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: 26 May 2013

Reviewer: Damalie Nakanjako

Reviewer’s report:

Reviewers report

Manuscript:

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

This is an important study to support the therapeutic options for the treatment of TB/HIV co-infections with rifampicin in the setting of NNRTI-based HAART, given that rifabutin may not be logistically feasible in resource-limited settings.

Minor essential revisions

Abstract

In the abstract as well as the entire paper HAART is used inter-changed with HAART. I suggest that the authors choose one and use it consistently.

In the methods section, the primary outcomes are all-cause mortality and HAART treatment failure. The time is not specified. Is it 6, 12, 24 moths or just at 24 months?

Anti-tuberculosis is interchanged with anti-tubercular treatment (ATT). The authors need to choose one of these and use it consistently through the document. In addition, once the abbreviation has been written in full, then it can be used subsequently in the document.

Methods

Second sentence; .......were enrolled as cases. The reader may start looking out for controls. So the word cases is not required; they could be refered to as study participants.

Under the paragraph on initial evaluation, BMI is given as an abbreviation for basal metabolic rate, yet it is later used as body mass index (last sentence in the results section). The authors need to clarify which one they wanted to refer to and use it consistently.

Under the subheading treatment; the second last sentence shows that patients on nevirapine were advised to take it at 9am and 9pm. The next sentence does not talk about the time that was advised for efavirenz. Was there any time
advised for efavirenz? The second and 3rd last sentence in this section could be modified to avoid the repetitions for example CD4 counts and viral loads were done at 0, 6, 12 and 24 months after HAART.

Compulsory changes

Methods section:

Details of randomisation should be provided to show clearly how patients were selected and who assigned the treatment arms.

It is not clear when the treatment arms were assigned; at the start of anti-tuberculosis treatment or at the start of HAART.

Under the subheading definitions; successful treatment; it is not defined yet it appears as an outcome at 6 months in Table 2. Does this refer to completion of TB treatment or TB cure or initiation of both TB and HAART treatment?

Under the subheading follow-up, last sentence: trough nevirapine concentrations ........... it is not mentioned how many patients received these measurements. If it is all then it should still be mentioned.

Statistical analysis

Third sentence; this is the first time it is mentioned that this study was a pilot study. If so why was this a pilot study?

Several aspects of the analysis done were not described in the analysis section for example

How combined incidence of ART failure was calculated and how the rates of clinical failure were analyzed and compared.

Results section:

The flow chart should include a level to show how many patients were eligible for the study i.e patients with CD4 200 cells and below then out of these they should indicate those that were excluded (for the reasons given).

Figures 2-4 should have a foot note summarizing what the figure shows.

Discussion

Paragraph 4: Our study found a favorable response in terms of cure and treatment completion rates. These variables/outcomes are not defined in the methods (see comment in methods) as well as in the statistics section it is not clear how these were calculated.

**Level of interest:** An article whose findings are important to those with closely related research interests

**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.