antibiotic treatment.

Eight weeks later, 40% of the placebo group but only 12% of the SER-109 group had developed recurrent C difficile infections. The microbiome therapeutic had a similar safety profile to placebo; most adverse events were mild to moderate. The findings appeared in the New England Journal of Medicine.

Intensive Glycemic Treatment Reduces Diabetic Foot Ulcers
Early intensive glycemic control among patients with type 1 diabetes decreases the long-term risk of diabetic foot ulcers, an analysis in Diabetes Care suggests.

The study’s participants were originally enrolled in the Diabetes Complications and Control Trial, which randomly assigned them to receive either intensive or conventional treatment and followed up with them for a median 6.5 years. At the time, the participants had diabetes for 1 to 15 years. Subsequently, 1408 of the trial participants were followed up for more than 23 years in the Epidemiology of Diabetes Interventions and Complications (EDIC) observational study.

In the current EDIC study analysis, participants who received intensive treatment had a 23% lower risk of developing diabetic foot ulcers. In total, 117 foot ulcers occurred among the 699 participants in this group, whereas 153 foot ulcers occurred among 709 participants who received conventional treatment. Although the researchers expected to see a reduced risk of lower-extremity amputation in the intensive treatment group, too few amputations occurred to gauge this.

Pneumococcal Vaccine Induces Immune Responses to 20 Serotypes
A 20-valent pneumococcal conjugate vaccine (PCV20) had a similar safety and tolerability profile to 13-valent PCV (PCV13) and elicited robust immune responses to 20 vaccine serotypes 1 month after vaccination in adults 18 years or older in a phase 3 trial, researchers recently reported in Clinical Infectious Diseases. Based on results from this trial and 2 others, the US Food and Drug Administration approved PCV20 for adults 18 years or older in June 2021.

PCV20 contains components of PCV13 plus polysaccharide conjugates for 7 other serotypes that substantially contribute to invasive pneumococcal disease. The study enrolled participants from 3 age groups—18 to 49 years, 50 to 59 years, and 60 years or older—and randomized them to receive 1 dose of PCV20 or PCV13. After 1 month, the 3009 participants aged 60 years or older also received 1 dose of saline or 23-valent polysaccharide vaccine (PPSV23), which also covers the 7 additional serotypes but does not induce lasting immunity.

Local reactions and systemic events were similar after vaccination with PCV20 or PCV13 and no safety issues were identified. Immune responses after PCV20 were noninferior to 13 matched serotypes after PCV13 and to 6 additional PPSV23 serotypes among participants aged 60 years or older. Immune responses to PCV20 among younger adults were noninferior to those among older participants. – Anita Slomski

Note: Source references are available through embedded hyperlinks in the article text online.