

EFFECTS ON GROWTH AND TOLERANCE AND HYPOALLERGENICITY OF AN AMINO-ACID BASED FORMULA WITH SYNBIOTICS

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BACKGROUND

Cows' milk protein allergy (CMA) is common with estimated prevalence during infancy, ranging from 2-5%. When poorly managed, it can lead to a detrimental effect on growth. The use of an amino acid formula (AAF) in severe CMA has been proven to provide symptoms relief whilst providing good infant growth rates. The present studies assessed growth and tolerance of CMA infants when using a new AAF with synbiotics (study 1). The hypoallergenicity of the same AAF with synbiotics was also evaluated in subjects with documented IgE mediated CMA (study 2).

METHODS

Study 1: In this prospective double-blind randomized controlled trial (DBRCT) 115 infants aged from birth to 15 days old with CMA, randomly received an AAF with synbiotics ((Bifidobacterium breve M-16V at a dose of 1.47 X 10⁹ CFU/100ml; and a prebiotic blend being a combination of neutral fructo-oligosaccharides and pectin derived acidic oligosaccharides in a ratio of 9:1 ratio) or a commercially available AAF for 16 weeks. The primary outcome measures were growth (weight, length and head circumference) and secondary outcome measures were stool characteristics and gastrointestinal symptoms (tolerance). Clinical examinations, dietary intake (acceptance), clinical laboratory results, and adverse events were recorded.
Study 2: The hypoallergenicity of AAF with synbiotics was evaluated in 30 subjects with IgE mediated CMA using a double-blind, placebo-controlled food challenge (DBPCFC), and a 7-day feeding period.

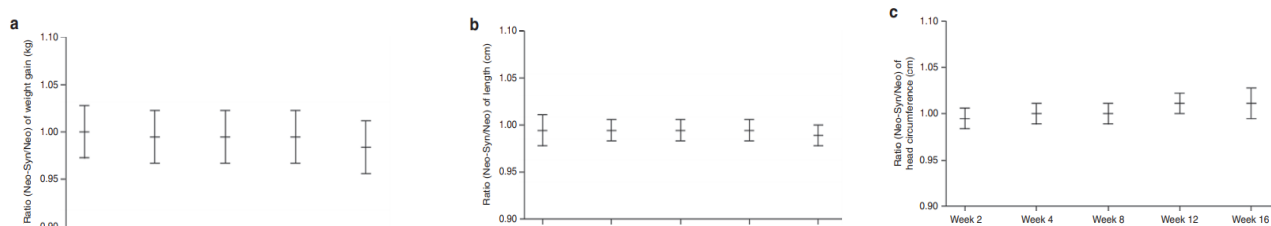
RESULTS

Study 1: Comparable results in growth parameters and tolerance were observed for both groups with minimal differences in GI symptoms and stool characteristics. There was no significant difference in weight gain, achieved length, or achieved head circumference between the two formula groups. (fig 1).

Study 2: All 30 infants and children with IgE-mediated CMA included in the study completed the DBPCFC. The study provided 95% confidence that at least 90% of infants and children with CMA would have no reaction to the AAF with synbiotics.

AAF Formula with synbiotics promotes normal growth

Figure 1: Growth parameter treatment ratios over time of the intention to treat (ITT) population of study 1 for (a) weight gain (kg), (b) length (cm), and (c) head circumference (cm)



CONCLUSION

The AAF formula with synbiotics is safe, well tolerated and promotes normal growth when fed to healthy full-term infants from birth to 16 weeks of age. The formula was hypoallergenic in subjects with CMA.