

Prebiotic-supplemented partially hydrolysed cow's milk formula for the prevention of eczema in high-risk infants: a randomized controlled trial

ABSTRACT

Background: Prevention guidelines for infants at high risk of allergic disease recommend hydrolysed formula if formula is introduced before 6 months, but evidence is mixed. Adding specific oligosaccharides may improve outcomes. **Objective:** To evaluate whether partially hydrolysed whey formula containing oligosaccharides (0.8 g/100 ml) (pHF-OS) can prevent eczema in high-risk infants [ISRCTN65195597]. **Methods:** We conducted a parallel-group, multicentre, randomized double-blind controlled trial of pHF-OS vs standard cow's milk formula. Infants with a family history of allergic disease were randomized (stratified by centre/maternal allergy) to active ($n = 432$) or control ($n = 431$) formula until 6 months of age if formula was introduced before 18 weeks. Primary outcome was cumulative incidence of eczema by 12 months in infants randomized at 0–4 weeks (375 pHF-OS, 383 control). Secondary outcomes were cumulative incidence of eczema by 12 or 18 months in all infants randomized, immune markers at 6 months and adverse events. **Results:** Eczema occurred by 12 months in 84/293 (28.7%) infants allocated to pHF-OS at 0-4 weeks of age, vs 93/324 (28.7%) control (OR 0.98 95% CI 0.68, 1.40; $P = 0.90$), and 107/347 (30.8%) pHF-OS vs 112/370 (30.3%) control in all infants randomized (OR 0.99 95% CI 0.71, 1.37; $P = 0.94$). pHF-OS did not change most immune markers including total/specific IgE; however, pHF-OS reduced cow's milk-specific IgG1 ($P < 0.0001$) and increased regulatory T-cell and plasmacytoid dendritic cell percentages. There was no group difference in adverse events. **Conclusion:** pHF-OS does not prevent eczema in the first year in high-risk infants. The immunological changes found require confirmation in a separate cohort.

Keyword: Eczema; Infant formula; Oligosaccharides; Hydrolysate; Randomized controlled trial