Reviewer's report

Title: Effects of highly active antiretroviral therapy with Nelfinavir in vertically HIV-1 infected children: 3 years of follow-up

Version: 2 Date: 28 June 2006

Reviewer: FRANCOIS DABIS

Reviewer's report:

General

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1) Methods: does the definition e) of therapeutic failure mean "stop HAART" or "stop NFV" only?
2) Methods: the authors should indicate for which specific analysis they used logistic regression or Cox regression: "virological or therapeutic failure" and "treatment failure" are not clear enough.
3) Results: The authors did not specify if there were children lost of follow-up, although it is important, particularly for the analysis at fixed endpoints (12 or 24 weeks).
4) Results: "virological and immunological response", Figure 2B: the authors should specify if N=28?. 17/28 children (60%) had a rebound of VL but on the figure it seems it is 80%.
5) Results, "therapeutic failure": Does "when these 3 criteria were used" mean the 3 criteria were combined or used separately?
6) Results, "therapeutic failure": it is not clear if endpoints at fixed-time or not are used. It would have been interesting to know the reasons for changing or stopping HAART with NFV.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

1) Results: Figure 1C would have been easier to read if it was a stacked bar chart.
2) Results, "virological and immunological response": the Cox regression is interesting to predict uVL, but it would have been good to see a table such as the following to better grasp the model findings: Univariate regression Multivariate regression
   Baseline variables HR 95%CI P-value HR 95%CI P-value
   % CD4
   VL continuous
dichotomous
   Age
   Previous HAART
   New ARV in the HAART regimen
3) Results, "therapeutic failure": again, a table would have also facilitated the reading of the results.
4) Figure 2F: legend is not clear: "Stopping" looks only for "HAART with NFV" whereas "Changing" should be more appropriate for "First line on HAART"
5) Results, "Clinical events": at what time of follow-up did the death and the AIDS cases occur?
6) In the text, the labelling/numbering of the Figures 2 are wrong.

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field
Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:
'I declare that I have no competing interests'