



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) IgG 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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