



July 22, 2025

***Bifidobacterium infantis* M-63 Found to Promote Formation of a *Bifidobacterium*-Dominant Gut Microbiota in Newborns and Reduce Intestinal Inflammation**

**Joint Research with Matsumoto City Hospital Published in Scientific Journal,
*Pediatric Research***

Morinaga Milk Industry Co., Ltd. has been conducting basic research on bifidobacteria for over 50 years, studying these beneficial bacteria that colonize the human intestine and provide various health benefits. Under a comprehensive partnership agreement with the government of Matsumoto City, Nagano Prefecture^{*1}, we have carried out clinical research on functional ingredients for many years, applying the results to support citizens' health and develop our proprietary ingredients.

In joint research with Matsumoto City Hospital^{*2}, we have confirmed that *Bifidobacterium infantis* M-63^{*3} reduces intestinal inflammation and enhances the production of beneficial substances by gut bacteria in healthy term infants. These research findings were published in the scientific journal *Pediatric Research* on July 18, 2025^{*4}.

1. Research Background

Bifidobacterium infantis M-63 is highly compatible with breast milk and is expected to benefit the infant gut environment and health. This study aimed to determine whether *B. infantis* M-63 contributes to suppressing intestinal inflammation during the neonatal period. In collaboration with Matsumoto City Hospital, we administered either *B. infantis* M-63 (1 billion CFU/day) or a placebo to 111 healthy term infants, starting within the first week after birth and continuing until 3 months of age. We assessed its effects on gut microbiota, fecal cytokines,^{*5} and metabolites produced by gut bacteria.

2. Research Methods

- Participants: 111 healthy newborns born at term (37 weeks, 0 days to 41 weeks, 6 days of gestation)
- Study Design: Randomized, double-blind, placebo-controlled, parallel-group comparative study
- Test Product Administration: Daily intake of powder containing 1 billion CFU of *B. infantis* M-63 or a placebo powder without *B. infantis* M-63, from within 7 days after birth until 3 months of age
- Evaluation Parameters: Gut microbiota analysis, fecal physicochemical parameters (cytokines and gut metabolites)

3. Research Results

- In the *B. infantis* M-63 group, we observed decreases in inflammatory cytokines such as interferon-gamma (IFN- γ) and interleukin-1 beta (IL-1 β) in the intestine at 1 month of age (Figure 1).
- The gut microbiota up to 3 months of age was classified into six types (Figure 2).

Types 1–3 were *Bifidobacterium*-dominant microbiota, while types 4–6 were dominated by non-*Bifidobacterium* bacteria, such as *Enterococcus* and *Streptococcus*.

- The *B. infantis* M-63 group exhibited a higher distribution of *Bifidobacterium*-dominant types (Types 1–3). Notably, in this group, indole-3-lactic acid (ILA), a metabolite with anti-inflammatory properties, was increased in the intestine (Figure 3).

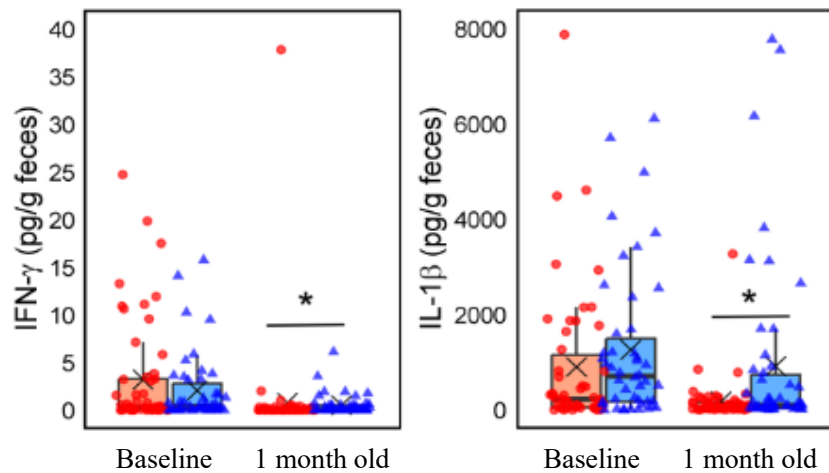


Figure 1. Cytokine production levels (Red ●: *B. infantis* M-63 group, Blue ▲: Placebo group)

* P < 0.05 indicates a statistically significant difference compared to the placebo group.

