primary studies - published RCT

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 16years of age, 51/95 female; median age of 103+/-50months).

Interventions

After 6months of baseline assessment, enrolled children received Lactobacillus GG (6x109CFU/day) or placebo for 12 months.

Outcome measures

Primary outcomes were proportion of subjects with at least one pulmonary exacerbation and hospitalisation over 12months. 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 6months 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

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Keywords

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