Reviewer's report

Title: Equal antipyretic efficacy of oral and rectal acetaminophen: a randomized controlled trial [ISRCTN 11886401]

Version: 2 Date: 2 May 2005

Reviewer: Diederik Dippel

Reviewer's report:

General
This is essentially a well-designed randomized clinical trial that compares the effect of medium and high dose paracetamol in children with fever. Dosages of 20 mg/g oral, 20 mg/kg rectal and 35 mg/kg rectal were compared. The purpose of the study is sound and clinically relevant.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
1. Methods/Results section: perhaps it would have been more informative to express the treatment effect as a difference in mean temperature with the reference treatment, with a 95% confidence interval. This would help us in deciding whether there is indeed equivalence. This goes for the primary and for the secondary outcomes. In my opinion, in the abstract, the conclusion that there is equal efficacy, does not follow from the results, as they are presented now.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
there are some peculiarities in the text that suggest that English is not the author's native language, for example "random list", "more incidence of " (p12).
page 10: use Epstein-Barr instead of Ebstein-Barr.

Discretionary Revisions (which the author can choose to ignore)
2. The primary outcome is a bit artificial in my opinion: time to maximum antipyresis, what to do with the patients in whom temperature goes down only 0.5 degrees, or not at all? Perhaps it would be better to study the time to temperature reduction of at least 1 degree Celsius. This would require a different (kaplan-meier) type of analysis
3. I was a bit worried about the high dose rectal group: 35mg/kg is a large dose, usually, we prescribe paracetamol in dosages of 10mg/kg, four or six times daily, because of the risk of hepatic injury. I understand that it concerns a single dose, but it might encourage others to give it four times daily, which almost ensures one of hepatic failure in a patient thus treated. The authors could comment on this in the discussion section.

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

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published

Statistical review: No

Declaration of competing interests:

I declare that I have no competing interests