Author's response to reviews

Title: Statistical analysis plan for erythropoietin in traumatic brain injury (EPO-TBI): a randomised controlled trial

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Editor
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Re: Erythropoietin in Traumatic Brain Injury (EPO-TBI) Statistical Analysis Plan manuscript

Dear Sir / Madam

I am pleased to enclose the statistical analysis plan (SAP) manuscript dated 23rd September 2014 for the above trial for your consideration.

We propose the manuscript is published because the trial is the largest multicentre, international, phase III trial of erythropoietin in the critically ill traumatic brain injury population. It is important to publish the SAP to minimize bias and to place in the public domain the principles and methods for analysing and reporting the trial results before research data is finalised.

Traumatic brain injury is a common and devastating condition with few proven, specific therapies available. Erythropoietin has recently emerged as a very promising agent to attenuate such injury. The administration of erythropoietin has the potential to reduce neurological damage and improve neurological outcome, and is supported by a scientific rationale and laboratory data. The EPO-TBI design aims to maximise the ability to detect a beneficial effect, if one exists, between erythropoietin and improved neurological function while minimising thrombotic risk after traumatic brain injury.

EPO-TBI aims to provide definitive guidance for clinicians regarding the true efficacy and safety of erythropoietin in the management of traumatic brain injury. EPO-TBI
aims to provide definitive guidance for clinicians regarding the true efficacy and safety of erythropoietin in the management of traumatic brain injury.

The authors declare that they have no competing interests.

We suggest Professor Andrew IR Mass (andrew.maas@uza.be) and Professor Paul C. Hébert (phebert@ohri.ca) as peer reviewers. These potential peer reviewers meet the criteria set out in the Trials Journal instruction for authors section.

Thank you for your consideration.

Kind regards

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