Reviewer’s report

Title: Inhaled PGE1 in neonates with hypoxemic respiratory failure: Pilot randomized clinical trials to assess feasibility

Version: 4 Date: 5 November 2014

Reviewer: Michelle Heys

Reviewer’s report:

Second review:
I thank the authors for addressing the comments from the review.
I feel additional clarification is needed on the sample size/power of the proposed main RCT and the pilot study to address the following:

Major compulsory revisions:
1. As I understand it when you conducted baseline screening of the neonatal units and identified 775 infants who received INO for NHRF – with around a third experiencing a suboptimal response – suggests 250 infants. Can you comment on why in 6 months only 46 were screened?
2. What power does the sample size of 149 per arm give you to detect what % difference in your need for ECMO or death outcome at what p-value? How does this vary with the pilot size of 50 per arm? It needs to be really clear to the reader what the probability of a false positive or negative would be with these sample sizes.
3. Please also comment on the power of your pilot (n=50) to detect your secondary outcomes – including correction for multiple testing. I suspect you are significantly underpowered and it is again important to be clear on this.

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