

Harvey BM, Langford JE, Harthoorn LF, et al. Effects on growth and tolerance and hypoallergenicity of an amino acid-based formula with synbiotics. *Pediatr Res.* 2014;75:343-51.

STUDY 1

Background:

This study was designed to examine the effects of an amino acid-based formula (AAF) with an added synbiotic blend on growth as well as tolerance in a group of healthy infants.

Methods:

In a prospective, randomized, double-blind controlled study, healthy, full-term infants (n = 115) received either an AAF with an added synbiotic blend or an AAF that was already commercially available. Subjects received formula for 16 weeks. Primary outcome measures were growth, assessed by weight, length, and head circumference. Secondary outcome measures included gastrointestinal symptoms and stool characteristics. Also recorded were dietary intake, clinical laboratory results, and clinical examinations.

Results:

There were comparable results between groups in the measured parameters of growth. Similar results between groups were also seen for tolerance. There were minimal differences seen between groups in stool characteristics and gastrointestinal symptoms through the course of the study.

Conclusion:

This study showed that an AAF with an added synbiotic blend supports normal growth of healthy, full-term infants when fed as the sole source of nutrition. This study also demonstrates the safety and tolerance of an AAF with an added synbiotic blend with healthy, full-term infants.

Neocate[®] with synbiotics and Neocate[®] Infant DHA/ARA were both demonstrated to support normal growth.

An amino acid-based formula with prebiotics and probiotics, Neocate[®] Syneo[™] Infant is a nutritionally complete formula that is backed by this clinical trial in healthy infants to support normal growth and development and to be safe and well tolerated.

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STUDY 2

Background:

This study was designed to evaluate the hypoallergenicity of an amino acid-based formula (AAF) with an added synbiotic blend in a group of subjects with confirmed cow milk allergy (CMA).

Methods:

30 infants and young children were recruited, all of whom had immunoglobulin E (IgE)-mediated CMA. Hypoallergenicity of an AAF with an added synbiotic blend was determined with double-blind, placebo-controlled food challenges (DBPCFC) as well as a 7-day feeding period.

Results:

None of the 30 subjects with IgE-mediated CMA demonstrated an allergic reaction to the DBPCFC. All 30 subjects completed the study.

Conclusion:

This study shows that an AAF with an added synbiotic blend is hypoallergenic in subjects with IgE-mediated CMA.

Neocate with synbiotics was found to be hypoallergenic.

An amino acid-based formula with prebiotics and probiotics, Neocate Syneo Infant is backed by this clinical trial to be hypoallergenic according to criteria set by the American Academy of Pediatrics.