Reviewer's report

Title: Compliance and mothers’ perception of withholding breastfeeding during rotavirus vaccination in North India: a randomized clinical trial

Version: 2 Date: 4 April 2014

Reviewer: Audrey Prost

Reviewer's report:

We sincerely apologise to the authors for the delay in finding suitable reviewers for their article.

The question posed by the authors is well defined and the study provides new, robust evidence on the acceptability of withholding breastmilk 30 minutes before and after rotavirus administration, which is an important finding if this practice is confirmed to enhance rotavirus efficacy.

The methods are appropriate, but there is a lack of reporting of any sample size calculation. Though this does not affect the credibility of the findings are quite unequivocal, it would be good to know how the authors had selected the sample size of n=200 in each group and what the assumed differences between groups were.

The data are well controlled and the manuscript adheres to the relevant standards for reporting and data deposition, though the trial profile figure could be improved.

The discussion is well balanced, but the conclusion reads much like an extension of the discussion, raising new issues to explore in further research, rather than a bona fide summative conclusion.

It would be useful to share the manuscript with a native English speaker to correct minor syntax errors. Some of them are identified below, in discretionary revisions.

Minor essential revisions:

1. Title:

Please consider modifying the title to more accurately reflect the study and its results. We suggest:

Mothers’ compliance following health worker recommendations to breastfeed or withhold breastmilk during rotavirus vaccination in North India: a randomized clinical trial

2. Methods
Please report any sample size calculations conducted prior to this study, or, if the sample size was based on that of the original trial, please specify this.

3. Enrolment and intervention delivery

3.1 Please specify who gave the recommendations to mothers and whether these were the same cadre of staff in both groups.

3.2 Please give the exact content of each of the two recommendations, including the rationale given to mothers for withholding breastfeeding or breastfeeding immediately after vaccine administration. This is important for readers to understand which factors secured compliance. The discussion argues that mothers will follow any recommendations as long as they think they are doing the right thing for their infant. How was this explained in the intervention process?

4. Data collection

Please describe the observation process. Where were the observer located and could they be seen by the mothers? This might have influenced compliance and needs to be reported.

5. Conclusion

Please consider making the conclusion a summary of the findings and moving some of the reflections that are currently in it to the discussion section.

Discretionary revisions

6. Abstract

Background: Insert a full stop after the second sentence.

7. Methods

Enrolment:

“Infants were enrolled if parents gave consent for participation, was aged 6-7 weeks, weight for age was not <-3 Z scores (WHO 2006) and”

should be

“Infants were enrolled if parents gave consent for participation, were aged 6-7 weeks, weight for age was not <-3 Z scores (WHO 2006) and”

8. Trial profile

The labelling of this profile is slightly confusing. The intervention labels should read ‘Recommendation 1: withholding breastfeeding’ and ‘Recommendation 2: breastfeeding encouraged’.

Yours Sincerely,

Dr Audrey Prost
Level of interest: An article of importance in its field

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.

Declaration of competing interests:

I declare that I have no competing interest.