Reviewer's report

Title: Banha-sasim-tang as a herbal formula for the treatment of functional dyspepsia: A randomized, double-blind, placebo-controlled, two-center trial

Version: 3 Date: 6 May 2010

Reviewer: Ronnie Fass

Reviewer's report:

This trial was designed to investigate the effects of an old Chinese herbal preparation on dyspeptic symptoms. The trial design (randomized, placebo-controlled, double-blind) is appropriate for this type of study. However, there are a few points that need further clarification.

1. The diagnostic criteria for functional dyspepsia (FD) are not clear. In order to make this trial valuable, the authors should consider using the Rome III criteria. The patients may need to be further classified to the FD subtypes.

2. Helicobacter pylori status is not assessed in this trial. Based on Rome III: “Noninvasive testing of H pylori infection, followed by eradication ('test and treat') is indicated for the patient with no alarm features.” Thus we recommend H pylori assessment as part of this study.

3. Medications that can result in dyspepsia such as aspirin and nonsteroidal anti-inflammatories (NSAIDs) need to be excluded to diagnose FD.

4. Endoscopy should be considered as part of the protocol.

5. The term “gastric dynamic agent” in the inclusion criteria is not clear.

6. I am not sure about the value of EGG in this study. Inconsistent correlations have been shown between symptoms and abnormalities of gastric function as assessed by gastric barostat or electrogastrography.

7. It is not clear how the duration of treatment (6 weeks) was determined. Could 4 weeks of treatment be enough?

8. Are the patients treated for FD during the 2-month period of follow-up? This needs to be specifically stated.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:

We have no competing interests.