# A SPECIFIC SYNBIOTIC-CONTAINING AMINO ACID-BASED FORMULA IN DIETARY MANAGEMENT OF COW MILK ALLERGY: A RANDOMIZED CONTROLLED TRIAL

Fox AT *et al.* Clin Transl Allergy. 2019;9:5.

## 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 cows' milk allergy (CMA).

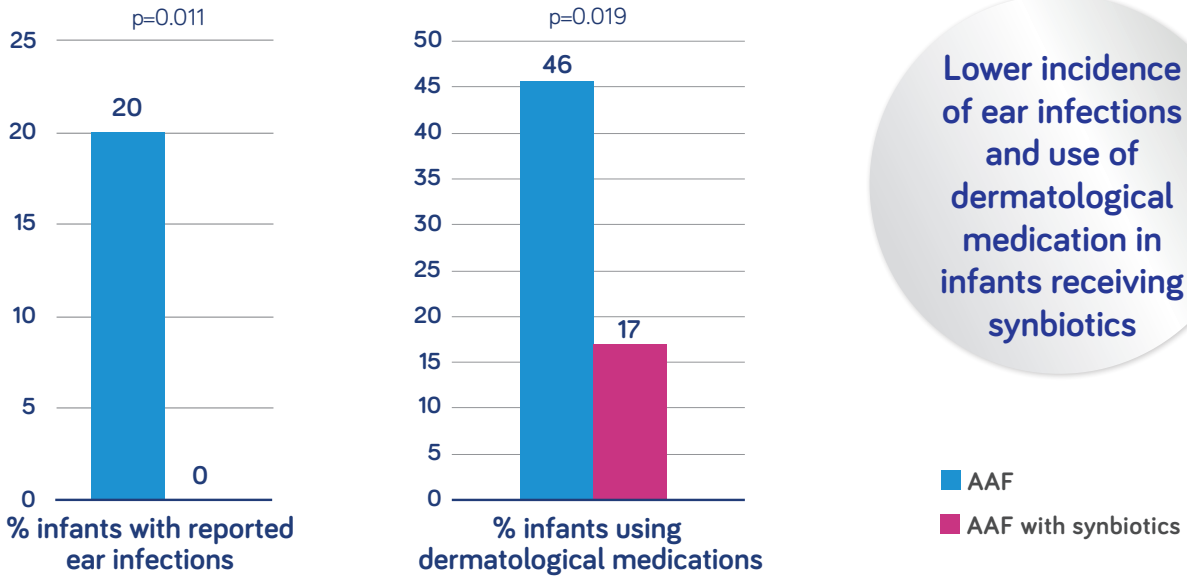
## METHODS

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.

## ADVERSE EVENTS AND MEDICATION USAGE†




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

## CONCLUSIONS

**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. Furthermore, analysis of adverse events and medication usage showed significantly lower use of dermatological medication and a lower incidence of ear infections for infants in the test group.**