

Abstract Submission

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COMPARISON OF TWO PROBIOTICS IN FOLLOW-ON FORMULAE IN CHINESE INFANTS: BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS HN019 PROTECTED AGAINST RESPIRATORY TRACT INFECTIONS

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Objectives and Study: A double-blind, placebo-controlled clinical trial was conducted in urban China to investigate the health benefits of probiotic bacteria in human infants.

Methods: The study was conducted in Fuyang, Anhui Province, China, and enrolled 192 healthy infants aged 6 to 12 months. Infants received one of three premium follow-on formulae daily for 12 weeks during the Chinese winter (December 2012 – March 2013). One group of infants (n=64) received a follow-on formula supplemented with 10⁶ CFU/g *Bifidobacterium animalis* subsp. *lactis* HN019, the second group (n=64) received a formulae with 10⁶ CFU/g *Lactobacillus rhamnosus* HN001, while the third group (n=64) received formula without added probiotics (control). The primary endpoint was physician-confirmed bacterial or viral respiratory infections during the 12 week treatment period. Secondary endpoints included antiviral or antibiotic treatments, hospitalization, stool frequency and consistency, and parentally-reported (i.e. unconfirmed) infections.

Results: According to intention-to-treat criteria, confirmed respiratory tract infections were observed in 9.4% of the control group, compared to 3.1% in the HN001 group (p = 0.28), and 0.0% in the HN019 group (p=0.03). A similar trend was observed for parentally-reported infections, with 25.0% in the placebo group, compared with 14.1% in the HN001 group (p=0.12) and 9.4% in the HN019 group (p=0.02). No infants in the HN019 group were prescribed antibiotics or antivirals, compared with 3 (4.7%) in the HN001 group and 7 (10.9%) in the control group. No cases of diarrhoea were reported in any of the infants over the 12-week study period, and no differences in stool frequency or characteristics were observed. The probiotic-containing follow-on formulae were well tolerated and no adverse events were reported. Interestingly, faecal analysis conducted at the end of the study, showed that while *B. lactis* was detected significantly more often in infants that received HN019, a PCR used to detect HN001 showed widespread occurrence of HN001 or HN001-like *L. rhamnosus* species across all three groups.

Conclusion: In conclusion, this study directly compared the benefits of two different probiotics when added to follow-on infant formula. While HN001 showed trends toward reduced infections, HN019 showed superior performance in terms of significantly reduced incidence of physician-confirmed respiratory infections, parentally-reported infections, and antibiotic/antiviral use in Chinese infants aged 6 to 15 months.

Disclosure of Interest: J. Dekker Conflict with: Study funded by Fonterra, NZ, Conflict with: Dr Dekker is an employee of Fonterra NZ, Conflict with: Fonterra NZ manufactures and markets the probiotic strains used in the study, L.-M. Xu: None Declared, H. Qian: None Declared, X.-Y. Sheng : None Declared