Reviewer's report

Title: Protocol for the prospective randomised trial comparing nasogastric with intravenous hydration in children with bronchiolitis (ACTRN12605000033640) The comparative rehydration in bronchiolitis study (CRIB)

Version: 2 Date: 17 February 2010

Reviewer: Joseph J Zorc

Reviewer’s report:

This manuscript presents a protocol for a multi-center randomized trial of intravenous versus nasogastric (NG) hydration for infants with bronchiolitis. The question is of interest to pediatric care providers as this is a common issue and evidence is limited to guide practice. There is equipoise for a trial to be conducted, particularly in Australia, where practice is apparently divided fairly equally based on the pilot study conducted by the investigators (in other parts of the world intravenous therapy is used more frequently). The trial is ongoing, so changes in the protocol are unlikely to be accepted at this time; I see no areas for major revision. Overall the protocol is well written, specific recommendations are listed below:

Justification

1. The authors make no hypothesis of which therapy they expect to be superior, although they hypothesize that there will be a difference. The presentation of the literature suggests that they expect NG to be superior with regard to adverse events. Typically specifying these expectations in advance is useful as confirmation of a pre-specified hypothesis makes a stronger scientific case than purely observational findings.

Methods

1. On page 8 of the Methods (Sample size, power, statistical methods) there are several areas where Pilot data on page 8 is referenced. I don’t see this information in the manuscript and this should be clarified.

2. The justification for sample size is somewhat different from what is done in many trials. Typically a clinically significant difference is designated for the primary outcome and sample size is based on that, with adjustments for different assumptions about the distribution of the outcome. Here the authors base the sample size on an effect size and describe the differences that will be observable without making any commitment of what would be a clinically significant improvement to justify choosing one therapy over the other. It appears that in fact the secondary outcome of adverse events may be the primary driver of the sample size (to achieve 80% power to detect a 10% absolute difference in complications). If so, specification of this could be helpful to the reader.

Limitations
3. There is no mention of potential limitations of the trial design. The area of most relevance for this trial is the lack of blinding. Since this is a controversial issue, providers likely have biases that may influence the subjective clinical decisions that are part of bronchilitis care. However, it would likely be unfeasible to attempt to blind an independent assessment. In addition, biases may drive actual clinical care and this study is attempting to assess impact of these therapies within the healthcare system. I don't disagree with the design the authors have chosen, but addressing this issue in advance as a limitation may be useful to address potential critiques.

**Level of interest:** An article of limited interest

**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