

Effect of Probiotic *Limosilactobacillus Reuteri* (L. Reuteri) on Crying Time in Infants With Colic

NCT05512234

Status	RECRUITING
Phase	Not Applicable
Sponsor	BioGaia AB
Enrollment	102 participants

Key Eligibility Criteria

Inclusion (12)

- Aged between 3-8 weeks at screening.
 - Gestational age 37+0 weeks - 42+0 weeks at birth.
 - Birth weight appropriate for gestational age (AGA - weight between 10th and 90th percentile) or Large for Gestational Age (LGA - weight above the 90th percentile) determined using WHO Weight-for Age percentile guides.
 - Parents/caregivers/legal guardians are ≥ 18 years.
 - Exclusively or predominantly breastfed infants ($\geq 50\%$ breast fed).
- ... and 7 more (see full listing online)

Exclusion (6)

- Infants with severe gastroesophageal reflux (throwing up or spitting up more than a teaspoon of milk ≥ 8 times daily, projectile, bilious or bloody emesis).
 - Infants with failure to thrive, intrauterine growth retardation, haematochezia (blood in the stools), diarrhoea (watery stools that takes the shape of a container $\geq 12x$ in breastfed and ≥ 5 in partially breastfed infants daily), or fever (38.0 degrees), as reported by parents/caregivers/legal guardians.
 - Infants with congenital heart disease, immunodeficiency, asplenia, cancer, cystic fibrosis, and those with liver disease.
 - Infants with reported exposure to probiotics in the 7 days prior to Screening Visit (V1) and throughout the study period.
 - Infants with reported exposure to oral and/or systemic antibiotics in the 7 days prior to Screening Visit (V1) and throughout the study period.
- ... and 1 more (see full listing online)

Locations (2 total)

Atlantia Clinical Trials, Cork, Ireland
Clinical Trail Consultants AB, Uppsala, Sweden