

A protective effect of *Lactobacillus rhamnosus* HN001 against eczema in the first 2 years of life persists to age 4 years

K. Wickens¹, P. Black², T. V. Stanley³, E. Mitchell⁴, C. Barthow¹, P. Fitzharris⁵, G. Purdie⁶ and J. Crane¹

¹Wellington Asthma Research Group, Wellington School of Medicine and Health Sciences, University of Otago, Wellington, New Zealand, ²Formerly Department of Pharmacology and Clinical Pharmacology, University of Auckland, Auckland, New Zealand, ³Department of Paediatrics, Wellington School of Medicine and Health Sciences, University of Otago, Wellington, New Zealand, ⁴Department of Paediatrics, University of Auckland, Auckland, New Zealand, ⁵Immunology Department, Auckland Hospital, Auckland, New Zealand and ⁶Dean's Department, Wellington School of Medicine and Health Sciences, University of Otago, Wellington, New Zealand

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Summary

Background Using a double blind randomized placebo-controlled trial (Australian New Zealand Clinical Trials Registry: ACTRN12607000518460), we have shown that in a high risk birth cohort, maternal supplementation from 35 weeks gestation until 6 months if breastfeeding and infant supplementation until 2 years with *Lactobacillus rhamnosus* HN001 (HN001) (6×10^9 cfu/day) halved the cumulative prevalence of eczema by age 2 years. *Bifidobacterium animalis* subsp *lactis* HN019 (HN019) (9×10^9 cfu/day) had no effect.

Objective The aim of this study was to investigate the associations of HN001 and HN019 with allergic disease and atopic sensitization among these children at age 4 years, 2 years after stopping probiotic supplementation.

Methods The presence (UK Working Party's Diagnostic Criteria) and severity SCORing Atopic Dermatitis (SCORAD) of eczema and atopy (skin prick tests) and parent-reported symptoms of asthma and rhinoconjunctivitis were assessed using standard protocols and questions.

Results Four-hundred and seventy-four infants were eligible at birth of whom 425 (90%) participated in this follow-up. The cumulative prevalence of eczema by 4 years (Hazard ratio (HR) 0.57 (95% CI 0.39–0.83)) and prevalence of rhinoconjunctivitis at 4 years (Relative risk 0.38 (95% CI 0.18–0.83)) were significantly reduced in the children taking HN001; there were also nonsignificant reductions in the cumulative prevalence of SCORAD ≥ 10 (HR 0.74 (95% CI 0.52–1.05), wheeze (HR 0.79 (95% CI 0.59–1.07)) and atopic sensitization (HR = 0.72 (95% CI 0.48–1.06)). HN019 did not affect the prevalence of any outcome.

Conclusions and Clinical Relevance This study showed that the protective effect of HN001 against eczema, when given for the first 2 years of life only, extended to at least 4 years of age. This, together with our findings for a protective effect against rhinoconjunctivitis, suggests that this probiotic might be an appropriate preventative intervention for high risk infants.

Keywords allergy prevention, atopic sensitization, *Bifidobacterium animalis* subsp *lactis* HN019, eczema, *Lactobacillus rhamnosus* HN001, paediatrics, probiotics, randomized controlled trial, rhinitis

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Correspondence:

Dr K. Wickens, Wellington Asthma Research Group, University of Otago, P O Box 7343, Wellington South, Wellington.

Email: Kristin.wickens@otago.ac.nz

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