Reviewer's report

Title: Human lactobacilli as adjuvant given to patients with bacterial vaginosis reduce the recurrence rate after vaginal clindamycin therapy; a 6 month double blind randomized placebo controlled study.

Version: 3 Date: 8 May 2007
Reviewer: Mark A Klebanoff

Reviewer's report:

General

This manuscript evaluated the use of probiotic lactobacillus vaginal capsules as adjunctive therapy in treating bacterial vaginosis.

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

A major concern was that 'intent to treat' analysis was not followed. One of the first principles of analysis is that everyone randomized must be included with their assigned group, regardless of what happens next. According to the section 'follow up', line 5, women who failed to respond to treatment (which, I might add included study capsules) were re-treated and excluded. Since this exclusion occurred after randomization (and indeed, after the first round of treatment), it is totally inappropriate. The authors must re-analyze their data according to accepted principles of trial design.

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

The authors emphasize the value of their treatment. They also note the presence of Mobiluncus to be related to success, but do admit the p-value was not significant. However, they give little emphasis to the fact that their treatment had a lower success rate at 1 month, with a p-value comparable to (and in fact, slightly lower than) that of Mobiluncus.

It appears that the placebo capsules differed from the treatment ones by more than the presence of lactobacilli. The authors should comment on why this is so, and how it might have affected their results.

Were the definitions of cure agreed upon a priori, or after the study was done?

More details need to be provided regarding the mechanics of randomization-- who made up the schedule? Did that person have any patient contact? Were the capsules pre-packaged and study personnel simply assigned the next one in sequence? Was randomization done with sealed envelopes? what was the role of the study pharmacy. The authors should refer to the CONSORT statement for more detail.

Did the authors test the blinding of staff (ie after a woman had completed her study visits, ask the staff what they thought that woman was receiving)?

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

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: No, the manuscript does not need to be seen by a statistician.

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