Reviewer's report

Title: Update of the Preventive Antibiotics in Stroke Study (PASS): Statistical Analysis Plan

Version: 2
Date: 11 August 2014

Reviewer: Nuria MH Perez-Alvarez

Reviewer's report:

The authors present a detailed and exhaustive statistical plan analysis. In the following I describe some changes that can improve this work.

Major Compulsory Revisions
1 (page 5) Statistical analysis plan-Handling of missing data
The LOCF method introduces bias in the results. It is wrong to apply it. Please, rethink this subsection.
You can check www.missingdata.org.uk
Concretely,

Minor Essential Revisions
1 (page 3) Summary study protocol:
The method to perform the randomization can be detailed: Is it based on a uniform distribution? How do you perform the stratification?

2 (page 9) Analysis of primary outcome
I understand the change in the method of analysis for the primary endpoint, but why to perform both (ordinal and logistic regression)? Do yo plan to compare the results obtained using these 2 methods?
If no comparison is planned I do not see the need to perform both.

3 (page 9) Analysis of primary outcome
What are you going to do if any of the categories in the primary outcome has a low number of individuals and it is not "representative"?

Discretionary Revisions
1 Consider include an statistician in the work team to design the statistical analysis plan, and also in the co-authors list.

2 (page 10)
The list of Subgroup analysis of primary and secondary outcomes is quite open, I would suggest a clearer and shorter list.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests