Reviewer's report

Title: Automated Bolus Advisor Control and Usability Study (ABACUS): Does use of an insulin bolus advisor improve glycaemic control in patients failing multiple daily insulin injection (MDI) therapy?

Version: 1 Date: 8 August 2012

Reviewer: Helen Murphy

Reviewer's report:

The study protocol is well written and the design will address the main research hypotheses. The detail is sufficient in most regards but there is some ambiguity, in particular, regarding the CGM and randomisation procedures.

Major comments

1. CGM detail
   It is unclear how the 50-60% CGM participants will be selected and whether or not they will be representative of the entire cohort.
   Is CGM available at all UK and German sites or just selected centres?
   Is CGM not possible for all participants? If not should this be listed as a potential limitation?
   Is CGM an optional extra for individual study participants or a requirement?
   How will glucose data from the Dexcom sensor be blinded to the study participants? I am not aware of a data blinding feature on that CGM device?

2. There is minimal information regarding the randomisation procedures. This should be added. Please also specify whether there are any proposed stratifications for centre, type of diabetes, country etc.

Minor comments

1. Please comment on whether the very large number of study sites (n=30) and relatively small number of participants (n=6) and therefore 3 control and 3 experimental may limit the investigator experience in utilising and/or optimising the bolus advisor settings.

2. The ClinicalTrial.gov register lists “change in magnitude of postprandial glucose excursions” as a secondary trial outcome. For CGM comparisons, this may require more sophisticated statistical analyses such as linear mixed effects modelling (to overcome the issues of multiple highly correlated glucose data measurements)

3. For readability please keep abbreviations to a minimum – BA (bolus advisor) is not a well recognised abbreviation and likewise there is little to be gained from replacing the control and experimental groups with EXP and CNL.

4. There is an unclosed bracket in the 1st line of the 2nd Introductory paragraph
5. If the study has not yet commenced recruitment (as suggested on the trial register) please review the sentence (page 20) – final data will be available in late 2012

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests'