Fox AT, Wopereis H, Van Ampting MTJ, et al. A specific synbiotic-containing amino acid-based formula in dietary management of cow milk allergy: a randomized controlled trial. Clin Transl Allergy. 2019;9:5.

The ASSIGN Trial

Background:

Here we report follow-up data from a multicenter, double-blind, randomized, controlled trial, which investigated fecal microbiota changes with a new amino acid-based formula (AAF) including synbiotics in infants with non-IgE-mediated cow milk allergy (CMA).

Methods:

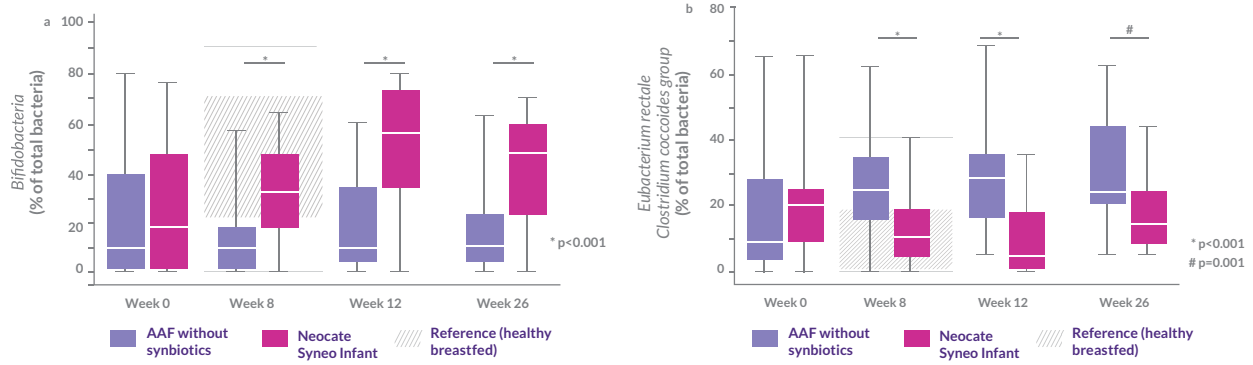
Subjects were randomized to receive test product (AAF including fructooligosaccharides and *Bifdobacterium breve* M-16V) or control product (AAF) for 8 weeks, after which infants could continue study product until 26 weeks. Fecal percentages of bifdobacteria and *Eubacterium rectale/Clostridium coccoides* group (*ER/CC*) were assessed at 0, 8, 12, and 26 weeks. Additional endpoints included stool markers of gut immune status, clinical symptoms, and safety assessments including adverse events and medication use.

Results:

The trial included 35 test subjects, 36 controls, and 51 in the healthy reference group. Study product was continued by 86% and 92% of test and control subjects between week 8–12, and by 71% and 80%, respectively until week 26. At week 26, median percentages of bifdobacteria were significantly higher in test than control [47.0% vs. 11.8% (p<0.001)], whereas percentages of *ER/CC* were significantly lower [(13.7% vs. 23.6% (p=0.003)]. Safety parameters were similar between groups. Interestingly, use of dermatological medication and reported ear infections were lower in test versus control, p=0.019 and 0.011, respectively†. Baseline clinical symptoms and stool markers were mild (but persistent) and low, respectively. Symptoms reduced towards lowest score in both groups.

Conclusion:

Beneficial effects of this AAF including specific synbiotics on microbiota composition were observed over 26 weeks, and shown suitable for dietary management of infants with non-IgE-mediated CMA.



Neocate® Syneo® Infant has been clinically shown to help address the hidden, underlying gut dysbiosis in infants with CMA with a consistent effect seen in increasing infant-like bifidobacteria and decreasing the adult-like *E. rectale/C. coccoides* group through 26 weeks (6 months).

Adapted from the publicly available full text article - https://ctajournal.biomedcentral.com/articles/10.1186/s13601-019-0241-3; https://creativecommons.org/licenses/by/4.0/

ASSIGN = Amino acid-based formula with Synbiotics – Study in Infants with Gastrointestinal Non-IgE-mediated cow's milk allergy

*The grey shaded area represents the sample 25th to 75th percentile of the reference group (healthy subjects) and the grey horizontal lines represent the minimum and maximum values of this reference group. The bottom and top edges of the box are located at the sample 25th and 75th percentiles. The center horizontal line is drawn at the 50th percentile (median). The whiskers of the box plots show the minimum and maximum values.

†Exploratory findings do not intend to offer final and conclusive results. Further research is needed to confirm the findings.

Nutricia North America supports the use of breast milk wherever possible. 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.