Reviewer's report

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

Version: 1 Date: 28 April 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)

Resino et al. present the results of a multicenter prospective cohort study including 42 vertically HIV-infected children on HAART with NFV, recruited between May 1997 and to October 2001, followed-up until October 2004 in five Spanish hospitals.

Introduction:
- What does it mean that nelfinavir is a selective HIV-1 PI?
- The authors does not develop every acronym at least once (ex PI) and does not use the same acronym to designate the same thing are not systematic with the use of acronyms (e.g. ex ART and HAART).
- The authors does not explain why it is a challenge to give it twice daily and what is the usual prescription.
- The objective should be more clearly stated: â€œto evaluate the useâ€ is too vague. These objectives seem to be:
o to describe virological and immunological response
o to assess the association between baseline characteristics and virological or therapeutical failure.

Methods
- BID (as per prescription is announced in the introduction) or whereas TID (as per Methods) prescription is conducted, this is not clear.
- The authors does not justifyied the inclusion criteria: are they criteria to prescribe NFV in the hospitals or criteria to be included in the study? Is this sample exhaustive of the children followed-up in the hospitals?
- The authors does not specify if a standardized form was used for clinical records among the five hospitals.
- Virological and therapeutical failures were not clearly distinguished in the definitions and clinical events were not announced in the methods whereas they are described in the results. Statistical significance is specified but no any p-value appears in the results section.
- It is not clear why the authors performed a logistic regression analysis: Cox regression analysis and HR should be enough and have better value more adequate to assess the association between baseline characteristics and virological or therapeutical failure.
- The authors does not specifyed if univariate and multivariate analyses are performed.

Results
- The sentence â€œ28/42 of children had new NRTI in first line of HAARTâ€ is not clear. Do the authors mean alt seems it designates novel NRTI?!
- The number of children who did not met inclusion criteria and the reasons for exclusion should be specified.
- The median time of follow-up is not specified.
- A survival analysis using Cox regression only could be used within this study, the use of logistic regression is not clear, and HR values does not appar
- One or two tables with the results of the univariate analysis and those of the last multivariale model, for virological failure and therapeutic failure should have been usefullwelcome.
- One or two particularly most relevant figures may be sufficientenough to illustrate the results
- The description of measurements of adherence should be in the method section, and â€œheightâ€ should be quantified.

Discussion was not difficult to review ed considering due to the importance of previous the comments on the
previous sections. Recent references could be taken into account in terms of methodology of analysis and results. The English style will need to be improved.

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)

What next?: Reject because scientifically unsound

Level of interest: An article of limited interest

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: No

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