Reviewer's report

Title: Optimal schedule of adjuvant chemotherapy with S-1 for stage III colon cancer: a multicenter randomized phase II trial

Version: 1 Date: 3 December 2012

Reviewer: Christopher Carroll

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The protocol is suitable.

1. Will the study design adequately test the hypothesis?
Yes. Hypothesis is that 3-week S-1 is non-inferior to 6-week S-1 in terms of efficacy and adverse events.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
Yes, on the whole.
p.11: Is there a threshold for "and adequate hematological, liver and renal functions"?
p.13: How is follow-up to be conducted? How is attrition to be minimised?

3. Is the planned statistical analysis appropriate?
I am not able to comment on this.

4. Is the writing acceptable?
Yes, on the whole.

pp.12-13 is written in past tense, but should be future (this is a protocol), e.g. "treatment will be discontinued if "

Also, there is the odd typo, e.g. p.6: "a favorable results" - delete "a"; p.9: "participating institutions included" - should be "include"; p.11: "PATIENT REGISTARION"; p.16: "financial supports" - should be "support"

Other comments:

I would take issue with the statement in cover letter and manuscript that "Although S-1 has not been approved yet as a standard treatment in an adjuvant setting, it is likely to become an important treatment option in the near future." This overstates the case, I think. The authors provide no evidence to support this claim, only the success of the therapy in another population in a single trial; there is a difference between something being a "promising option" (as the authors also claim) and a likely "important treatment option in the near future".
This study compared uracil and tegafur (UFT)/LV with 5-FU/LV as an adjuvant chemotherapy for patients with stage III colon cancer, and demonstrated that the 3-year disease-free survival (DFS) of all patients was 78.6%.” Was this the FU result? If across both arms, what was it in each arm?

Declaration of competing interests:

I have no competing interests.