Reviewer's report

Title: Neoadjuvant chemotherapy versus surgery first for resectable pancreatic cancer (Norwegian Pancreatic Cancer Trial - 1 (NorPACT)) - Study protocol for a national, multicentre randomized controlled trial

Version: 1 Date: 16 Jun 2017

Reviewer: Fuyuhiko Motoi

Reviewer's report:

Labori KJ et al described the protocol of Neoadjuvant chemotherapy versus surgery first for resectable pancreatic head cancer for exploratory randomized controlled trial. The protocol might be well written, however, there are several concerns to be addressed.

1. In some cases pathological examination might reveal that the resected tumor is not optimal target for this study, such as intra-ductal papillary mucinous neoplasm or neuroendocrine neoplasms, even though the cytological confirmation was obtained before enrollment. How will you manage such cases?

2. Why do you use non-equal (3:2) randomization? Please explain and add the reason.

3. You estimated one-third of the NT group would not reach resection. However previous reports you cited showed that the resection rate of resectable tumor was 87% in ref.16 and 75% in ref.17. Please explain why you estimate the resection rate of your cohort such low.

4. Do you have any stratification factors to balance the randomization such as radiological tumor size or value of serum tumor marker after biliary drainage? You mentioned that randomization would be balanced only by each centers.

5. When the patient with obstructive jaundice and randomized to NT group efficacy of drainage must influence and (in some cases) it might break down the randomization (Figure 1). Randomization should be performed after app
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?
If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests.

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal