Reviewer’s report

Title: Alternative statistical methods for estimating efficacy of interferon beta-1b for multiple sclerosis clinical trials

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Reviewer: Nils Koch-Henriksen

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Minor essential revisions:

1) Questions:
In the simulation, the authors generated values for time by using random numbers between 0 and 1 and reading which value of time corresponded with a Weibull cumulative probability of exactly the magnitude of each random number.

In the text, they should state on what ground they did choose the specific Weibull distribution parameters gamma and delta for observation/censoring time and for time to event in the two scenarios? It appears from table 1 that the bias and the mean square error (MSE) for all the models are very sensitive to the scenario chosen.

Were the Weibull parameters in the two scenarios chosen a priori by looking at the natural distributions from the real life data, or were they chosen a posteriori to fit better with the expectations?

2) Presentation.
Although written in good English with a generally good clarity, the article is difficult to read. The readability would improve greatly, if the authors refrained from denoting their models as "Model 1, Model 2", etc. but in stead throughout the article (and in the tables and figures) used the full name of the model, e.g. "Cox", "Andersen-Gill", "Prentice-Williams-Peterson", "Wei-Lin-Weissfeld", "Lee-Wei-Amato", "Poisson regression", "GEE-Poisson model", especially in the results-section. It will certainly help the reader, who will not need to look back as many times.

3) In the conclusion, the authors could stress (as they did in the discussion) that they prefer the Poisson regression model with Generalized Estimating Equations (GEE).

Figure 1 is very helpful in interpreting the different models.

4) Discretionary revisions:
It would be helpful to some, if the appendix also provided the readers with SPSS-codes, as many scientists only use SPSS. However, if the authors are not familiar with SPSS, it will probably be to much to ask for.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

No to all the questions.