Reviewer's report

Title: An approach to trial design and analysis in the era of non-proportional hazards of the treatment effect.

Version: 1 Date: 31 March 2014

Reviewer: Honghua Jiang

Reviewer's report:

The authors proposed a joint test for the treatment comparison, combining the logrank test and Grambsch-Therneau test of proportional hazards due to the fact that non-proportional hazards may be common in clinical trials. When the hazards are not proportional, the joint test provides greater power to detect the treatment difference compared to the logrank test only. However, the joint test may also result in a false claim of significance when actually there is no or little treatment difference but the hazards are significantly non-proportional (for example, treatment effect cross at some time point). So the joint test has major flaw to be used as a method for treatment effect comparison.

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

I declare that I have no competing interests