Reviewer’s report

Title: A multi-centre randomised placebo-controlled trial for the treatment of non-complicated acute watery diarrhoea using an oral preparation of Lactobacillus acidophilus in Vietnamese children.

Version: 1 Date: 20 September 2012

Reviewer: SHINJINI BHATNAGAR

Reviewer’s report:

Major Comments

The major limitation of this study is that the hypothesis is not clearly stated and the definitions of primary and secondary end points are not objectively defined.

1. Why is the determination of the primary end point of the study “start of the first 24 hour diarrhea free period” dependent on the parents/guardians (‘as assessed by the parents/guardians) and not the research staff? Asking parents/guardians to judge the primary endpoint will introduce subjectivity in the measurement of the outcome. The research staff can be trained to remove inter and intra observer variability which may not be possible with the parents/guardians

2. The definitions of some of the outcomes are very subjective:
   • “Discontinuation of the study medication will depend on the discretion of the study physician”
   • “Physicians will determine day and moment of discharge at their discretion”

   These definitions should be clearly stated and not depend on the discretion of the study physician.

3. Details on randomization process are not not adequately provided.

Minor comments

The authors need to explain why subjects screened for the study are between 9-60 months?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
'I declare that I have no competing interests'