

Infant Formula in Infants and Children With Cow's Milk Allergy

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 3 months to 12 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Participant's parent(s) is/are willing for their child to undergo confirmatory testing or must have had at least one of the following within 6 months of enrollment:
- 1. Physician diagnosis of IgE-mediated CMA, according to the participant's clinical history (e.g. gastrointestinal symptoms, hives, respiratory symptoms or angioedema) AND, detectable serum milk-specific IgE >0.7 kUA/L or positive skin prick test wheal ≥5 mm;
- 2. Documentation of milk-specific serum IgE ≥15 kUA/L or ≥ 5 kUA/L if younger than 1 year;
- 3. Documented cow's milk skin prick test wheal ≥8mm;
- 4. Physician-supervised oral food challenge that elicited immediate, objective, allergic symptoms.
 - Participant's parent(s) agree for their child to stop oral steroid use within 14 days and antihistamine use within 7 days prior to confirmation of diagnosis and food challenges.
 - Participant had followed a strict cow's milk protein-free diet for at least 2 weeks prior to enrollment.
 - Parent(s) confirm their intention not to administer any products containing cow's milk protein during the study.
 - Participant is between 3 months and 12 years of age at enrollment.
 - Participant's parent(s) has voluntarily signed and dated an Informed Consent Form (ICF), approved by an Independent Ethics Committee/Institutional Review Board (IEC/IRB) and provided Health Insurance Portability and Accountability Act (HIPAA) (or other applicable privacy regulation) authorization prior to any participation in the study.

Exclusion Criteria:

- Participant is partially or exclusively breastfed at the time of enrollment.
- Participant is consuming an amino acid-based formula due to failure on an extensively hydrolyzed formula.
- Significant chronic medical diseases including major chromosomal or congenital anomalies, gastrointestinal diseases, or abnormalities other than CMA, immunodeficiencies, unstable asthma, eczema and/or food allergies treated with biologics (omalizumab or other monoclonal antibody), FPIES, eosinophilic esophagitis, and severe uncontrolled eczema.
- Previous severe anaphylactic reaction to cow's milk within the last two years.,
- An adverse medical history or current condition that is thought by the investigator to have potential for effects on tolerance or the hypoallergenicity test.
- Participant has an allergy or intolerance to any ingredient in the study product, as reported by the parent.
- Participant is consuming baked milk products.
- Use of and/or changing dose of high potency steroids.
- Participant is treated with any oral immunotherapy (sublingual, subcutaneous, and epicutaneous) for any food allergy.

Conditions & Interventions

Interventions:

OTHER: Experimental Extensively Hydrolyzed Formula, OTHER: Placebo Extensively Hydrolyzed Formula

Conditions:

Cow's Milk Allergy

More Information

Description:

This is a multi-center, randomized, double-blinded, placebo-controlled food challenge to be conducted in infants and children with confirmed IgE-mediated cow's milk allergy (CMA), followed by a 7-day open feeding of the experimental formula.

Contact(s): Jennifer Jennings - jennifer.jennings2@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT06456541

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