Reviewer’s report

Title: Allogeneic mesenchymal stem cell as induction therapy to prevent both delayed graft function and acute rejection in deceased donor renal transplantation: study protocol for a randomized controlled trial

Version: 1 Date: 25 Sep 2017

Reviewer: Erik Cobo

Reviewer’s report:

I tried to read carefully the paper "Allogeneic mesenchymal stem cell as induction therapy to prevent both delayed graft function and acute rejection in deceased donor renal transplantation: study protocol for a randomized controlled trial" but I was disappointed that the authors did not follow the SPIRIT recommendations. I just comment 3 examples bellow.

1) The SPIRIT figure should highlight that recruitment precedes allocation. Please divide the first column of your spirit figure in 2 columns (please, consider avoiding overlapping information between this figure and table 1).

2) Although your Spirit table states that sample size rationale is explained in page 8, the only provided information is just that the number of cases per group is 50, but you do not justify the reasons for this number. Please, see examples in the SPIRIT explanatory document. [Additionally, it is not clear to me what "stage" means, since figure 1 shows them as different 'arms' of the trial. Please, note this flowchart is a Consort figure, to show losses during trial conduct, but not the design of the trial. Please, consider dropping it.]

3) Please, to prevent selective outcome reporting, specify the main outcome and the main statistical analysis, maybe with the help of an additional statistical analysis plan. [Additionally, please note that ITT, nor mITT are no more recommended populations. Please, read carefully the SPIRIT or the CONSORT statements and do your best to avoid missing data. Please consider useful advice to prevent it at http://www.nejm.org/doi/full/10.1056/NEJMsr1203730.

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**Statistical review**
Is it essential that this manuscript is seen by an expert statistician? If so, please give your reasons in your report.

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