Reviewer's report

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

Version: 7 Date: 13 February 2010

Reviewer: Per G Farup

Reviewer's report:

I am grateful for the revisions made by the authors, but I am not satisfied.

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.

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%.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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.