Reviewer's report

Title: Nevirapine versus Efavirenz-based highly active antiretroviral therapy regimens in antiretroviral-naive patients with HIV and Tuberculosis infection in India: A Randomized Control Trial.

Version: 2 Date: 12 May 2013

Reviewer: Weerawat Manosuthi

Reviewer's report:

The authors aimed to compare two first-line NNRTI-based ARV regimens in the patients who had HIV and TB co-infection. Overall, this study is important in its field but there are a number of issues need to clarify. Please find my comments as below.

Major comments
1. The authors claimed that this study was a non-inferiority RCT but the rationale to calculate sample size was not stated. How many patients do need to enroll? In addition, the authors stated that sample size calculation was not planned due to being a pilot study. If so, “non-inferiority RCT” is not an appropriate study design of this study. Ultimately, only 48 patients and 52 patients continued to completed treatment. What is the remaining of power of test? Please clarify and revise.

2. This study aimed to examine safety and efficacy with the outcomes of clinical progression, Immunological and virological responses, mortality, and drug toxicity. Which one is the primary outcome or secondary outcomes of the study? In addition, a composite endpoint of unfavorable outcome was shown in the result section and was discussed in the discussion section without describing in the method section.

3. Day 180 of measuring nevirapine concentration should be the time point that most of the patients discontinued rifampicin. Please give more data of nevirapine concentrations between those who did/did not receive rifampicin.

Minor comments
1. I suggest to shortening the background section of abstract and give more details on the results instead.

2. In the result section of manuscript, the authors stated “No correlation was found between plasma levels of nevirapine and incidence of unfavourable outcomes in this group.” Please give more details and P value.

3. Figure 3: I do not agree to present x-axis as number of viral copies because it is not an ordinal scale. It should be changed to log scale. However, it would be much better to present as the proportion of patients with undetectable viral load at each time point.

4. Figure 1: This schematic is not justified because the screening process of this
study did start with HIV and TB co-infected patients, not 1469 HIV mono-infected patients.

5. Please discuss more on the reason why gave 2-week lead-in nevirapine strategy in the study patients who received rifampicin even if results of day 14 nevirapine concentration of previous studies and also the present study were low.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**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 interests.