Lack of efficacy of Lactobacillus GG in reducing pulmonary exacerbations and hospital admissions in children with cystic fibrosis: A randomised placebo controlled trial.

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Study design (if review, criteria of inclusion for studies)
Multicentre, randomised double-blind, clinical trial

Participants
95 Children with CF (2 to 16 years of age, 51/95 female; median age of 103 +/- 50 months).

Interventions
After 6 months of baseline assessment, enrolled children received Lactobacillus GG (6x10^9 CFU/day) or placebo for 12 months.

Outcome measures
Primary outcomes were proportion of subjects with at least one pulmonary exacerbation and hospitalisation over 12 months. Secondary endpoints were total number of exacerbations and hospitalisations, pulmonary function, and nutritional status.

Main results
In a multivariate GEE logistic analysis, the odds of experiencing at least one exacerbation was not significantly different between the two groups, also after adjusting for the presence of different microbial organisms and for the number of pulmonary exacerbations within 6 months before randomisation (OR 0.83; 95% CI 0.38 to 1.82, p=0.643). Similarly, LGG supplementation did not significantly affect the odds of hospitalisations (OR 1.67; 95% CI 0.75 to 3.72, p=0.211). No significant difference was found for body mass index and FEV1.

Authors' conclusions
LGG supplementation had no effect on respiratory and nutritional outcomes in this large study population of children with CF under stringent randomised clinical trial conditions. Whether earlier interventions, larger doses, or different strains of probiotics may be effective is unknown.

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See also

Keywords
Adolescent; Child; Hospitalization; Hospital care; Lactobacillus; Probiotics; Supplementation; Exacerbation; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Bacterial Infections; Oral; Immunoregulatory; pharmacological intervention;