

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

NCT06456541

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Abbott Nutrition
Enrollment	61 participants

## Key Eligibility Criteria

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### Inclusion (10)

- 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:
- 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  $\geq 0.7$  kU /L or positive skin prick test wheal  $\geq 5$  mm;
- Documentation of milk-specific serum IgE  $\geq 15$  kU /L or  $\geq 5$  kU /L if younger than 1 year;
- Documented cow's milk skin prick test wheal  $\geq 10$ mm;
- Physician-supervised oral food challenge that elicited immediate, objective, allergic symptoms.

... and 5 more (see full listing online)

### Exclusion (8)

- 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.

... and 3 more (see full listing online)

## Locations (8 total)

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Children's Hospital Colorado, Aurora, Colorado, United States  
Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois, United States  
University of Michigan Food Allergy Clinic, Ann Arbor, Michigan, United States  
... and 5 more locations

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<https://clinicaltrials.gov/study/NCT06456541>

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