Author's response to reviews

Title: Maternal Safety of the Delayed-Release Doxylamine and Pyridoxine Combination for Nausea and Vomiting of Pregnancy; A Randomized Placebo Controlled Trial

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Response to Reviewers' Comments

“Maternal Safety of the Delayed Release Doxylamine and Pyridoxine”

We wish to thank the reviewers for their comments. In general we have found these comments most useful and have addressed them as follows:

Referee 1:

Minor Essential Revisions

(1) Results, 3rd paragraph; Tables 3-5: Authors stated the term TEAEs (Treatment Emergent Adverse Events) was defined by the investigators. Please provide definition and/or parameters used for this classification.

Thank you. A definition has been added.

(2) Tables 1-5: Must change drug name from Diclectin to Diclegis.

Name has been changed.

(3) Table 2: Please define ‘mild’, ‘moderate’, and ‘severe’ adverse events.

A definition has been added.

Referee 2:

An excellent paper overall, very clearly written and will add to this field; discussion of results linked to BMI and dose is welcome.

Discretionary Revisions

page 3(2nd paragraph in background): Can it be conclusively stated ('in fact') that
the withdrawal of Bendectin 'was associated' with a two-fold increase in rate of hospitalisation for HG- in other words that untreated NVP leads to HG- are they not substantively different- perhaps at least outline and examine the claims of the references used to support this point- (refs 6-7).

Thank you. We have revised the text to make it clear that the removal of Bendectin was temporally associated with a twofold increase risk of hospitalization. This of course does not prove causation, but rather supports it. Throughout- while it is understandable the Diclegis(r) is used to identify the brand/drug used, is it feasible/preferable to use the 'doxylamine succinate & pyridoxine hydrochloride' generic name in place of the drug name? It the brand name is used, it is useful that it is made clear that it has the same composition as Diclectin and Bendectin

Thank you. The text has been checked to ensure that it explicitly says “Diclegisâ, an identical combination to the original Bendectinâ and its Candadian equivalent Diclectinâ “

We wish to thank the reviewers for their help in improving the quality of our presentation.