Reviewer’s report

Title: Effects of vildagliptin as compared to glibenclamide on glucose variability after a submaximal exercise test in patients with type 2 diabetes - DIABEX VILDA: study protocol for a randomized controlled trial

Version: 3 Date: 28 July 2014

Reviewer: Harald Sourij

Reviewer’s report:

Fofonka et al. submitted a protocol of a study investigating glucose variability after submaximal exercise testing in subjects treated with either vildagliptin or glibenclamide.

Major compulsory revision:
1.) The authors need to provide the standard deviation used for MAGE in the sample size estimation in order to make the estimation reproducible.
2.) The section study intervention is not very clear: when will they increase the glibenclamid dose (second week?). In whom will the dose be further increased – the authors mention to aim for an HbA1c of 7.0%, but firstly I think HbA1c will not be of much help given the short treatment period and secondly I have not seen any HbA1c measurements at the 4 or 8 weeks follow up visits.
3.) The authors state that they will evaluate glucose variability after the submaximal exercise test. However, I have not seen a clearly defined time period after the exercise test, which will be used for data analysis for the primary endpoint.

Minor revision:
4.) The authors mention 10 visits (eligibility, 3 days of assessments, week 4, week 8 and another 3 days of assessment) – did I miss a visit?
5.) P6 “… bring the medicine tablets with them to count the pills” should be rephrased (e.g. Drug accountability will be assessed at each follow up visit.)

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

Quality of written English: Needs some language corrections before being published

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.