

Omalizumab for the Treatment of Food Allergy in Patients With Elevated Total IgE Levels

NCT06934200

Status	RECRUITING
Phase	Phase 2
Sponsor	Johns Hopkins University
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (5)

- Age 1 to 55 years
- A positive prick skin test (PST) with a wheal \geq 6 mm to at least one of the relevant foods (peanut, cashew, walnut, egg, milk, or wheat)
- Positive food-specific IgE (\geq 2.0 kilo units of allergen-specific IgE per liter (kUA/L)) to at least one of the study specific foods
- A weight / IgE level that would have excluded the participant from the OUTMATCH study based on the dosing table noted above
- Positive double-blind, placebo-controlled food challenge (DBPCFC) to one of the relevant foods at a cumulative dose of \geq 144 mg (maximum tolerated dose \geq 30 mg)

Exclusion (13)

- Clinically significant laboratory abnormalities at screening.
 - Dose-limiting symptoms during the blinded food challenge to placebo during the screening DBPCFC.
 - Poorly controlled or severe asthma/wheezing at screening
 - History of severe anaphylaxis to participant-specific foods that will be used in this study, defined as neurological compromise or requiring intubation.
 - Treatment with a burst of oral, intramuscular (IM), or intravenous (IV) steroids of more than two days for an indication other than asthma/wheezing within 30 days of screening.
- ... and 8 more (see full listing online)

Locations (1 total)

Johns Hopkins, Baltimore, Maryland, United States