

# 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.

## 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® Syneo® Infant and Neocate® Infant DHA/ARA were both demonstrated to support normal growth.**

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

Adapted from publicly available abstract - Full text available at <http://www.nature.com/pr/journal/v75/n2/full/pr2013211a.html>

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.

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## Background:

Amino acid-based formulas (AAF) have been shown to effectively manage cow milk allergy and resolve symptoms while supporting normal growth. This study was designed to evaluate the hypoallergenicity of an AAF with an added synbiotic blend in a group of subjects with confirmed cow milk allergy (CMA).

## Methods:

Thirty infants and young children were recruited, all of whom had immunoglobulin E (IgE)-mediated CMA. Hypoallergenicity of an AAF with an added synbiotic blend (Neo-Syn) was determined with double-blind, placebo-controlled food challenges (DBPCFC) as well as a 7-day feeding period. In the DBPCFC, subjects were randomized to either receive Neo-Syn followed by the control hypoallergenic formula, Neocate Infant with DHA and ARA (Neo), or vice versa. Dietary intake and clinical symptoms were monitored.

## Results:

Thirty infants and children with a confirmed history of IgE-mediated CMA were recruited. A majority of the subjects (23/30) reported other food allergies (see table). All 30 subjects completed the DBPCFC. None of the 30 subjects demonstrated an allergic reaction to either formula in the DBPCFC.

## Conclusion:

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

ALLERGENS REPORTED BY 23 OF 30 SUBJECTS IN ADDITION TO COW MILK	
Egg	n = 9
Peanut	n = 9
Soy	n = 7
Fish	n = 1
Other food allergies (incl. tree nut, oatmeal, corn, sweet potatoes)	n = 10

Adapted from Harvey et al. 2014.

**Neocate® Syneo® Infant was found to be hypoallergenic when compared to a control hypoallergenic formula, Neocate® Infant DHA/ARA.**

**Neocate Syneo Infant is a nutritionally complete, amino acid-based formula with prebiotics and probiotics (synbiotics) that is backed by this clinical trial to be hypoallergenic according to criteria set by the American Academy of Pediatrics.**

Adapted from full text article – Publicly available at <http://www.nature.com/pr/journal/v75/n2/full/pr2013211a.html>

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.