

Gut function

REFERENCE	STUDY OBJECTIVES	STUDY DESIGN*	SUBJECTS AND (DAILY DOSE)	RESULTS
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 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>
Garofoli S, 2014	To test if early administration of <i>L. reuteri</i> DSM 17938 to breast-fed, full-term healthy infants can prevent functional GI symptoms during the first 28 days of life, and to study if the probiotic administration will affect salivary sIgA concentrations at the end of the intervention period	R, DB, PC 28 days	<i>L. reuteri</i> : 20 (1x10 ⁸ CFU) Placebo: 20	• The mean number of daily regurgitations was significantly lower in the <i>L. reuteri</i> group at day 28 compared to placebo. • The daily frequency of other functional GI symptoms was similar in the two groups (stool frequency and consistency, crying duration) • There was no difference between groups in salivary IgA concentrations at day 28. Baseline values were not measured.
Dinleyici EC, 2014	The efficacy of <i>L. reuteri</i> DSM 17938 in children aged 3 – 60 mo, and hospitalised for acute diarrhoea. Both groups of children received conventional rehydration therapy, but the control group received no probiotic.	Randomised, single blinded (effects analyst) 5 days	<i>L. reuteri</i> : 64 1x10 ⁸ CFU Control: 63	Compared to controls: • <i>L. reuteri</i> significantly reduced the duration of diarrhoea • The proportion of children with watery diarrhoea after 48h and 72h was significantly reduced • Duration of hospital stay was significantly reduced • Prolonged diarrhoea was only reported in the control group of children
Papagaroufalos K, 2014	To assess the safety of infant formula containing <i>L. reuteri</i> DSM 17938 during the first month of life, with special reference to D-lactic acid, in comparison to infants fed a control formula. Other outcomes were GI tolerance, sleeping and crying behaviour, growth and occurrence of adverse events.	R, DB, PC 28 days Follow-up on days 112 and 168	<i>L. reuteri</i> : 36 (1x10 ⁸ CFU) Control: 35 31 infants in each group took part in the follow-up on days 112 and 168	Compared to control formula: • Regurgitation episodes were significantly fewer in the <i>L. reuteri</i> group • The probiotic group had significantly lower frequency of hard stools and higher percentage of soft stools at day 28
Francavilla R, 2012	Effect on acute gastroenteritis caused by rotavirus in children 6-36 months old, and hospitalized due to clinical signs of mild to moderate dehydration.	R, DB, PC 7 days	<i>L. reuteri</i> : 20 (1x10 ⁸ CFU) Placebo: 20	Compared to placebo <i>L. reuteri</i> significantly: • reduced the duration of diarrhoea by 1.2 days • the frequency of watery diarrhoea was significantly reduced on treatment days 2 and 3 • the number of children with normal stool consistency was significantly higher on days 2 and 3
Coccorullo P, 2010	To evaluate the effect of <i>L. reuteri</i> DSM 17938 in 6-12 month old infants with chronic functional constipation.	R, DB, PC 8 weeks	<i>L. reuteri</i> : 22 (1x10 ⁸ CFU) Placebo: 22	<i>L. reuteri</i> significantly improved: • Defecation frequency compared to placebo • Faecal consistency compared to baseline
Indrio F, 2011	To evaluate the efficacy of <i>L. reuteri</i> DSM 17938 on gastric function in full term formula-fed infants with ≥ 4 regurgitation episodes/day.	R, DB, PC 30 days	<i>L. reuteri</i> : 19 (1x10 ⁸ CFU) Placebo: 15	• <i>L. reuteri</i> significantly reduced regurgitation episodes by 50% • <i>L. reuteri</i> significantly increased gastric emptying rate at 30 days compared to baseline
Eom T-H, 2005	Reduction of symptoms in children hospitalised for acute gastroenteritis and aged 6 months - 3 years.	R, DB, PC 5 days or until discharged	<i>L. reuteri</i> : 25 (2x10 ⁸ CFU) Placebo: 25	<i>L. reuteri</i> significantly reduced: • Frequency of watery diarrhoea • Frequency of vomiting • Hospital stay
Shornikova A, 1997a	Treatment of children hospitalised for acute gastroenteritis and aged 6 months - 3 years.	R, DB, PC 5 days or until discharged	<i>L. reuteri</i> : 19 (10 ¹⁰ -10 ¹¹ CFU) Placebo: 21	<i>L. reuteri</i> significantly reduced: • Frequency of watery diarrhoea • Frequency of vomiting
Shornikova A, 1997b	Treatment of children hospitalised for acute rotavirus gastroenteritis and aged 6 months - 3 years.	R, DB, PC 5 days or until discharged	<i>L. reuteri</i> : 21 (10 ⁸ CFU) <i>L. reuteri</i> : 20 (10 ⁷ CFU) Placebo: 25	<i>L. reuteri</i> in the high dose significantly reduced: • Duration of watery diarrhoea • Frequency of diarrhoea Positive, but non-significant, effects were seen also in the low dose group compared to placebo

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