Reviewer’s report

Title: The use of LiDCO based fluid management in patients undergoing hip fracture surgery under spinal anaesthesia: Neck of femur optimisation therapy - targeted stroke volume (NOTTS)

Version: 2 Date: 5 September 2011

Reviewer: Charlie Goldsmith

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For the most part the replies to the issues provided in the last review have been handled well. However, the issue of stratification has still not been properly handled in the analysis sections and the fact that the authors do not plan to do an Intent To treat Analysis should be cited in the paper. Suggestions as to how to handle these and several other editorial suggestions are provided next.

1. P(age) 2, p(aragraph) 1, l 3. The figure [23.5] does not correspond to to the [26] listed on P 3, p 1, l 4. Should these not be the same?

2. P 5, p 3, l 3 to 5. The new text should be changed to what is intended and the order of the process. Here is a suggested rewording: [To achieve similar numbers and balance on risk, patients will be stratified according to predicted 30-day mortality (2 levels).] Stratification on one factor does not guarantee equal numbers unless blocking is employed and this happens for the risk score and not necessarily other covariates. If approximate balance is need on the other covariates they need to be stratified as well.


4. P 9, p 6, l 4. Suggest inserting [using the stratification risk categories] after [ANOVA]. Thus ANOVA will for the adjustment of the stratification factor, that is necessary since it is a constraint on the randomization. If the stratification does not change the results of the study conclusions, then it may also be reported as such as well as the simpler analysis.

5. P 9, p 6, l 5 to 8. Consider deleting the sentence: [This is ... ANOVA.] since it duplicates much of what is said in previous lines.

6. P 10, p 2. Again, the stratification should be used in the analyzes reported here and will involve more than an elementary use of Fisher’s exact test and Chi-square and the Cox model. Software such as StatXact or LogXact may be needed instead of SPSS.

7. P 10, p 2, l 5. Suggest including [time dependent] between [for] and [covariates].

8. P 10, p 3, l 1. Delete [appropriate] since you have not stated which you will use and there is no guarantee what you use will be appropriate. This will depend on the data and their properties that may not be known until the analyzes are completed.
9. P 10, p 4, l 2 and 3. Suggest replacing [trends towards] by [approaches] since a trend is a straight line function in time, and you do need to have it to be that.

10. P 10, p 5, l 3. Replace [p = 0.05] by [alpha = 0.05]. Since p depends on your data, it is still not known. You may be able to use a Greek symbol for alpha; however, various versions of word processing software sometimes change this to an octothorpe, or sharp sign during conversion.

11. P 10, last heading. Suggest changing [populations] to [data sets]. You will not have any populations here; at best they are samples.

12. P 11, p 1, l 5. Since you have not defined the Intention-To-Treat data set, suggest adding at the end of the line: [; not the Intervention-To-Treat set.]. Neither of the full analysis nor the per protocol set will necessarily be statistically valid for efficacy as they may not contain all the patients randomized.

13. P 13, 14 and 16. The R(eferences) 4, 38 and 39 use a different date notation than you introduced on P 11, p 5. To rectify this why not change [08] to [Aug] in each case.

14. P 14, R 5. Suggest including the last access date here as well. Also P 16, R 41.

15. P 16, R 37, l 1. Is [Payment by Results] listed twice in the title?

16. P 17, right hand box, l 1. Suggest rewriting as [< 10], ie, adding a space.