Reviewer’s report

Title: The effect of insulin degludec on risk of symptomatic nocturnal hypoglycaemia in adults with type 1 diabetes and high risk of nocturnal severe hypoglycaemia (the HypoDeg trial): study rationale and design

Version: 0 Date: 03 May 2019

Reviewer: Baqiyyah Conway

Reviewer's report:

This is an important concept paper describing an ongoing the purpose and methods of an ongoing case-cross over clinical trial of hypoglycemic events among persons with Type 1 diabetes using the insulin degludec vs. glargine. A couple of concerns are that

1) The article is written more like a grant proposal than a article manuscript. Please write the manuscript in article manuscript style.

2) The paper needs to be better organized. For example, it may be more logical to place the description of the study population before visit procedures rather than after it

3) It needs to be better emphasized in the Introduction that the purpose of this paper is to Introduce this study, providing the rationale and study design for this ongoing study. I had to go back to the title to figure out the purpose of this paper.

4) On page 10, please spell out CRF

5) On page 11, line 55. Where the authors state: " Subjects were included", do they mean "recruited" or do they mean "seen"

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

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

Acceptable

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