Reviewer's report

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

Version: 1 Date: 15 March 2010

Reviewer: Massimo Rugge

Reviewer's report:

GENERAL COMMENTS

This study is designed to compare the effect of two Zhizhu pills in the treatment of FD of spleen-deficiency and qi-stagnation syndrome (the authors should notice the reader about the definitions they used).

Patients with FD were randomly allocated into the two groups (IFCA and IFCS groups), and treated with the two Zhizhu pills respectively, 6g, three times a day, for 28 days.

The trial showed a significantly higher therapeutic effect of the IFCA versus the IFCS treatment.

This manuscript may provide some new information about the FD treatment. The manuscript has to be clarified, simplified, shortened (it is really long) in all its sections.

The English editing needs to be revised.

TITLE

The title could be actually simplified and shortened.

INTRODUCTION

In this section the Authors mention Rome I and Rome II criteria in FD definition: …what about the most recent Rome III criteria?

The introduction should provide some more information about some of the addressed points.

Just as examples:

1) “In western medicine, the treatment of FD remains a major unsolved problem in digestive system, and is a discouraging, unsatisfactory situation for treating physicians. FD nearly equivalent to TCM term “fullness and distension in the abdomen”, of which spleen-deficiency and qi-stagnation syndrome is the most frequent syndrome.”
- What about the sub-categorization of FD?
2) “The information obtained from clinical observations and from experimental animal research indicates that a substantial benefit in outcome can be expected in patients” with FD of spleen-deficiency and qi-stagnation syndrome …."
- What about references?
3) “This paper presents a concrete example of a comparative trial design and analysis based on the group sequential methods: the triangular test (TT).”
- What about references?

METHODS

More than one point should be clarified.

The Authors wrote: " The statistical design was that of a group sequential design with 3 stages, rejection boundaries and a potential sample size adjustment for the last stage.”
- Please clarify.

The Authors wrote: " We assessed the change of patients’ symptoms and signs before and after the treatment by means of questionnaire. The questionnaire was completed in physician interview before-treatment and end-of-treatment (baseline, and 28d), and it was consisted of 9 items"
- The questionnaire should be included.

The Authors wrote: " Analysis."....
- The paragraph needs to be clarified... I would like to know something more about the triangular test (some reference about TT should be included).

RESULTS

General comment: this section is really difficult to understand.

The Authors wrote: " The accumulating evidence of the advantage of IFCA was summarized, in terms of the log-rank statistic, this statistic was denoted by Z, as the interim analysis proceeded, a sample path was obtained by plotting Z against the amount of information accumulated (sample size), denoted by V. The statistic V is approximately equal to one quarter of the number of improvement. The straight-line boundaries that determined stopping in this study (a triangle for the triangular design) are shown in figure 1.”
- I can not follow the meaning of this sentence. Probably, this reviewer ignores the sophisticate statistical analysis which was applied…; many potential readers -however- could be in the same condition!
DISCUSSION
Difficult, long, frequently bewildering.