

Colic

REFERENCE	STUDY OBJECTIVES	STUDY DESIGN*	SUBJECTS AND (DAILY DOSE)	RESULTS
Savino F, 2014	Test the preventive effect of <i>L. reuteri</i> DSM 17938 combined with vitamin D, on infantile colic	12 weeks Randomized, open label study, blinded outcome analyst. Commercial vitamin D drop product as the comparator.	<i>L. reuteri</i> + vit. D: 51 (1x10 ⁸ CFU) Vit. D only: 54	Prevention of colic was significantly more successfully achieved in the <i>L. reuteri</i> group compared with the control group. The effect was indirectly measured, and demonstrated by significantly less use of pain-relieving agents, contacts with doctor (calls and visits due to symptoms of colic), and change of feeding to partially or exclusively infant formula.
Indrio F, 2014	Investigate if oral supplementation with <i>L. reuteri</i> DSM 17938 during the first 3 months of life can reduce the onset of colic, gastro-oesophageal reflux, and constipation in term newborns, and in addition reduce the socio-economic impact of these conditions	R, DB, PC 90 days Multicentre study	<i>L. reuteri</i> : 238 (1x10 ⁸ CFU) Placebo: 230	Compared to placebo: • Daily administration of <i>L. reuteri</i> early in life reduced the duration of daily inconsolable type of crying, frequency of regurgitation, and incidence of functional constipation in the first 3 months of life • Private and public costs for the management of these conditions were significantly reduced for infants receiving <i>L. reuteri</i>
Chau K, 2014	Investigate the efficacy of <i>L. reuteri</i> DSM 17938 for the treatment of infantile colic in breastfed infants ≤ 6 months	R, DB, PC 21 days	<i>L. reuteri</i> : 24 (1x10 ⁸ CFU) Placebo: 28	Compared to placebo: • <i>L. reuteri</i> significantly improved colic symptoms by reducing median crying and fussing times at days 7, 14 and 21. • The rate of responders (50% reduction in daily crying time) was significantly higher in the <i>L. reuteri</i> group compared with the control group at day 21.
Sung V, 2014	Efficacy of <i>L. reuteri</i> DSM 17938 on infantile colic in infants < 3 months, with mixed feeding types. Colic defined as daily combined screaming or fussing of 180 minutes or more. Maternal mental health and family quality of life (QoL) were also studied.	R, DB, PC 28 days + follow-up at 6 months	<i>L. reuteri</i> : 67 (1x10 ⁸ CFU) Placebo: 60 Other probiotics than <i>L. reuteri</i> were allowed for mothers and/or infants, and also use of proton pump inhibitor	Compared to placebo: • At day 28 mean values: 49 min more daily screaming + fussing time in the <i>L. reuteri</i> group (p<0.02), due to more fussing time in this group • At day 28 median values: no difference • No difference in duration of screaming time • No difference in number of episodes of screaming/fussing, or in sleeping time • No difference between groups in family QoL or maternal mental health ^a
Szajewska H, 2012	Efficacy of <i>L. reuteri</i> DSM 17938 on infantile colic in infants younger than 5 months, exclusively or pre-dominantly breastfed. Effect on screaming intensity and family quality of life. The trial included follow-up one week after termination of ingestion of the study product.	R, DB, PC 21 days + 7 days follow-up	<i>L. reuteri</i> : 40 (1x10 ⁸ CFU) Placebo: 40	• <i>L. reuteri</i> significantly reduced daily crying time compared to placebo • Significantly more responders on day 7, 14, 21 and 28 (follow-up) compared to placebo • Parents' rating of screaming intensity and family quality of life was significantly decreased and increased, respectively, at all time points
Karadag N, 2012 (abstract)	Efficacy on infantile colic and mother's postpartum depression comparing <i>L. reuteri</i> DSM 17938 with herbal drops and sterile water. Baby massage was practiced in all three groups.	R 21 days + follow-up on mother's mental health after 2 months	<i>L. reuteri</i> : 25 (1x10 ⁸ CFU) Herbal drops: 24 Sterile water: 25	• <i>L. reuteri</i> and sterile water significantly reduced daily crying time compared to herbal drops at three weeks • At three weeks the daily crying time was 35 minutes in the <i>L. reuteri</i> group compared to 188 minutes in the sterile water group and 300 min in the herbal drops group • a significant drop in depression and anxiety scores were seen only for mothers in the <i>L. reuteri</i> group at the follow-up at two months
Savino F, 2010	To study the effect of <i>L. reuteri</i> DSM 17938 on infantile colic in infants 2-16 weeks old, and investigate changes in the faecal microbiota.	R, DB, PC 21 days	<i>L. reuteri</i> : 25 (1x10 ⁸ CFU) Placebo: 21	<i>L. reuteri</i> significantly reduced daily crying time compared to placebo. • Significantly more responders on day 7, 14 and 21 compared to placebo. • Reduced faecal <i>E. coli</i> and increased counts of lactobacilli in the <i>L. reuteri</i> group only
Savino F, 2007	Efficacy on infantile colic in infants 11–80 days old.	R, open 28 days	<i>L. reuteri</i> : 41 (1x10 ⁸ CFU) Simethicone: 42	<i>L. reuteri</i> significantly reduced: • Daily crying time compared to simethicone • On day 28, 95% were responders in the probiotic group vs. 7% in the simethicone group

* R= randomized, DB= double blind, PC= placebo controlled.  A video presentation of this study is available on www.biogaia.com

Studies on newborn term infants and young children receiving the probiotic *L. reuteri* DSM 17938 (*L. reuteri*) showed significant effect on gastro-intestinal and immune health. There were no clinical safety or tolerance problems.