

24th July 2015

Biostatistics statement

Title: 12-month efficacy and safety of the conversion to everolimus in maintenance heart transplant recipients

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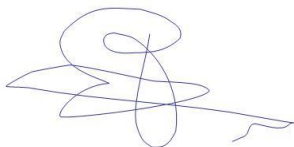
The statistical methods of this study were reviewed by **Juan José de la Cruz Troca** from the Department of Preventive Medicine and Public Health, Universidad Autónoma de Madrid.

The review by the biomedical statistician was conducted with respect to the following points: (1) the use of appropriate statistical methods to meet the study objectives; (2) the results estimates according to the methodology described; (3) the statistical techniques were suitable and correct.

Comments:

- In statistical methodology it is assumed that the descriptive values of qualitative variables take into account the normality of the variables; in case of non-normality median and interquartile range should be presented.
- It is also not made explicit that percentages (eg of adverse events), should be compared with Chi-square test or Fisher exact test. Also, to compare qualitative variables, only two values should be compared; if normality is correct Student t test, and otherwise the Mann-Whitney test. In comparisons of paired samples, these tests should be the Student t test for paired samples if normality is present and Wilcoxon otherwise.
- Descriptive values could be more informative if corresponding 95% confidence intervals are also presented, at least in Table 2, 3 and 4.
- The normality of the quantitative variables should be checked. In particular, for immunosuppressive doses, which do not seem to fit the normal distribution, median and interquartile range should be presented (and if it appropriate, also give the minimum and maximum values).

Sincerely,



Juan José de la Cruz Troca