Reviewer's report

Title: Antibiotic prophylaxis for caesarean section at a Ugandan Hospital: a randomised clinical trial evaluating the effect of administration time on the incidence of post-operative infections

Version: 2
Date: 31 October 2014

Reviewer: Hassan Ba’aqeel

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Comments to authors:

The authors addressed some of the points that I raised. Other points were either not addressed or addressed in an unsatisfactory manner.

The serious methodological limitations that I referred to in my initial review were not addressed adequately by the authors. This is a single blinded trial when even in low resource setting it could have been designed to be double blinded with ease. I expected the authors to acknowledge this serious limitation in the discussion section. Instead in the methods section they stated and I quote:

The patients were blinded to the timing of the treatment received investigator was not blinded as had to know when to give antibiotic yet the observers on follow up were blinded.

The authors responded to the point about describing the block randomization I quote from the revised manuscript:

patients were block randomised into groups A and B by selecting lettered numbers from the envelopes with computer generated numbers in four blocks. I could not understand the term lettered numbers. There is a failure of adequately describing the allocation method (in my initial review I specifically asked if sealed envelopes were used? Is this failure of linguistic ability? I am not sure if the authors are familiar with block randomization. They stated that they created four blocks. Given their sample size each block would have contained 116 allocations. The rule of thumb is that block size should not be too large (leading to imbalance of allocation) nor to small that may jeopardize concealment. Traditionally the block size should be at least twice the number of arms in the trial. The authors failed to explain why they chose such a large block size.

The authors did not respond to the point about febrile morbidity being only performed on the 10th postoperative day.

The point about defining neonatal outcomes was corrected in the manuscript as admission to neonatal intensive care and treatment for infection, but the results section and table 3 were not modified to reflect the change in the text.

There is a discrepancy in describing the intervention, in the manuscript I quote:

Patients in group A were administered ceftriaxone 2 g intravenously 15 to 60
minutes before the skin incision and those in group B were administered the same dose after performing the skin incision.

While in the Pan African Trial Registry. A screen shot is uploaded in a separate file. It indicates that control group will be given more than one dose.

CONSORT statement recommends that binary outcome be reported as risk ratio, odds ratio or risk difference. I suggested that the authors report their results as RR instead of incidence rate ratio. In their covering letter I quote:

Incidence risk ratio with 95% confidence intervals was calculated so the statement has been corrected.

Neither the text in the results section nor table 3 were corrected. It seems to me that the authors do not differentiate between risk ratio and rate ratio. Risk ratio is a measure of outcome probability while rate ratio is a measure of causality.

Based on my first review, the response of the authors, the revised manuscript and checking the Pan African Clinical Trials Registry where the trial was registered, I am of the opinion that the reported trial from conception to reporting lacked scientific rigor. This casts some doubts on the validity of the results and hence the conclusions.

**Level of interest:** An article whose findings are important to those with closely related research interests

**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.