

Reviewer's report

Title: Active management of the third stage of labour without controlled cord traction: a randomized non-inferiority controlled trial

Version: 1 **Date:** 2 January 2009

Reviewer: Olufemi Taiwo Oladapo

Reviewer's report:

General

This is the protocol of a randomized trial that addresses an important topic within the context of the fifth MDG considering the need to extend low technology interventions to peripheral maternity units around the world. The protocol is well written and the trial is well designed to achieve the set out objectives.

1. Is the question posed by the authors new and well defined?

Yes, the posed question is new and well defined.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?

Yes, the methodology is appropriate and provides sufficient details necessary for replication of the work. The rationale for the trial design is also adequately addressed by the authors.

3. Are the data sound and well controlled?

This is a study protocol and no data is available yet. However, the listed outcomes are appropriate and the data collection methods are feasible and appropriate.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?

Yes, the standards for preparing study protocol were adhered to.

5. Are the discussion and conclusions well balanced and adequately supported by the data?

Not applicable

6. Do the title and abstract accurately convey what has been found? The title appears appropriate.

7. Is the writing acceptable?

Yes.

- Major Compulsory Revisions (which the author must respond to before a decision on publication can be reached)

None.

- Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct).

Background

4th Paragraph: Should be rephrased to allow readers to understand the 'technical consultation' that is being referred to.

CCT

It would be nice to describe (if known) the basis for the introduction of CCT into obstetric practice in the first place so as to express the plausibility of obtaining a result comparable to that of full AMTSL package. For instance, it is unlikely that anyone would think of excluding administration of prophylactic uterotonic in an attempt to simplify AMTSL package in view of the known physiological action of oxytocin. Does CCT have a similar underlying reason why it is essential in the first place? because if not, it makes it easy to appreciate why its absence wouldn't really be missed.

2.1.3 Uterine massage: Provide reference for POPPHI surveys.

Methods

4.11:

It might be nice to be specific about the timing for uterotonic administration- 'soon after birth' may be interpreted differently by investigators. If not, it might be necessary to document the time of administration such that appropriate corrections can be made during analysis if need be.

4.2: Please define "use of additional uterotonics"

4.3: Exclusion criteria: What about women already on oxytocin drip for augmentation and those who continue the drip after delivery? Are they going to be excluded?

4.4.3 Typographical error – 2nd to the last line. 5th paragraph (please write sPPH in full).

Interim analysis: write GCP in full.

References:

No. 1 & 11 are the same. I think the journal citation published by ICM/FIGO may be better than the internet communications being cited.

No. 9 is incomplete.

No. 10: format of the journal name not consistent with others.

No. 13: the book needs to be referenced as appropriate.

No. 14: The published review is now available.

- Discretionary Revisions (which are recommendations for improvement but which the author can choose to ignore).

None

Level of interest: An exceptional article

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests