Reviewer's report

Title: Efficacy of single dose Gentamicin in combination with Metronidazole versus multiple doses for prevention of post caesarean infection

Version: 1 Date: 3 December 2011

Reviewer: Fiona Smaill

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Major points for revision

1. The hypothesis being studied is that there is a difference in post-caesarean infections between a single dose of gentamicin in combination with metronidazole and multiple doses of gentamicin and metronidazole. In the background the authors reference two studies (24, 25) that demonstrate that a single dose of antibiotics is as effective as multiple doses. They do not describe in enough detail why, despite these studies and other evidence supporting just a single dose of antibiotics for prophylaxis, their study is still needed.

2. Although their hypothesis is that there is a difference between a single and multiple doses of antibiotics, in the section on data analysis they say “there (this) will be an equivalen(ce) trial to test the hypothesis that there is no significant difference in … infection”. The sample size is calculated to show a difference of 20% between the two groups, not calculated as an equivalence study and a 20% difference is too large for an equivalence trial.

3. There is no rationale for the antibiotic regimen chosen, and although it probably is reasonable, there should be a discussion about the likely organisms covered rather than the statement in the background “the effectiveness of the current regimen is unknown”. There are some studies that have used this combination for prophylaxis (for a complete list, the authors could review the Cochrane Reviews on C-section prophylaxis and comparison of regimens). There should be a discussion about what are the commonest organisms associated with surgical site infections in their centre and the pattern of resistance. Is Staphylococcus aureus common (which wouldn’t be expected to be covered by the combination)? The doses are not justified – gentamicin is usually dosed as mg/kg.

4. There is no justification for the estimated infection rate of 40% used to calculate the sample size. This seems like a very high rate of infection and not consistent with the reports in the literature, even when antibiotics are not used for prophylaxis.

5. Although there may be operational and practical issues why the study is not double-blinded (with placebo doses given post-partum), there should be a discussion of this in the protocol. Similarly there should be a discussion as to how to reduce bias – the choice of envelopes to allocate patients can be subject
to bias and other ways (e.g. a call to the pharmacy) should be considered. There should be an attempt to blind the patient and observer to study allocation, or at least have a discussion that the person making an assessment about the outcomes should not be aware of the study group allocation.

Minor points for revision

1. Urinary tract infection (with definitions) should be included as an outcome as should side effects from the medication.

2. As part of data dissemination, the authors should discuss how they could implement the results of their study in their unit to improve the outcome of their patients. It seems in fact as though the real problem is not the absence of evidence, but no consistent protocol in the unit and this could be studied as a quality improvement activity.

Level of interest: An article of limited interest

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

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interest