Reviewer's report

**Title:** To compare the efficacy of two kinds of Zhizhu pills in the treatment of functional dyspepsia of spleen-deficiency and qi-stagnation syndrome A randomized group sequential trial

**Version:** 3  **Date:** 22 March 2011

**Reviewer:** Carl J Lombard

**Reviewer's report:**

The authors have re-written the manuscript to make it clear that it is the results of a comparative trial that is being reported. Comparative between two compounds. Looking at the title of reference 18 made the design clear to me: answering the question which of the compounds is the best? The word comparative might be included in the title: a randomized group sequential comparative trial.

The description of the stopping boundary and test statistics is fine. Once the boundary is crossed in the study we can say that the one compound is significantly better than the other with some p-value. The comments that was not addressed is the answer to: how much better? The effect size or difference between the compounds is 22%. You have to provide the estimate and its appropriate confidence interval since this is the main result of the trial. The problem you face is the correct calculation of the confidence interval since this is not a SSD but a sequential design in which you had three looks and then stopped the study.

You provide the symptom score at baseline were it is good enough for information purposes but it is not provided for the post randomisation time point. Your main outcome is based on this and the descriptive statistics of the post score will be useful for other researchers planning other studies.

P-values should no be reported for baseline comparisons since the difference observed is known to be due to chance only- the effect you achieved by randomisation.

**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'