Reviewer's report

Title: Quality of reporting of non-inferiority and equivalence randomised trials - update and extension

Version: 2 Date: 16 September 2012

Reviewer: Jordi Ocana

Reviewer's report:

Major Compulsory Revisions:
The paper is interesting and well written, but possibly it suffers from an initial bias in the election of the population of citations under study. This bias should be corrected, or clearly justified and reflected in the paper. In my opinion, the bias comes from the exclusion of bioequivalence (BE) trials. They are equivalence randomized trials whose primary goal is research in healthcare. I can’t see any reason to exclude BE trials. They are fully in the scope of the paper, and CONSORT statement fully applies to them. If BE trials were considered, the main consequence would be a significant increase in the proportion of crossover trials. In my opinion, the authors should follow one of the following two strategies in order to clarify the question posed in the paper, to provide sufficient details and to make data sound and well controlled:

1) To include BE trials. Then obviously many the figures and tables would need some correction, although the main conclusions will remain essentially the same. Admittedly, this is more a problem of CONSORT incompleteness than a problem of the paper, but the discussion should be completed with some consideration for the need of an extension of the CONSORT statement to crossover trials, a significant proportion of equivalence trials (if BE trials were included). The main issues to be considered would be washout periods between treatments and the related problem of carryover. The possibility of carryover (even the major design error of not including any washout period at all) is pointed as a main problem of many crossover trials (e.g. in similar revisions like Mills EJ, Chan A-W, Wu P, Vail A, Guyatt GH, Altman DG “Design, analysis, and presentation of crossover trials”, Trials 2009; 10:27 and Diaz-Uriarte R “Incorrect analysis of crossover trials in animal behaviour research” Animal Behaviour 2002; 63:815–822).

2) Alternatively, the authors should reflect in the tittle and the abstract that an important part of randomized equivalence trials are not included in the study. This exclusion should be justified in the introductory section, perhaps in terms of comparability with preceding studies, which is one of the main goals of the paper.

Discretionary Revisions

Even under the second possibility above, some consideration to the particularities of crossover trials (not fully absent in the paper) and the need of its consideration in CONSORT, and some reference to how the conclusions may be different if BE trials were included, would be very valuable.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests