Author’s response to reviews

Title: Glycerin Suppositories Used Prophylactically in Premature infants (SUPP) Trial: a study protocol for a pilot randomized controlled trial

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Author’s response to reviews:

Greetings,

Many thanks for reviewing our revised study protocol entitled: “Glycerin Suppositories Used Prophylactically in Premature infants (SUPP) Trial: a study protocol for a pilot randomized controlled trial.”

We agree that the previous version of the study protocol is confusing and ambiguous. We have made it clear in the revised version that this is an external pilot study that will be conducted separately and prior to a multicenter randomized controlled trial. We have not obtained funding or finalized a study protocol for the multicenter study and we anticipate that several changes will be required in terms of the interventions and frequency of follow-up. Once the external pilot study is finalized, we will submit our results for publication, design a revised study protocol for the multicenter trial, and apply for more substantial funding. We were initially hoping to pool results from the pilot and full-scale study. We realize now that this will not be feasible and probably not appropriate given the design changes that will be required.

We would like that the editor and reviewers for encouraging us to carefully consider these issues. We recognize now that pooling data from the pilot study and full-scale trial will not be appropriate and have removed the section that relates to this in the Methods/Design section. We hope that the revised version is clearer and more accurately conveys our intentions for the pilot study.

Sincerely,

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