Reviewer’s report

Title: Improving lactose digestion and symptoms of lactose intolerance with a novel galacto-oligosaccharide (RP-G28): a randomized, double-blind clinical trial

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Reviewer: Eamonn Quigley

Reviewer’s report:

This is a very interesting paper with novel and potentially important findings. However, several issues need to be clarified:

1. What was/were the primary endpoint/s? This is critical; the authors performed a power calculation which means that they must have defined at least one primary endpoint but I cannot make out what that was.

2. Efficacy was calculated on the PP, not the ITT population; this is far from an ideal approach. At the very least, both the PP and ITT data should be presented.

3. What were the prescribed (rather than post hoc) secondary endpoints? This must be clarified.

4. What was the precise schedule of dose escalation; was this also performed for the placebo?

5. Subjects were excluded due to product discoloration; why were placebo subjects also excluded for this reason?

6. I cannot understand the presentation of the HBT results. The tables present data on deltas and the authors could, I assume, present AUCs but instead refer to a "random likelihood" calculation which was never mentioned previously and is not explained in any detail. Also, the abstract refers to trending of data but the results suggest that differences were significant.

All of these manipulations of the data are a concern.

Quality of written English: Acceptable

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

Declaration of competing interests:

No competing interests