

## Long-term safety and efficacy of prebiotic intake in infants and young children

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### Abstract:

There is increasing evidence that colonization of the gut after birth has a long-term “programming” effect on health mediated through the immune system. This has led to the hypothesis that the gut microbiota has an important role in the modulation of the immune system, and therefore, in the prevention of infections in the infant. In a public-private partnership project, the long-term effects of an infant formula supplemented with a mixture of prebiotic inulin-type oligosaccharides on health outcomes, safety and tolerance, as well as on fecal microbiota composition during the first year of life were studied in a prospective, multicenter, randomized, double-blind study. 160 healthy term infants under 4 months of age were randomized to receive either an infant formula enriched with 0.8 g/dL of an inulin-type oligosaccharide or an unsupplemented control formula until the age of 12 months. The per protocol population consisted of 123 infants. Both formulae were well tolerated. Mean duration of infections was significantly lower in the prebiotic fed infants ( $p = 0.034$ ). The prebiotic group showed higher Bifidobacterium counts at month 6 (8.91 (8.31, 9.41) vs. 8.15 (7.24, 9.09), median (IQR),  $p = 0.006$ ), and higher proportions of Bifidobacterium in relation to total bacteria at month 2 and 6 ( $p = 0.042$  and  $p = 0.013$ , respectively). Stools of infants receiving the prebiotic formula were softer ( $p < 0.05$ ). The prebiotic formula tended to beneficially impact total daily amount of crying ( $p = 0.0594$ ). These results will be discussed in context with findings from other trials using prebiotic inulin-type oligosaccharides in infants and children.