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: 1 September 2014

Reviewer: maria rosaria rizzo

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

COMMENTS TO AUTHORS:

The general aim of the study which will be conducted by Aline Fofonka et al. is to evaluate glucose variability after the submaximal exercise test under the treatment with vildagliptin or glibenclamide, while the specific aims are to evaluate the oxidative stress, endothelial function, metabolic and cardiovascular responses to exercise under the treatment with vildagliptin or glibenclamide.

The study is of interest. I have some Minor Essential Revisions.

1. Page 3 – The sentence: “The primary outcome will be glucose variability reduction” it should be “The primary outcome will be glucose variability evaluation”;

2. Page 4- Sample size calculation section: According to ref 8, in which the authors, however, assessed only one specific aim, this study, that has several aims, will include 20 patients (METV group 10 pts vs METG group 10 pts). Please verify that the samples size calculation provide a valid statistical comparison;

3. Page 4 -Exclusion criteria section: no mention of cancer, dysthyroidism, cognitive decline and dementia, recent ischemic cardiovascular and neurological events or the use of antidepressive, insulin, betablockers drugs is done. Please add these informations in the text;

4. Page 5 – Data collection section: in this section does not describe the caloric intake and the meal used before and during the exercise test execution. Again is not clear if glycemic index of the meal is equal in all patients. Will be patients undergoing to a standardized diet during CGM to avoid meal interference? This point should be specified in this section;

5. Page 5 – Data collection section: in this section does not describe the heart
rate variability analysis. Please specify and add when such data will be recorded (Day 2 ?) and the recording time;

6. Figure 1 – Please add metabolic evaluation (glucose, HbA1c, insulin, glucagon and GLP1 -blood samples) and heart rate variability recording in the flow diagram of the study design.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

yes, I have received in the past five years a reimbursement by novartis.