Author's response to reviews

Title: A pragmatic multi-centre randomised controlled trial of fluid loading and level of dependency in high-risk surgical patients undergoing major elective surgery: trial protocol.

Authors:

Brian H Cuthbertson (brian.cuthbertson@sunnybrook.ca)
Marion Campbell (m.k.campbell@abdn.ac.uk)
Stephen Stott (sstott@nhs.net)
Luke Vale (l.vale@abdn.ac.uk)
John Norrie (johnn@stats.gla.ac.uk)
John Kinsella (j.kinsella@clinmed.gla.ac.uk)
Julie Brittenden (j.brittenden@abdn.ac.uk)
Adrian Grant (a.grant@abdn.ac.uk)
Jonathan cook (j.a.cook@abdn.ac.uk)

Version: 2 Date: 1 April 2010

Author's response to reviews:

30th March 2010

Dear Editor

Many thanks for the opportunity to reply to these helpful reviewers comments.

In answer to these comments-

Comment a) A figure showing the number expected to be screened, eligible, randomized at each stage, and analyzed for each of the hypotheses would be helpful. This is particularly so because although the first paragraph under Data Analysis states that “analyses will be based on all people randomised,” the Abstract and the first paragraph under Sample Size suggests otherwise. Clarification of these apparent discrepancies would also be useful.

Reply to comment a) We apologise for the lack of clarity on this point. We will use the intention to treat principle in our analysis but since we expect that patients will be lost to follow up for the 6 month outcome (and have allowed for this loss in the study recruitment) we identify that not all patients will have data available for the second co-primary outcome (6 month cost-effectiveness). We have clarified this in the text. A trial patient pathway is now presented in table 1.

b) A table listing the inclusion criteria would be preferable than simply citing reference 10.

Reply to comment a) These criteria have been added to the paper thank you
c) Because the trial is not blinded, what efforts are being made to be confident that outcome assessments, use of concomitant therapy, timing of hospital discharge, and other key measurements are not biased?

Reply to comment a) Extensive comment has been added to page 8 thank you

d) A minor issue: pagination would be helpful.

Reply to comment a) This has been added thank you

Yours sincerely

Professor Brian Cuthbertson, Chief Investigator