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: 19 Jul 2017

Reviewer: Sowmyanarayanan Thuppal

Reviewer's report:

The manuscript describes the protocol of a blinded randomized control study to understand the effect of maternal vitamin D supplementation on maternal and infant outcomes among HIV-infected Tanzanian pregnant women. The manuscript is very well written and covers all the aspects of a RCT. The results of the study will answer important questions about prenatal vitamin D supplementation in women living with HIV. I have a few minor suggestions/comments for the authors.

1. In page 10/line 256 of the manuscript it is mentioned that randomization will be stratified by study clinics. How many study clinics will be there? Are the study clinic different from HIV clinic? Will the enrollment take place at the HIV clinic and follow-up will happen at study clinic? Where will the delivery take place? If you are using multiple study clinics then how are the clinics selected. Will you train all the staff in the clinics to have consistent methods for data collection? Please provide more information so the readers can understand how the data collection is managed.

2. Are the house visits done by field workers? How are they trained and how frequently? Is there any mechanism in place to check for the accuracy of data collection?

3. Is there any provision in the statistical analysis to account for multiple study clinics and multiple testing?

4. Though the content of placebo is generally known, it is advisable to mention it clearly in the manuscript instead of just mentioning that it is identical to the drug.

5. Does the study provide any compensation to the participants?

6. How frequently does the study plan to provide information about AE and SAE to the DSMB? Will it be provided within the first 24 hours? Is there any specific reason for the DSMB to meet only at 6 months and not earlier?

Level of interest
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An article of importance in its field
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Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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