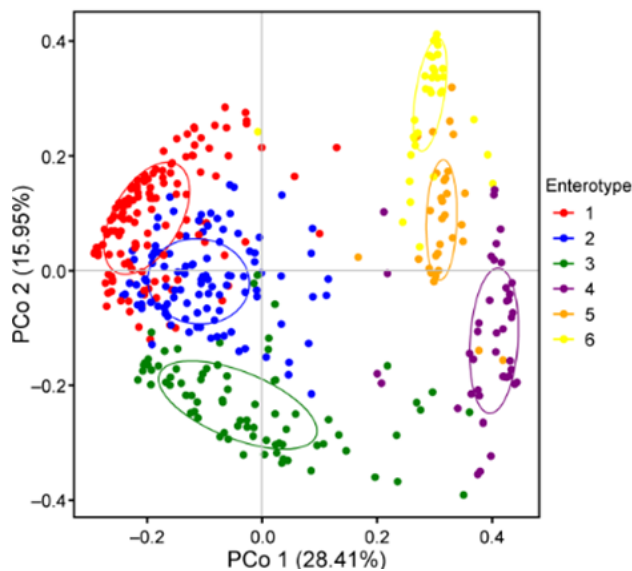


Figure 2. Classification of gut microbiota (1–3: *Bifidobacterium*-dominant microbiota, 4–6: Non-*Bifidobacterium*-dominant microbiota)

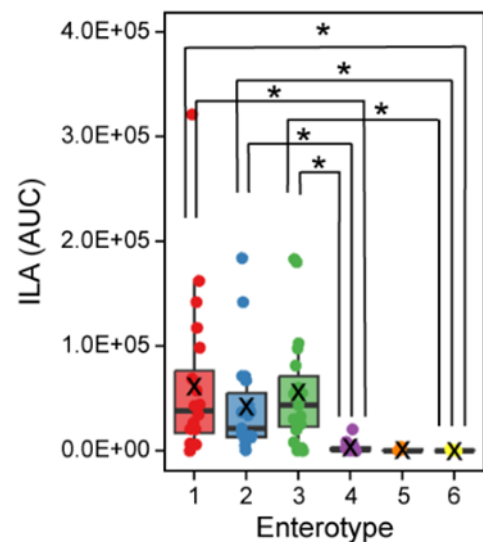


Figure 3. ILA production levels

4. Future Outlook

This study revealed that *B. infantis* M-63 suppresses intestinal inflammation in the early postnatal period

of healthy term infants and exhibits anti-inflammatory effects. The *B. infantis* M-63 used in this study received GRAS (Generally Recognized as Safe)^{*6} status in the United States in 2022 for general food use and infant applications, and was registered in China's New Food Ingredient system^{*7} in 2024, demonstrating high safety recognition internationally. By accurately communicating the characteristics and research findings of *B. infantis* M-63 to consumers and partner companies, we aim to increase opportunities for product applications and boost overseas sales. Morinaga Milk Industry will continue to provide accurate information and excellent ingredients that support people's health.

<Reference>

*1 Comprehensive Partnership Agreement with Matsumoto City, Nagano Prefecture

We signed a Comprehensive Partnership Agreement with the Matsumoto City government in 2021. We are working on initiatives to support the health of local residents through clinical trials of functional ingredients and collaboration with the local community.

<https://www.morinagamilk.co.jp/release/newsentry-3776.html>

*2 Joint Research with Matsumoto City Hospital, Nagano Prefecture

In 2019, we launched the "Survey on Infant Health and Support for Childbirth and Childcare for Matsumoto Citizens" in collaboration with Matsumoto City Hospital and the Matsumoto City government.

<https://www.morinagamilk.co.jp/release/newsentry-3239.html>

*3 *Bifidobacterium longum* subsp. *infantis* M-63

Our proprietary functional ingredient, *Bifidobacterium longum* subsp. *infantis* M-63, is a type of bifidobacteria discovered in infants that primarily colonizes the intestines of human infants. It has a high capacity to utilize human milk oligosaccharides, such as 2'-FL and 3'-FL, which are present in breast milk. Studies have reported that when combined with other bifidobacteria (*Bifidobacterium longum* BB536 and *Bifidobacterium breve* M-16V), it encourages early intestinal colonization of bifidobacteria in low-birthweight infants.



Bifidobacterium longum subsp. *infantis* M-63

*4 Article Title and Authors

Chendong Xu, Toshitaka Odamaki, Akari Hiraku, Setsuko Nakata, Satoshi Arai, Noriyuki Iwabuchi, Miyuki Tanaka, Takahisa Tsuno, and Masahiko Nakamura. "Anti-inflammatory effects of *Bifidobacterium infantis* M-63 during early postnatal period in term infants." *Pediatric Research* (2025); <https://doi.org/10.1038/s41390-025-04263-y>

*5 Cytokine

A general term for proteins secreted by cells that are bioactive substances involved in cell-to-cell interactions. They can either induce or suppress inflammation and help regulate immune responses.

***6 GRAS (Generally Recognized as Safe)**

When introducing new food ingredients in the United States, experts assess their safety as food ingredients. They review factors such as ingredient characteristics, manufacturing process, quality control, product specifications, usage history, and clinical trial results. GRAS status is required when selling something as a food ingredient within the United States.

***7 New Food Ingredient system**

The New Food Ingredient system allows for the selling in China of food ingredients that are not part of the traditional Chinese diet. Ingredients that may be used in foods for infants and toddlers under the age of three, in particular, must possess food properties and satisfy stringent nutrition, health, and safety standards.

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