Reviewer's report

Title: Efficacy and tolerability of PEG-only laxative on faecal impaction and chronic constipation in children: a randomized controlled study vs a standard PEG-electrolyte laxative.

Version: 5 Date: 28 September 2012

Reviewer: Mike Geraint

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Reviewer’s response to author’s comments

Reviewer: Dr Mike Geraint

Title: Efficacy and tolerability of PEG-only laxative on faecal impaction and chronic constipation in children: a randomized controlled study vs a standard PEG-electrolyte laxative.

Authors: Savino et al

Reviewer’s response

The authors have failed to address several of the points I made in my review:

1. The authors have not satisfactorily addressed my main point regarding the relative doses of these two products. In this study, depending on the weight of the child, children taking PEG-only were dosed with almost double the amount of the active ingredient PEG than those taking the PEG-electrolytes product. The modification to the manuscript to insert the sentence “Another possible explanation for the better efficacy of the PEG-only formulation is that it contains a higher amount of PEG as compared to PEG plus electrolytes” is totally unacceptable. The higher dose of PEG is not ‘another possible explanation’ for the higher efficacy seen, it is the only possible and credible explanation. I would be content that this point was addressed if the authors replaced the phrase ‘Another possible explanation’ with the phrase ‘The probable explanation’. Also the abstract needs to accurately reflect this point, which currently it does not. It currently reads “At doses recommended by the manufacturers, children in the PEG-only group had higher and more regular soft stool frequency than PEG_EL”. I would be content that this point was adequately addressed if this sentence read: “At the higher PEG doses recommended by the manufacturers, children in the PEG-only group had higher stool frequency than PEG-EL.”

2. In my previous review, I asked for a reference or references to support the author’s assertion that there is “increasing evidence that electrolytes are only important when the amount of PEG is very high”. They have now referenced this by referring to De Giorgio R et al (2011). I have been through this reference and can only find this quote: “PEG/macrogol 4000 does not cause fluid or electrolyte imbalance even in prolonged treatment18-20.” This does not support the assertion of increasing evidence that electrolytes are only important if the amount
of PEG is very high. I suggest that the authors either justify this statement with supportive references or delete it.

3. I did comment previously that it is not the function of the electrolytes in PEG-EL to make the solution iso-osmotic. This has not been addressed. I would be content that this point was addressed if the relevant sentence read: “PEG-EL when dissolved in the specified amount of water is iso-osmotic relative to plasma which therefore reduces the potential loss of water and accompanying electrolytes from plasma.”

4. On the same point, PEG-only formulation is not necessarily “a hypo-osmotic solution which may favour rehydration”. Depending on the amount of water in which PEG 3350 is dissolved, the resulting solution can be either hyper-osmotic, iso-osmotic or hypo-osmotic. As this sentence is misleading, I suggest that the authors delete it.

I would not support publication of this manuscript in its current form unless my remaining concerns about its scientific accuracy are addressed.

Level of interest: An article of limited interest

Quality of written English: Acceptable

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