Reviewer's report

Title: To compare the effect of two Zhizhu pills in the treatment of functional dyspepsia of spleen-deficiency and qi-stagnation syndrome, a randomized, double-blinded multicenter and group sequential study design

Version: 1 Date: 27 October 2010

Reviewer: Carl J Lombard

Reviewer's report:

Major

The purpose of this paper is not clear to me. I am not sure if this paper is about reporting the results of the trial or whether it is an example of a comparative trial with a particular type of stopping boundary.

If it is the first then I have problem with the reporting of the results of the trial since no effect size of confidence interval is reported. The pre-post distribution of the symptom score is not given by group.

If it is the second option one would expect a much more detailed expose of why the whitehead design was used and not any of the other group sequential design even those of whitehead in 2001 for example. This outline would be of benefit to the reader. Showing the calculation of the effect size and confidence intervals using the stopped trial will also be useful in 'this' type of paper.

At the moment this paper is neither of the cases outlined above.

What was the basis for assumming that the one product will have a superiority of 15%? Why was equivalence not considered?

From checking the details on the stopping boundaries given in the analysis section I could deduce that the metric of comparison was the log odds ratio and that theta 1 given in this section is the value of this statistics under H1. These descriptive details are missing. In the Results section under TT the test statistic referred to is a log-rank statistic which is incorrect

Table 1

The presentation of the descriptive statistics in this table is not good.

What are the statistics - mean, median, standard deviation? Why brackets in the one group and +_ in the other? The main critique is that of presenting p-values for the baseline comparisons. Why is this done - was the randomisation flawed? Please drop the column of p-value in this table

Results table - no sure why no estimated effects within and between groups are presented with the necessary confidence intervals taking the interim monitoring into account?
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:

'I declare that I have no competing interests'