Author's response to reviews

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.

Authors:

Per-Goran Larsson (p-g.larsson@vgregion.se)
Babill Stray-Pedersen (babill.stray-pedersen@klinmed.uio.no)
Kjeld R Ryttig (krr@farmaservice.dk)
Stig Larsen (Stig.Larsen@veths.no)

Version: 6 Date: 3 December 2007

Author's response to reviews: see over
Dear Dr Lolu da-Silva  
Senior Assistant Editor, BMC-series journals  

I am very pleased that you invited a member of the editorial board as a new referee and I am happy to rapidly provide you with a point-by-point response to her concerns. I hope that this will also make it possible to finally publish our manuscript.

P-G

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: 5  Date: 26 November 2007  
Reviewer: Marika Mikelsaar  
Reviewer’s report:

General

This is an important study confirming that with repeated administration of lactobacilli the relapse rate of bacterial vaginosis (BV) can be reduced after successful initial clindamycin therapy.

The study is well organized, the sample size is appropriate, the methods and results are reliable and interesting yet there are some important issues still needing correction before publication.

I fully agree with prof. Gregor Reid in some points that need to be corrected. However, by my understanding these revisions are easy and quick to perform.

1) Lactobacilli as adjuvant. Really, the term "adjuvant" indicates a supportive material/substance that is usually added as a component to the active compound/substance or administered at the same time with the main active compound.
For instance - in polysaccharide pneumococcal vaccines the extra added proteinaceous compounds serve as adjuvant.

It seems that the authors mention the use of lactobacilli as "adjunct to clindamycin therapy". It can be defined also as "supplementation of clindamycin therapy by lactobacilli".

2) The concern of Prof. Reid about the rationale for repeated therapy is true and still not clear in the last version of the paper. It seems that the AIM of the study has to be rephrased by authors for increased clarity showing the repeated supplementation with lactobacilli during 3 months after initial therapy.

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

1) The title of the paper is inappropriate (see comment 1 for "adjuvant")

The title has been changed, adjuvant has been replaced with supplementation of clindamycin.

2) The possible new version for AIM:
"The primary objective of this study was to investigate if supplementary lactobacilli treatment could improve the initial cure rate after vaginal clindamycin therapy, and secondly, if lactobacilli as repeated adjunct treatment during 3 menstrual cycles could lengthen the time to relapse after initial cure.

This has been changed according to the suggestion both in the abstract – background and at the end of background section.

3) In methods section the 3 times for 10 days administration of lactobacilli has not clearly shown though it has been stated in Abstract.

In the methods section “adjuvant” has been deleted and to the paragraph “Treatment” we have added “during 10 days”. And in “study design” the phrase “The capsules were given for 10 days during 3 consecutive menstrual cycles” has been added.

4) Conclusion - the more precise statement is necessary according to the rephrased AIM.
In the abstract- conclusion – supplementary has replaced adjuvant and the following has been added. “for women initially cured, adjunct treatment of lactobacilli during 3 menstrual cycles increases” This has been added also at the end of the discussion section which starts with “in conclusion… After lactobacilli treatment given for three menstrual cycles, there are a…”

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
Some errors have been detected as Figure 2 was not referred to in the text. Table I has been changed to Table 1. The numbering of pages has been changed and the running head has been deleted. For one author, competing interest have been added.

The English language revision is necessary.

The manuscript has once again been sent to a professional linguistic rewriter.

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Discretionary Revisions (which the author can choose to ignore)
All the other concerns of Reviewer 2 have been sufficiently answered by authors and can be considered as scientifically well disputable.

What next?: Accept after minor essential revisions
Level of interest: An article of importance in its field
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'
M. Mikelsaar