Reviewer's report

Title: Early versus delayed initiation of antiretroviral therapy for Indian HIV-infected individuals with tuberculosis on antituberculosis treatment

Version: 4 Date: 22 March 2012

Reviewer: Naimish Patel

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Major Compulsory Revisions:

Methods:
The authors state that ART could be started at any other suitable time at discretion of the care providers. Only those patients who satisfied the protocol were followed as part of the study”. This would suggested that the analysis presented was not “intention to treat” as subjects who did not adhere to protocol were not followed. – Is this correct? Elsewhere in the under “Statistical Methods” it says analysis was performed according to intention to treat, but these seems not to be true. Please clarify.

Under sample size – 75 patients per arm were chosen – how was this number picked? Why not 50 or 100? Also a power calculation should be provided for the 75 subjects to determine what was the power to detect a difference in the primary outcome of interest between the two groups if there are 75 subjects per arm.

Results:

It is unclear why the trial results are presented before all subjects have completed the 12 months (only 118 out of 150).

It’s is also unclear why more subjects were randomized to early (64) rather than late (54) treatment – why isn’t there equal randomization?

On page 10, it says 4 patients in the early ART arm will complete their courses in Feb 2011. – Shouldn’t they have completed already?

Under baseline data – category I versus category II ATT needs to be defined.

IRIS classically occurs 4-6 weeks after ART initiation. IRIS in this study seems to have occurred at 10weeks – any explanation for this?

The specific therapy for IRIS should be mentioned as this could impact outcomes in the trial.

Discussion:

There is no significant difference in mortality between two groups. Is this because the study is underpowered? – power calculation should be provided and this
point discussed.

Minor Revisions:

In the second paragraph and third paragraph of Discussion is somewhat confusing. Instead of saying “this study”, the study by Sinha, et al can be referred to as “the current study” or “our study” as this would be clearer as to what study is being discussed.

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

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have no competing interests.