Reviewer's report

Title: Toremifene, a selective estrogen receptor modulator, significantly improved biochemical recurrence in bone metastatic prostate cancer: a randomized controlled phase IIA trial

Version: 0 Date: 31 Jul 2015

Reviewer: Zhanwei Wang

Reviewer's report:

This study explored the effects of additional selective estrogen receptor modulators (SERMs) on the durability of androgen-deprivation therapy (ADT). Fifteen subjects were divided into 3 groups, the sample size is relative small, and the results need to be validated in the other studies.

I have some major concerns:

1. In the statistical analyses part, the author mentioned "BCR-free survival curves were plotted using Kaplan-Meier method and verified using the log-rank test". I do not think it is enough for this study. The author should do univariate and multivariate Cox proportional hazards regression models to check the hazard ratios among these three groups.

2. In Table 1, the author should add one more column for the P value to test the difference of variables among the three groups, and then make corresponding changes in the statistical methods.

3. For the explanation of the results shown in the Figure 2: p=0.04, ADT v.s. TOPADT, p = 0.48, ADT v.s. RAPADT, and p = 0.12, TOPADT v.s. RAPADT. There was no significant difference between TOPADT and RAPADT on the BCR-free rate. Could the author explain why RAPADT does not have the same effect as TOPADT?

4. There are 6 figures in Figure 3, however, the legend of Figure 3 only described A and B. For the Figure B, C, D, E, and F, the p values should be presented like that in Figure A.

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.

No

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 am able to assess the statistics

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

Needs some language corrections before being published

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