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).

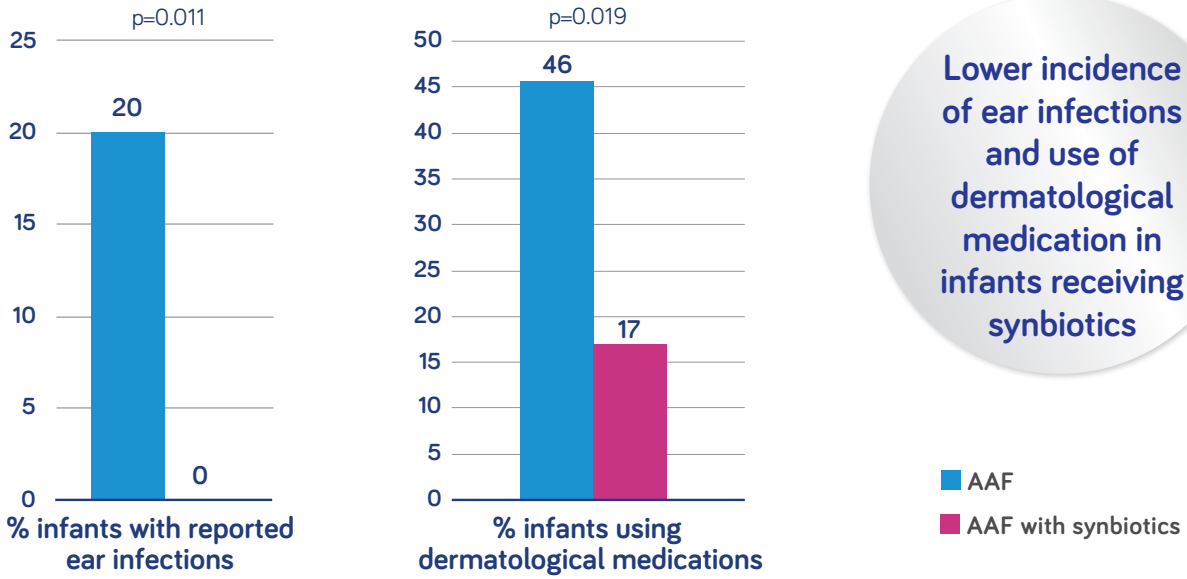
METHODS

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.