Author's response to reviews

Title: Hypoxia and Outcome Prediction in Early-Stage Coma (Project HOPE): An Observational Prospective Cohort Study

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Dear editorial team,

as requested per Email by Jhonell De Los Santos on 6 April 2015. I would like to clarify the following points:

1. Ethical and Funding Approval Documentation: We sent today to BMCSeriesEditorial@biomedcentral.com original German documentation on ethical and funding approval. Since these documents are not in English we requested the institutions that granted such approval to provide us with confirmation letters signed by a contactable person. We sent these documents in English together with original German documentation per Email today (8 April 2015).

2. Funding: Our study is being funded by the Else-Kroener-Fresenius Stiftung, a charitable organization. The study protocol was sent for external peer-review by the Else-Kroener-Fresenius Stiftung prior to approval of funding.

3. Study Status: Our study is ongoing. We are still collecting data.

4. Related Articles: Since we still do not have enough data to warrant publication we have not published any paper related to this study yet.

As for changes to the manuscript, we just added the word "ongoing" to the abstract and the the methods section to describe the study and the word "observational" in the discussion.

Please find below a copy of the cover letter we sent you earlier with some modifications based on your requests:

We are submitting for publication the study protocol of the ongoing observational prospective cohort study "Hypoxia and Outcome Prediction in Early-Stage Coma (Project HOPE)". Project HOPE was approved by the Ethics Commission of the University of Munich and receives funding from the Else Kroener-Fresenius Foundation. The study is still in the data collection phase and there are not publications containing results from this study. Although it is an observational study we registered it at ClinicalTrials.Gov (NCT02231060 on 29 August 2014) for the sake of transparency. To our best knowledge HOPE is the first multicentre
prospective cohort study on coma prognosis to control for the effect of a possible self-fulfilling prophecy at the ICU and to cover the acute and neurorehabilitation phases with a long-term follow-up longer than the usual three or six months. We strongly believe that we will be able to make a significant contribution with HOPE to the revision and improvement of current outcome prediction methods in anoxic-ischemic encephalopathy (AIE) patients. As a result, neurocritical care specialists worldwide will have considerably more accurate methods for prognosticating the outcome of AIE following cardiac arrest. This will facilitate the provision of treatment tailored to individual patients and the attainment of an optimal QOL. It will also inform the decision to withdraw treatment with a level of accuracy never seen before in the field. Project HOPE was approved by the ethics commission of the University of Munich and currently receives funding from the Else-Kröner-Fresenius Stiftung, a charitable foundation. Funding was awarded following a peer-review process. We have sent documentation relevant to ethical and funding approval per Email to BMCSeriesEditorial@biomedcentral.

Yours faithfully,

Alex Lopez-Rolon and Andreas Bender