BioGaia

November 3, 2026

BioGaia publishes clinical study evaluating Protectis® Plus BABY in infants with colic

New clinical data demonstrate significant reductions in infant colic after seven days with BioGaia's next-generation patented dual-strain probiotic formulation.

BioGaia announces the publication of a clinical study evaluating BioGaia® Protectis® Plus BABY drops, the company's next-generation patented dual-strain probiotic formulation for infants. The study, published in the scientific journal Nutrients, showed that supplementation with the combination of *L. reuteri* Protectis® (*L. reuteri* DSM 17938) and *L. reuteri* BG-R46® reduced infantile colic, now referred to as infant distress syndrome under the Rome V criteria, compared with placebo.

The study included 50 infants with infantile colic who were randomized to receive either the probiotic formulation or placebo for 21 days. The primary endpoint was the change from baseline to Day 7 in total infant distress time, defined as awake fussing, crying and inconsolable crying.

After 7 days, total infant distress time had decreased by 43% in the probiotic group compared with 13% in the placebo group. This corresponded to a reduction of approximately three hours per day from baseline in the probiotic group. The difference between groups was statistically significant. In addition, at day 7 there was a 75% reduction of inconsolable crying which is defined as prolonged, unsoothable crying.

The improvement continued over the 21-day study period, and at day 21, total infant distress time had decreased by 62% in the probiotic group compared with 26% in the placebo group. The formulation was well tolerated throughout the study.

BioGaia® Protectis® Plus BABY combines BioGaia's well-established *L. reuteri* Protectis® strain with the company's new, patented *L. reuteri* BG-R46® strain. The product represents the next generation of BioGaia's Protectis® BABY drops and builds on more than 35 years of research into *L. reuteri* probiotics.

Gianfranco Grompone, Chief Scientific Officer at BioGaia, comments: "This first publication on clinical effects of BioGaia® Protectis® Plus BABY is an important milestone. The results show a significant reduction in infant distress already after seven days with the combination of *L. reuteri* Protectis® and *L. reuteri* BG-R46®. Particularly encouraging is the observed effect on inconsolable crying, one of the most challenging aspects of infant colic for both babies and their families. These findings provide important clinical evidence supporting the scientific rationale for our dual-strain formulation."

Theresa Agnew, President and CEO of BioGaia, comments: "BioGaia has conducted research in infant health for decades. With BioGaia® Protectis® Plus BABY, we are building on the scientific foundation of Protectis and continuing to advance our probiotic portfolio. These new clinical results are an important milestone as we introduce our next-generation product to more families around the world."

BioGaia® Protectis® Plus BABY has already been launched in the UK, Sweden, Finland and France and is soon being rolled out across additional markets.

About the study

The randomized, double-blind, placebo-controlled trial included 50 infants randomized to receive either the probiotic formulation or placebo for 21 days. Forty-eight infants, 24 in each group, were included in the analyses. The primary endpoint was change in total infant distress time from baseline to Day 7, measured using a scientifically validated diary. Secondary outcomes included crying time, behavioral regulation, maternal emotional well-being and safety.

The study,"Efficacy of a *Limosilactobacillus reuteri* DSM 17938 and BG-R46® Formulation in Predominantly Breastfed Infants with Infant Distress Syndrome: A Randomized Double-Blind Placebo-Controlled Trial," was published in Nutrients on October 22, 2026.

Read the full study in Nutrients: https://www.mdpi.com/2072-6643/18/21/3468

Read our press release about the launch of BioGaia® Protectis® Plus BABY here: https://www.biogaiagroup.com/press/biogaia-ab-launches-biogaia-protectis-plus-next-generation-patented-probiotic-drops

References:

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Limosilactobacillus reuteri DSM 17938 and BG-R46® Formulation in Predominantly Breastfed Infants with Infant Distress Syndrome: A Randomized Double-Blind Placebo-Controlled Trial. Nutrients. 2026;18(21):3468. doi:10.3390/nu18213468.

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About BioGaia
BioGaia is a Swedish probiotics company that has been at the forefront of microbiome research for more than 35 years. BioGaia develops, manufactures, markets, and sells probiotic products focused on gut health, immune health, and oral health. The products are sold through local distribution partners or via own distribution in over 100 markets. The class B share of the Parent Company BioGaia AB is quoted on the Mid Cap segment of Nasdaq Stockholm. biogaiagroup.com