

primary studies - published RCT

## **The effect of short-term, high-dose oral N-acetylcysteine treatment on oxidative stress markers in cystic fibrosis patients with chronic *P. aeruginosa* infection - A pilot study.**

**Code:** PM25458464

**Year:** 2014 **Date:** 2017

**Author:** Skov M

### **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 (6x10<sup>9</sup>CFU/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.

<http://dx.doi.org/10.1016/j.jcf.2014.09.015>

### **See also**

J Cyst Fibros. 2014 Oct 23. pii: S1569-1993(14)00227-6. doi: 10.1016/j.jcf.2014.09.015.

### **Keywords**

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