Author's response to reviews

Title: A randomised clinical trial of intrapartum fetal monitoring with computer analysis and alerts versus previously available monitoring

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Reviewer comment 1.
I do not accept the justification for the choice of primary outcome. The fact that other studies used the cord pH measurements in the past does not make it right. The fact the clinically more meaningful outcomes may require bigger sample size is precisely my point. In any case, there are better alternatives (low Apgar score at 5 minutes, for example) as it is less likely that this outcome will not be available for ALL randomised women.

Answer: The study protocol, as in the original manuscript submitted to the journal, has now been approved by the Cambridgeshire 1 Research Ethics Committee and by the financing bodies, aspects that did not occur at the time of first submission. We are therefore at difficulty to alter, at this stage, such important aspects as the primary outcome measure and the pilot analysis performed at 1500 cases, to re-evaluate sample size. We understand the reasons behind Prof. Alfirevic’s suggestion to adopt a primary outcome that will be more easily available in all cases than metabolic acidosis, but these alternatives have many other disadvantages, as they are much less related to intrapartum hypoxia, the main focus of intrapartum monitoring. Low Apgar scores, neonatal encephalopathy, and perinatal mortality have many other causes besides intrapartum hypoxia, so it is unlikely that intrapartum monitoring will be able to affect these outcomes, except perhaps in a very large study, which has not been attempted before, and which meta-analysis of individual RCTs has not been able to demonstrate.
Reviewer comment 2.
Also the rationale for a pilot analysis after 1,500 women and how this may impact on the rest of the trial and what is the role of DMC in this analysis remains unclear.

Answer: The number of patients in this pilot analysis was chosen arbitrarily, based on the experience of other RCTs in intrapartum monitoring. This analysis will allow an evaluation of the incidence of metabolic acidosis in the study population, and a re-calculation of the study's sample size, if necessary. The Independent Data Monitoring Committee will evaluate the incidence of adverse outcomes in both study groups at regular intervals (every 3 months) and may decide to discontinue the study at any time, if there is justification for this.