Reviewer’s report

Title: Lactobacillus casei strain GG in the treatment of infants with acute watery diarrhea: A randomized, double-blind, placebo controlled clinical trial

Version: 1  Date: 28 April 2004

Reviewer: H. Szajewska

Reviewer’s report:

General
This RCT looked at the effect of Lactobacillus GG in 160 boys, aged 3 to 36, months with acute diarrhea treated as inpatients in a tropical developing country. There was no significant reduction in diarrhoea duration in subjects given Lactobacillus GG compared with control subjects. The study is the second (previous study also from Peru) to include stool output as an outcome. The intervention did not result in any statistically significant difference. The lack of efficacy of Lactobacillus GG in this study is in contrast to the results of many previous trials with Lactobacillus GG, and therefore it is an important negative study.

Internal validity
· Adequate allocation concealment (randomisation method described and adequate)
· Adequate blinding of investigators, participants, outcome assessors and data analysts
· No intention-to-treat analysis: I would strongly suggest that intention to treat analysis, instead of analysis per protocol, is performed.
· Completeness to follow-up: 89% (acceptable).

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Results:
o I suggest that the results of intention to treat analysis are presented (not per protocol analysis)

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Abstract:
o Dose of Lactobacillus GG used in the study should be stated.
o Detailed data on total stool output, duration of diarrhea etc. might be useful

Methods:
o Clearly defined primary and secondary outcome measures should be presented (not only measurement of clinical outcomes)

Results:
o The diagram showing the flow of participants through each stage of the study would be recommended.
o I suggest that the results of intention to treat analysis are presented (not per protocol analysis)
Criteria for stopping treatment and discharging the patient: I do not understand the policy of withdrawal replacement.
Adverse effects, or their absence, in each intervention group should be reported.

Discussion:
Recent meta-analysis suggested a dose-dependent inverse relationship between a daily Lactobacillus dose and the reduction of diarrhea duration.
More detailed discussion on dose could be included in the discussion section.

Table 2.
I would suggest to present difference between means (with 95% CI), not only p value.

Discretionary Revisions (which the author can choose to ignore)
Study population: the study was performed in 1991-92. What is the reason that it took such a long time to summarize the results?

What next?: Accept after minor essential revisions
Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No