Reviewer's report

Title: Perilla Extract improves GI health in a randomized placebo controlled double blind human study

Version: 4 Date: 19 December 2013

Reviewer: Luis Vitetta

Reviewer's report:

Study Title: Perilla Extract improves GI health in a randomized placebo controlled double blind human pilot study.

The authors present a small pilot double blind placebo controlled randomized clinical study.

I have a number of points that I would like clarified.

Major compulsory revisions:

Queries:

1. Please add numerical results with statistics in the abstract. The results in the abstract should clearly summarize the data observed. Also indicate clearly in the abstract that this is a pilot trial.

2. It would be advantageous to set-out the inclusion and exclusion criteria in a clearer fashion in the subject population section of the article. Were pregnant women allowed to participate? Were participants with alcohol intake and smokers allowed to participate…these may be strong confounders in a gastrointestinal clinical study.

3. The statistical data is presented as means (SD) this tends to suggest that the data is normally distributed. This is not clear to this reviewer…the data would be better served if it was treated as not normally distributed. Can the authors please comment on this?

a. What was the pre-study specified number of participants needed to reach statistical significance?

b. How did the authors choose their ‘n’ number?

c. The separation between active and placebo does not facilitate comparisons, which is the main objective of a clinical trial in tables 2 and 3. Also, in tables 2 and 3, report 95% confidence intervals rather than the P#values. This in effect applies to the entire article, including the abstract, which should include the 95% confidence interval of the difference between the reduction in the active and placebo groups.

4. The discussion can be structured better…please use the following as a guide:

a. Concise statement of the principal findings (in a few sentences) at the beginning of the discussion.
b. Strengths and weaknesses of the study.
c. Strength and weaknesses in relation to other studies, discussing particularly any differences in results. Also, it is here that the authors should address/discuss further the placebo response and the possible implications of this for this trial.
d. What is the meaning of the study? Possible mechanisms and implications for clinicians or policy makers.
e. Were there any unanswered questions and what of future research…this should be clearly out-lined.

Minor revisions:
5. There are a number of small edits that require attention.

Level of interest: An article whose findings are important to those with closely related research interests

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

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
No competing interests