Dietary management of non-IgE mediated cow's milk allergic infants with a synbiotics-supplemented amino acid-based formula: effects on faecal calprotectin, eosinophilic cationic protein and α1-antitrypsin concentrations

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Food allergy such as cow’s milk allergy (CMA) can be divided into IgE-mediated and non-IgE mediated responses. IgE-mediated allergic patient population has been studied intensively whereas the non-IgE patient population, with complex gastro-intestinal (GI) disorders, is not well understood. This study investigated the effects of a new amino acid-based formula (AAF) with pre- and probiotics (synbiotics) in infants with suspected non-IgE mediated CMA.

In a prospective, randomised, double-blind controlled study (registered as NTR3979), infants with suspected non-IgE mediated CMA were enrolled to receive either an AAF (control n=36) or an AAF with synbiotics (oligofructose, inulin, Bifidobacterium breve M-16V) (test n=35) for 8 weeks. Faecal samples were collected at baseline and weeks 8, 12 and 26 after initiation of dietary management. Faecal samples from non-randomized healthy breastfed infants, which were age-matched with age of CMA infants at wk 8 of intervention, were collected as a reference group. Primary outcomes were bifidobacteria and the Eubacterium rectale/Clostridium coccoides (ER/CC) cluster as percentage of total faecal bacteria determined by fluorescent in situ hybridization. To monitor intestinal inflammation and immune status secondary outcomes included Faecal Calprotectin (FC) and Eosinophilic Cationic Protein (ECP), as markers for activation of neutrophils and eosinophils in the gut mucosa, respectively. In addition faecal α1-antitrypsin (A1A), as marker for GI protein-losing enteropathy, was determined.

Average age (±SD) of CMA infants (n=71) was 6.00±2.98 months at inclusion of the study and 7.84±3.25 months in the reference group (n=51). Of the CMA subjects, 90% presented predominantly GI symptoms and 10% dermatological symptoms; stratification was based on these manifestations. Sixty CMA infants completed the 8 weeks intervention (control n=32; test n=28). Using the intention-to-treat data set and ANCOVA technique, levels of bifidobacteria at 8 weeks were significantly higher in the test (35.6%) vs. control group (14.7%) (p=0.001) and ER/CC cluster was significantly lower in the test (12.1%) vs. control group (26.6%) (p<0.001). Secondary outcomes, including FC, faecal ECP and A1A, and data from the healthy breastfed reference group will be presented.