Study of Oral Food Challenge Biomarkers (SAFER)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 months to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Parent or guardian must be able to understand and provide written informed consent and participant must be able to understand and provide assent (if applicable)
2. Are 12 months - 17 years of age during Screening.
3. Are sensitized to peanut, as demonstrated by one of the following:

a. A participant-reported reaction to peanut (at any time) deemed by the investigator to be consistent with an IgE-mediated reaction and one of the following within the past 12 months

i. Positive Skin Prick Test (SPT) to peanut (wheal diameter that is ≥ 3mm larger than saline control) ii. Positive peanut-specific IgE (sIgE; ≥ 0.10 kUA/L) determined by ImmunoCap

b. An Ara h 2 sIgE ≥ 1.0 kUA/L, measured within the past 12 months
4. Are currently avoiding peanut

Exclusion Criteria:

1. Are pregnant
2. Are currently receiving treatment or have received treatment within the prior 2 years for peanut allergy
3. Have a history of life-threatening anaphylaxis to peanut, defined as neurological compromise or requiring intubation
4. Have received treatment with dupilumab/Dupixent® within the prior 2 years, OR treatment with omalizumab/Xolair®, other biologics, or systemic immunomodulatory agents within the prior year
5. Inability to comply with the required aspects of the study protocol
6. Have past or current medical conditions or findings from the physical examination, not already listed, that, in the judgment of the site investigator, may pose additional risks related to participation in the study, interfere with the participant's ability to comply with study requirements, or impact the quality or interpretation of the study data
7. Have been treated with oral steroid or beta blockers within 14 days of the Oral Food Challenge (OFC)
8. Are unable to discontinue medications, as specified in the Protocol CoFAR-15 MOP, for the minimum wash-out periods prior to Skin Prick Test (SPT) or OFC
9. Have poorly controlled atopic dermatitis (AD) at Screening, per the PI's discretion
10. Have poorly controlled or severe asthma/wheezing at Screening, as defined as experiencing or including any of the following:
    1. Meeting the Global Initiative for Asthma (GINA) criteria for uncontrolled asthma
    2. History of two or more systemic corticosteroid courses within six months of Screening or one course of systemic corticosteroids within three months of Screening to treat asthma/wheezing;
    3. Prior intubation/mechanical ventilation for asthma/wheezing;
    4. One hospitalization or ED visit for asthma/wheezing within six months of Screening;
    5. Forced expiratory volume in one second (FEV1) <80% of predicted or FEV1/forced vital capacity (FVC) <75% of predicted, with or without controller medications (only for participants who are aged seven years or older and are able to perform spirometry);
    6. Inhaled corticosteroid (ICS) dosing of >500 mcg daily fluticasone (or equivalent ICS based on the CoFAR Inhaled Corticosteroid Equivalency Tables MOP)
11. Refuse blood sample collection during Screening
12. The SPT performed during Screening is negative to peanut allergen without dilution (wheal diameter that is < 3mm larger than saline control).

Conditions & Interventions

Interventions:
DRUG: Oral Food Challenge (OFC): Peanut Protein
Conditions:
Allergy
Keywords:
Food Allergy, Peanut Allergy, Oral Food Challenge, CoFAR-15, SAFER, Biomarkers

More Information

Description:
This is a multi-center, mechanistic study. It is designed to learn more about signs in the body, called biomarkers, that might show if someone will have a reaction to peanut during a feeding test. The trial will enroll children ages 12 months to17 years old who are suspected of having an allergy

to peanut. The primary objective is to identify a biomarker (or a combination of biomarkers) that will predict oral food challenge (OFC) (feeding test) results for participants with suspected peanut allergy.

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