

Randomized, placebo-controlled trial.

Patients age 5-21 years old in remission (PCDAI<11) at least for 2 months, were randomized to:

-Probiotic Lactobacillus rhamnosus strain GG (LGG) 2 times per day. (1 capsule at least 10^{10} bacteria and 295mg inulin) or placebo added to their standard therapy (thiopurines, low dose steroid alternate days).

Follow-up for 2 years.

Primary endpoint: CDAI remission at 8 weeks

Results:

- Relapse 31% LGG vs 17% placebo group, $p=0.18$
- Median time to relapse 9.8 months LGG vs 11 placebo, $p=0.24$
- LGG was well tolerated with no differences to placebo

Conclusions:

This study suggests that LGG does not prolong time to relapse in children with CD when given as an adjunct to standard therapy.

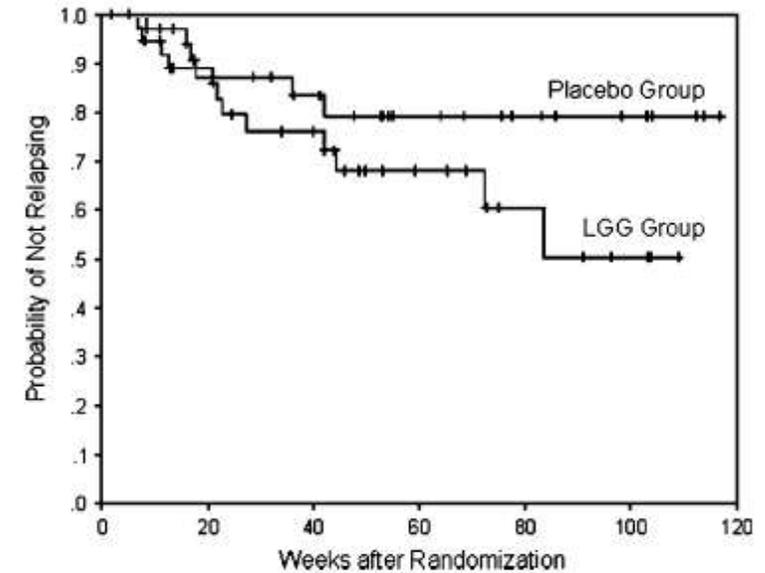


FIGURE 1. Survival curve showing the probability of staying relapse free during the duration of the study. Individual tick marks represent censored patients (patients who did not develop a relapse or an adverse event, necessitating withdrawal at the time of the study was stopped). The 2 curves and median survival times were not significantly different by the log-rank test.

