Author's response to reviews

Title: Central Nervous System Stimulants for Secondary Attention Deficit-Hyperactivity Disorder after Paediatric Traumatic Brain Injury: A Rationale and Protocol for Single Patient (N-of-1) Multiple Cross-Over Trials

Authors:

Hugh EJ Senior (h.senior@uq.edu.au)
Lynne McKinlay (lynne_mckinlay@health.qld.gov.au)
Jane Nikles (uinikkle@uq.edu.au)
Philip J Schluter (philip.schluter@canterbury.ac.nz)
Sue Ann Carmont (s.carmont@uq.edu.au)
Mary Clare Waugh (MaryW@chw.edu.au)
Adrienne Epps (adrienne.epps@sesiahs.health.nsw.gov.au)
Owen Lloyd (Owen_Lloyd@health.qld.gov.au)
Geoffrey K Mitchell (g.mitchell@uq.edu.au)

Version: 3 Date: 22 May 2013

Author's response to reviews: see over
Dear Editors,


We believe you should consider the manuscript as it is describing the use of aggregated n-of-1 trial methodology and analysis by Bayesian statistics in pediatrics. Further, it is a study designed to provide evidence on therapy of secondary Attention Deficit-Hyperactivity disorder in Children with an acquired brain injury. N-of-1 methodology is appropriate to the study design as this population is difficult to recruit. N-of-1 trials allow a smaller sample size than a traditional RCT while maintaining statistical power and controlling for confounding. We are hopeful that this protocol will be of interest to your readers.

All authors have reviewed and approved the manuscript, as well as contributed to its content. No authors have any potential competing interests.

The study is externally funded by the Children’s Health Foundation Queensland and underwent extensive peer-review, and by the Motor Accident Insurance Commission (MAIC) of Queensland. I have uploaded the funding letter from the Children’s Health Foundation Queensland and the contract between the hospital and MAIC for the additional funding.

We have ethics approval from (i) University of Queensland Medical Research Ethics Committee (ii) Royal Children’s Hospital and Health Service District Ethics Committee, Queensland Health; (iii) The University of Sydney and Health Service District Ethics Committee, HREC, Sydney prior to study commencement.

Approval was also obtained from Education Regulatory Authorities in Queensland and Archdiocese of Brisbane, NSW.

There are no other manuscripts under submission with other journals based on this study protocol.

The trial is registered with the Australian New Zealand Clinical Trials Registry

ACTRN The Trial Registration 12609000873224

The trial complies with Consort Guidelines for Trials.
I have ensured that the revised manuscript conforms to the journal style

Thank you for considering this manuscript and please let me know if you require any further information.

Sincerely,
On behalf of my co-authors

Hugh Senior PhD