Reviewer's report

Title: Clinical trial: Probiotic treatment of acute distal ulcerative colitis with rectally administered Escheria coli Nissle 1917 (EcN)

Version: 6 Date: 4 January 2010

Reviewer: Per Farup

Reviewer's report:

The revised manuscript has been improved, but my main objections remain unchanged. I comment only on the major and important points.

• Intention to treat (ITT) analyses should always be the primary results when presenting the results of RCTs. The response rates in the groups treated with 40, 20, 10 ml and placebo were 10/23, 11/23, 8/22 and 7/20 respectively, and statistics with Jonckheere-Terpstra Test gives a p-value of 0.44 (asymptotic, 2-sided). There is no effect of the treatment, and these results (with the numbers and statistics given above) should be given in the abstract as well as in the conclusion on the last page. But, they could then report the results of the PP-analyses and give the results with Jonckheere-Terpstra Test which gives a p-value of 0.0446 (asymptotic, 2-sided) or 0.0464 (exact, 2-sided).

• I do not accept the use of 1-sided tests. Use 2-sided tests all over, in the text as well as on the figures. In the present version of the paper it seems as if the result of a 2-sided test is given on figure 2.

• The authors have clarified the randomization procedure. The patients got different volumes of the enema, which means that this is not a double blind study (because everyone knew the volume) but a randomized and in part open study.

• I disagree with the conclusion that the treatment was well tolerated. 4 out of 88 (4.5%) had to stop treatment because of intolerable adverse events, which is a rather high prevalence of intolerable adverse events to a probiotic drug.

• The presentation could still be improved, the language as well as the figures. Leave out figure 2 (the numbers are given in the text and appear from figure 3a. Does figure 4 give any meaning with a lot of missing data (e.g. 55% not available after treatment in the placebo group)?

Ardyepharm GmbH financed the study and employees in Ardyepharm GmbH are authors who have taken part in the analyses, discussions, writing and presentation. Has the sponsor had a high influence on the presentation?

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.