Author's response to reviews

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

Authors:

Harald Matthes (hmatthes@havelhoehe.de)
Thomas Krummenerl (krummenerl@gastro-muenster.de)
Manfred Giensch (dr.med.m.giensch@t-online.de)
Corinna Wolff (corinna.wolff@ardeypharm.de)
Juergen Schulze (corinna.wolff@ardeypharm.de)

Version: 8 Date: 18 March 2010

Author's response to reviews: see over
Dear Editor,

below you will find our answer to Mr Farup.

Concerning your requests regarding the affiliations, "private practice" means that the 2 doctors in question do not have any relationship with a university or hospital. They are what is often referred to as "family doctors". They will surely prescribe probiotics whenever they consider this appropriate, but they have no relationship with the study sponsor beyond the project to be published here. Therefore we extended the declaration conflict of interest at the end of the manuscript.

We added the authors contribution section and revised the acknowledgement, adding the statistician.

On page 5 we added one sentence clarifying the blinding.

Hopefully, all concerns are now clarified. In case of further questions or remarks we are always willing to help.

Kind regards on behalf of all authors,
Dr. H. Matthes

**Answers to Reviewer’s report**

**Reviewer's report:**
If I understand correctly, this is not a double blind trial. For example, in patients given 10 ml, everyone knew that they did not receive a high dose. Therefore, the study was in part completely open.

For clarifying the blinding procedure we added to the section „study medication“ the sentence: **Therefore, blinding was granted with regard to the use of the active substance or placebo.**

A drug, which has to be stopped prematurely in 3/68 (4.4%) due to intolerable adverse events, is not a well tolerated drug. This drug seems to have common and serious adverse events. Treatment is not stopped prematurely for mild adverse events in a clinical trial treating patients with a serious disorder, and according to international recommendations, common adverse events are events with a prevalence above 1%.

**Reply:**
None of the AEs were serious and mostly related to flatulence. However the patients stopped treatment when it appears to be ineffective or because the general course of their disease was mild.