Reviewer’s report

Title: Rationale and protocol for the Assessment of Impact of Real-time Continuous Glucose Monitoring on People Presenting with Severe Hypoglycaemia (AIR-CGM) Study

Version: 0 Date: 15 Jun 2019

Reviewer: Ulrk Pedersen-Bjergaard

Reviewer's report:

This manuscript describes the protocol for a randomized clinical trial, the AIR-CGM trial, which aims to assess the effect of introducing RT-CGM to people with type 1 diabetes immediately after a severe hypoglycaemic event. The area of intervention is important as such events often do not lead to interventional follow-up and as patients may be highly motivated during this particular period. The manuscript is well-written and describes the protocol in a clear manner. The overall design is appropriate.

Concerns:

1 The inclusion criteria are very broad. This may result in inclusion of a very heterogenous cohort, which may challenge the premises for the power calculation. E.g. there may be well-controlled participants experiencing their only severe hypo, people running at very low glucose levels, who will contribute massively to the primary endpoint, and people with excessive use of alcohol or other substances, who may benefit less from the intervention. I would recommend to seek for a more homogenous population or increase the number of participants.

2 Intervention: It is a little unclear whether the intervention is limited to improving glucose control or if behavioural issues are dealt with as well. To release the full potential of the CGM, this is important to include. In the same line: are the study personnel familiar with the patients a forehand?

3 Endpoints: The hypoglycaemic endpoint are only defined according to CGM data. It would be important to know the clinical consequence: asymptomatic, symptomatic or even severe?

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.

Unable to assess

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.

Not relevant to this manuscript

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

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?
4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?
5. Do you have any other financial competing interests?
6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

No competing interests
I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal