Author's response to reviews

Title: Study protocol: safety and efficacy of propranolol in newborns with Retinopathy of Prematurity (PROP-ROP)

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Author's response to reviews: see over
To the Editor of

BMC Pediatrics

Florence, October 19, 2010

Dear Editor,

we hereby submit the revised version of the paper “Study protocol: safety and efficacy of propranolol in newborns with Retinopathy of Prematurity (PROP-ROP)” by Luca Filippi et al. We definitely appreciated the referees’ suggestions and amended the manuscript accordingly. Point by point responses to the reviewers’ comment are listed below.

REPLY TO REVIEWER #1:

You wrote: “… Please write a plan for data analysis. What specific data will be obtained and how will it be analysed. A statistician's consultation will be helpful”.

As you suggested, we added the “Experimental plan and data analysis” paragraph (from page 14, line 21 to page 15, line 22).

You wrote: “… What is the maximum duration of exposure of the baby to the study drug. An upper limit should be incorporated”.

As you suggested, we added the following sentence: “… although this administration can not last more than 90 days” (page 18, lines 7-8).

You wrote: “… What are the criteria to stop the participation of the infants in the study”.

We added the paragraph “Stop criteria” with the following sentence, according to your suggestion: “The study could be stopped if severe hypotension, bradycardia or bronchospasm develops, and the opportunity to reduce the dose of propranolol may be considered” (page 17, lines 3-5).

You wrote: “… Exclusion criteria should include failure to thrive”.

Among the exclusion criteria we added “failure to thrive”, as you suggested (page 16, line 22)

You wrote: “… Propranolol in healthy adults has been shown to have significant effect on whole body protein metabolism, i.e. increased protein turnover and oxidation. This
can lead to excessive protein catabolism and failure to accrete protein and gain excessive fat. The authors should incorporate some measures to monitor for these potential side effects”.

We added in the text: “… urea plasma levels will be compared to evaluate the effect of propranolol on whole body protein metabolism” (page 19, lines 4-5).

You wrote: “… Needs some language corrections before being published”.

The manuscript has been reviewed by a native English speaking person.

The manuscript has been reformatted to ensure accordance to the journal style

Thank you for your attention to our paper.

Yours sincerely,

Dr. Luca Filippi