Reviewer’s report

Title: A proof-of-concept study to evaluate the efficacy and safety of BTI320 on post-prandial hyperglycaemia in Chinese subjects with pre-diabetes

Version: 0 Date: 27 May 2018

Reviewer: Kathleen E. Bethin

Reviewer's report:

This is a prospective randomized trial to show that BTI320 (a mannan) was safe and effective in lowering glucose in male Chinese subjects with prediabetes.

The background should include more about the prevalence of type 2 diabetes in Chinese adults, rate of conversion from pre-diabetes to diabetes and a little more about what has been shown to reduce the conversion from prediabetes to diabetes. Also, more details about previous studies with galactomannans.

Please include more details about how the subjects were identified and recruited. Were they followed in an endocrine clinic for obesity? Did the authors advertise to the public? Please define what you mean by high-risk Chinese adults with prediabetes. How many of the women were premenopausal? How were subjects randomized?

The authors conclusions are overstated. In the discussion section the authors state that BTI320 suggested that it would applicable to subjects with Type 2 diabetes. However, the BTI320 did not meet the primary outcomes and the secondary outcomes were weak at best. How can the effects of BTI320 in prediabetes where changes in post-prandial glucose are small be generalized to subjects with T2 diabetes who have larger increases in post-prandial glucose? How can you say the changes in post-prandial glucose are significant when there is no change in levels of glycosylated proteins (fructosamine and HbA1c). If protein glycosylation is not changed, this does not appear to be a clinically significant change. With negative results the authors should not state that BTI320 has the potential to prevent diabetes in adjunct with lifestyle modification.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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