



POSTER PRESENTATION

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Partially hydrolysed, prebiotic supplemented whey formula for the prevention of allergic manifestations in high risk infants: a multicentre double-blind randomised controlled trial

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Background

We have for the first time evaluated whether a partially hydrolysed whey based (pHF) formula combined with specific mixture of prebiotic oligosaccharides would reduce the risk of allergic manifestations (AM) in formula-fed infants at increased risk of allergy.

Methods

We recruited term, healthy newborn infants from 10 centres in Australia, Singapore, England and Ireland. They had at least one parent with allergic disease and were randomised to receive a pHF-prebiotic formula (active; 432) or standard cow's milk formula (control; 431) for the first 26 weeks of life if parents decided to stop or supplement breastfeeding < 18 weeks. 324 infants were followed up for occurrence of AM until 3-5 years (ISRCTN65195597).

Primary outcome was cumulative incidence of atopic dermatitis (AD) up to 12 months in the key group of interest (KGI), which consisted of those infants that started formula < 28 days of age (active 375; control 383). Secondary and post-hoc outcomes are reported on all subjects randomised.

Results

In the KGI, AD developed in 93/324 (29%) infants randomised to control and 84/293 (29%) to active (OR 0.94 -

[95%CI 0.65-1.36]). We found no difference in AM at 3-5 years. The active group had lower serum cow's milk (CM) IgG1 at 6 months than the control ($p < 0.0001$) and this difference was still observed at 3 years ($p = 0.007$). Higher CM-IgG1 levels at 6 months were significantly associated with development of specific IgE (CM, hen's egg) at 3 years ($p < 0.05$). We found no difference between groups in adverse events.

Post-hoc analyses were performed on infants who had not introduced solids < 18 weeks ($n = 312$). In this subgroup, active formula was associated with reduced AM at 3-5 years ($n = 144$; $p = 0.0334$) and lower levels of total-IgE and hen's egg IgE at 6 months ($n = 239$, $p = 0.0092$ and $n = 244$, $p = 0.0061$) compared with control group.

Conclusion

Early feeding with a pHF-prebiotic formula was not associated with a reduced risk of AD at 12 months or AM at 3-5 years. The pHF-prebiotic formula use did show a persistent immune-modulatory effect and possibly a reduced occurrence of AM in infants who introduced solids according to guidelines (> 18 weeks).

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