Reviewer’s report

Title: Pediatric Intensive Care Stress Ulcer Prevention (PIC-UP): A protocol for a pilot randomized trial

Version: 0 Date: 30 Mar 2017

Reviewer: Mark Peters

Reviewer's report:

Well written manuscript outlining a carefully constructed pilot study by a team with extensive experience in clinical trials including in critically ill children.

I have only a few minor comments

1) Why is the inclusion limited to >12 months? While I assume this relates to the baseline bleeding risk - perhaps this should be made clear and referenced. If this is not well evidenced then suggest reconsidering this very significant proportion ~50% of critically ill children as this will limit both the feasibility of the study and the potential impact of the findings. Note that the cited reference from Brazil has not limited to >12 months and hence there is apparently an unanswered question on the utility of acid suppression in this population.

RR is introduced without spelling out in full (paragraph 2)

What is the time window for consent? I couldn't see this specifically mentioned.

Consent rate for placebo drug trials is often lower than for other interventions = 80% sounds ambitious to me - but will clearly be determined by the pilot.

"Participants will be randomized to intravenous pantoprazole or matching placebo once daily."

Suggest better as

Participants will be randomized to receive intravenous pantoprazole or matching placebo once daily.

Otherwise suggests they are randomised each day!

The sample size doesn’t appear until page 12 - I think this should be in the page 7 study population also.
2 or more cases per month is a very low target given the inclusion criteria - but again will be confirmed in the pilot.

I did not see a planned duration of the trial.

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