

# Burks AW, Harthoorn LF, van Ampting MTJ, et al. Synbiotics-supplemented amino acid-based formula supports adequate growth in cow's milk allergic infants. *Pediatr Allergy Immunol.* 2015;26:316-22.

## Background:

Cow milk allergy (CMA) places children at risk for insufficient nutrient intake and poor growth. Because of this, the dietary management of CMA in children necessitates a diet that excludes allergens, while also promoting normal growth and development. This study set out to evaluate the growth of infants with CMA consuming a new amino acid-based infant formula (AAF) with an added synbiotic blend (prebiotics and probiotics). Safety was also evaluated.

## Methods:

This prospective, double-blind controlled study involved full-term infants aged 0-8 months diagnosed with CMA. The infants were randomized to receive either a control AAF (Neocate Infant with DHA and ARA; n = 56) or a test AAF with synbiotics (Neocate + oligosaccharide blend + probiotic *Bifidobacterium breve* M-16V; n = 54). The study duration was 16 weeks and the primary outcome, growth, was assessed using weight, length and head circumference. Secondary outcome measures were parameters that assessed allergic signs and symptoms as well as stool characteristics.

## Results:

At inclusion, infants were  $4.5 \pm 2.4$  months of age. Results showed that both groups, infants receiving the AAF or the AAF with synbiotics, achieved adequate and similar growth during this study. Based on WHO 2006 growth charts, there were no significant differences (90% CI) between groups in Z-scores (test/control) after 16 weeks: weight ( $p = 0.32$ ), length ( $p = 0.21$ ) and head circumference ( $p = 0.40$ ). There were also no significant differences between the two groups in weight-for-age or length-for-age Z-scores. In addition, both formulas were well tolerated and both reduced symptoms of CMA, with no difference in numbers of adverse events between the two groups.

## Conclusion:

This study is the first to demonstrate that an AAF with an added synbiotic blend of specific components, suitable for infants with CMA, promotes normal growth, as well as growth in infants with CMA similar to a reference AAF. Neocate with synbiotics and Neocate Infant DHA/ARA were both demonstrated to support normal growth and resolve food allergy symptoms in infants with IgE- and/or non-IgE-mediated CMA.

### This large clinical trial studying CMA infants supports that:

- Both Neocate® Syneo® Infant and Neocate® Infant DHA/ARA support normal growth and development of CMA infants.
- Neocate Syneo Infant is as safe and well tolerated as Neocate Infant DHA/ARA
- Neocate Syneo Infant resolves food allergy symptoms as effectively as Neocate Infant DHA/ARA

Adapted from publicly available abstract - Full text available at <http://onlinelibrary.wiley.com/doi/10.1111/pai.12390/full>

Neocate® Syneo® is a hypoallergenic, amino acid-based medical food for use under medical supervision. Neocate® Syneo® Infant is indicated for the dietary management of cow milk allergy, multiple food allergies and related GI and allergic conditions, including food protein-induced enterocolitis syndrome, eosinophilic esophagitis and gastroesophageal reflux.