Reviewer’s report

Title: The effects of varying protein and energy intakes on the growth and body composition of very low birth weight infants

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Reviewer: Winston Koo

Reviewer’s report:

This is a report on the effect the increase in protein and energy intake of formula fed preterm very low birth weight (VLBW) infants. Study design is a longitudinal, randomized interventional study over ~28d period. Subjects included a control group fed standard preterm formula (PTF that provided 3.7g Protein & 129 kcal/kg/d) compared to those fed 2 higher protein but similar and higher energy content formulations (4.2g or 4.7g protein with both formulas providing 150 kcal/kg/d). These subjects were grouped as A, B, and C respectively. Outcome measures were anthropometry and body composition based on bioelectrical impedance analysis (BIA). Although several biochemical parameters were also measured. An additional 6 VLBW infants fed enriched human milk were also studied and served as a descriptive reference group.

This is an area of great importance in the care of small preterm infants. The authors have done extensive analysis and writing of this manuscript. However, there are concerns with the study design. The description of the randomization procedure and blinding is unclear. What was the reason for discontinuing the study at 38 subjects when the randomization was done in blocks of 6 with 3 study groups and recruitment appears to have discontinued without consideration of the potential dropouts? Not sure what the authors meant by “Along the randomized trial the infants were never unblinded …” on p5 para1, line5? What was the rationale for analyzing the data after 5 subjects were studied in the control group and 5 subjects in the combined protein/energy enriched groups and using the preliminary data to calculate the sample size? There is no mention of the extent of difference expected from this sample size. The calculated sample size is normally based on the number of subjects completing the study. Thus a dropout of 4 subjects out of a total of 12 in one of the groups posed great concerns on the power of this study and the validity of the conclusion.

Other details:

1) Not sure of the value of the very small number of subjects fed human milk as a reference group

2) More details of the anthropometric measurements and the interoperator errors are needed. There is no mention of the measurement of foot length although it was used to calculate the TBW. Most clinical scales provide weights rounded to 5 or 10g. Should provide the brands of the scale used for the study.

3) The birth weights of subjects in group C appear higher and with a larger
scatter. The small number of subjects presumably contributed to the non-significant difference among groups

4) Not sure of the rationale for the use of BMI in young infants especially in the VLBW infants?

5) Would the authors speculate on the possible reasons for the higher urea concentrations in the groups received the higher protein intake?

**Level of interest:** Reject as not of sufficient priority to merit publishing in this journal

**Quality of written English:** Needs some language corrections before being published

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

**Declaration of competing interests:**
'I declare that I have no competing interests'