Reviewer's report

Title: Effect of maternal vitamin D3 supplementation on maternal health, birth outcomes, and infant growth among HIV-infected Tanzanian pregnant women: study protocol for a randomized controlled trial

Version: 0 Date: 07 Jul 2017

Reviewer: Jean Joel R Bigna

Reviewer's report:

Sudfeld and colleagues reported on a RCT protocol that aimed at determining the effect of adding vitamin to antiretroviral therapy on maternal and infants health. The trial recruitment and follow-up of participants are ongoing; meaning any comment by reviewers would not modified the trial procedure. The manuscript is well written and I have only some suggestions for the improvement of the paper. Below are my comments.

Major comments

1) Page 5. Background. For the paragraph on the effect of the vitamin D on pregnancy neonatal outcomes, authors SHOULD cite and comment a systematic review and meta-analysis that included 13 studies.

2) Study population
For the Inclusion criteria d), it is reported from some places in Africa that women doesn't know their last menstrual period. Since the recruitment is ongoing, how do clinical investigators to determine the gestational age of the pregnancy?

3) Screening and Randomization
Page 9. Lines 238-240. What was/will be done in the case of undetermined/inconclusive results after the two rapid HIV testing? Please, give details.

4) It would be interesting if investigators also stratified randomized by WHO HIV stage (clinical profile) or initial viral load (virological profile); since the rationale for using vitamin D is based on immunological response in the presence of low/high vitamin D concentration. Initial profile may be source of heterogeneity on the effect of vitamin D on outcomes. I suggest that this heterogeneity be investigated during statistical analysis.
Minor comments

5) Study population. Please correct the second "(d)" to "(e)" …

6) Authors can remove all "(n)" in the figure since this is the protocol.

Discretionary revisions

7) I suggest to authors to add some sentences on dissemination plan.

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