Reviewer’s report

Title: Palonosetron versus ondansetron as rescue medication for postoperative nausea and vomiting: a randomized, multicenter, open-label study

Version: 2

Date: 13 March 2014

Reviewer: Stefania Nobili

Reviewer’s report:

Major Compulsory Revisions

This trial compares the newer 5HT3 antagonist palonosetron with the classical 5HT3 antagonist ondansetron in the treatment of postoperative nausea and vomiting (PONV).

Results show no difference in the percentage of complete control of PONV (primary end-point) between the drugs. Also, no difference was reported in relation to secondary end-points (complete response and change from baseline nausea scoring).

1) Abstract: in the ‘conclusion’ paragraph of the abstract, the authors reported they found a trend for emesis. However, they did not specify the drug for which the trend was observed. Please, specify.

2) ‘Background’ paragraph: Ref 12 refers to Guidelines for the treatment of PONV published by SAMBA in 2007. However, in February 2014, New Guidelines for surgical patients with post-operative nausea and vomiting have been published by the same Society. Thus, this reference should be updated.

3) ‘Methods’ paragraph: the authors affirm that Guidelines for PONV treatment recommend the use of a drug from a different class (i.e. with a different mechanism of action) from that used for the antiemetic prophylaxis. Thus, the authors should better explain in the text why they used not only a drug from the same class (i.e. palonosetron group underwent ondansetron as prophylaxis followed by palonosetron as medication rescue) but also the same drug in both treatments (i.e. ondansetron group underwent ondansetron as prophylaxis followed by ondansetron as medication rescue).

4) ‘Patient selection’ paragraph: in this kind of studies, among the exclusion criteria the body weight (i.e. obesity) is usually considered. The authors should indicate if they considered it and if available, they should insert this data in table 1.

5) ‘Discussion’ paragraph: the authors wrote that the study could have been underpowered and this could be the reason for which not statistically significant difference between treatments was observed. However, some considerations must be done: first, results indicate a trend for emesis in favour of palonosetron at later time points. An explanation could be the different pharmacokinetic profile of palonosetron compared to that of ondansetron (see for example the different...
half-lives). This, but also other hypotheses should be suggested. Second, if no statistically significant difference has been found this is not necessarily due to the limited number of patients. In fact, sometimes a limited case series may be representative of a larger case series. It is clear that this must be verified but it cannot be excluded a priori. Thus, the authors should try to better discuss their findings and to suggest some other hypothesis for their results (for instance, what about concomitant medications, etc.?)

Third, the authors should better contextualize their results with those of other available recent studies in which palonosetron and ondansetron are compared.

Minor Essential Revisions

1) ‘Background’ paragraph: Ref 17 and 18 are indicated as ‘recent’ studies. However, the year of publication is 2008. The sentence should be modified. In addition, more recent studies (e.g. Moon et al, 2012; Kim et al., 2013; Baisakhi et al, 2013) should be added and commented.

2) Table 1: please delete the line indicating the IV level of physical status according to ASA. It is not due since according to the inclusion criteria, patients with IV ASA were excluded.

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 have no competing interest