Reviewer’s report

Title: Two-stage optimal designs with survival endpoint when the follow-up time is restricted

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Reviewer: Lisa Belin

Reviewer’s report:

The author proposed a new optimal design with survival endpoint optimizing the recent proposal of Belin's design in the same context. I am actually very proud that my work is considered as a competitor. This work allows to improve the Belin’s design by using the exact variance estimate developed by Wu.

Formulation of Simon's design without interruption of accrual during interim analysis is relevant and is an appropriate competitor because it is also used even when comparing survival probabilities. So the work is actually well developed with good choice of competitor. Nevertheless, some point could have been improved and I have some comments on.

1. The hypotheses testing described in equation (1) (line 16 page 4) is formulating as a punctual test in clinically meaningful time tc. However, the proposed design used the one-sample logrank test, so it allows taking into account the information all along the follow-up (even when restricted). I think hypotheses could be changed.

2. I think the optimal design search must be described precisely. In part 2.2.1, it seems that the optimal design is selected:

(i) as meeting alpha and power at the nominal level

(ii) as improving the ESS0 by 10% compared to Belin's design

(iii) as meeting alpha and power at a simulated level

If (ii) is respected, why in the results part, ”the ESS0 of the proposed minimax or optimal design is often less than of the Belin's design” (line 37-38 page 8)?

3. in Table 3, TIE and power are reported. Could you add the 95%confidence interval to evaluate if the proposed design is conservative? In fact, TIE seems always be lower than the nominal level. Please comment.

4. How could you explain that the proposed two-stage design could require more patient than the Simon's design when the survival rate under the null hypothesis is high?

Moreover, some minor revisions could improve the work:
Line 36 page 4, "when the number of response is low..." sometime few response could be sufficient, so I would recommend to use a relative term like "insufficient". Use relative terms when talking about designs (same example line 19 page 6).

Why do you study this range of critical value for c1? Is it a way to avoid local maximum during optimization process?

It would be easier to make conclusions on Figure 1, 2, 3 and 4 if the same scale would be used for each line.

The result part mix some results and some explanations that could be in the method, maybe it could be re-structure a little bit

In the Examples, could you add the Belin's design at least for the first example where exponential assumption is realistic?

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**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 am able to assess the statistics

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