Reviewer's report

Title: Does Dapagliflozin Regress Left Ventricular Hypertrophy in Patients with Type 2 Diabetes? A Prospective, Double-blind, Randomised, Placebo-Controlled Study

Version: 0 Date: 11 Jul 2017

Reviewer: GianLuca Colussi

Reviewer's report:

The paper shows the protocol of the DAPA-LVH clinical trial which will assess the effect of dapagliflozin on left-ventricular function of normotensive or well-controlled hypertensive diabetic patients. The study will be randomized, double-blinded, and placebo controlled. The study aim is very interesting and of some impact in the research community. The protocol is well written and the study is well designed. My only suggestion is to improve the patient and methods section.

1) Patients included in the study will be diabetic normotensives (without antihypertensive drugs) and well-controlled hypertensives (with antihypertensive drugs). This should be better specified. A run-in period to optimize blood pressure control should be considered before starting the study and a 24h not 16h ABPM should be used to confirm a good blood pressure control. Specify protocol for in-office blood pressure measurement.

2) Are new onset diabetic patients included? How author will manage therapy in these patients?

3) Screening for left ventricular hypertrophy should be performed also with ECG criteria that should be indicated. Also author should specify ASE criteria for diagnosing LVH (echocardiographic method, indexing for body surface area, for height, etc.)

4) In the paper study will end in May 2017! In clinicaltrial.gov this end is in December 2018. Please specify a correct study end date.

5) Describe in detail how will you perform ABPM measurements: protocol, daytime and nighttime hours and blood pressure cut-off values, number of valid measures for an acceptable exam, etc.
6) Specify in detail laboratory methods for measuring analytes for research purposes. Specify what FIRI means and how it is measured. Specify how will you assess eGFR and if 60 ml/min will be also indexed for 1.73 m²

7) Specify magnetic resonance protocol to assess LVH in patients.

8) Specify protocol for measuring CMRI visceral and subcutaneous abdominal fat mass

9) Specify details of instruments that you use for echocardiography, magnetic resonance, office blood pressure, and ABPM.

10) What's the meaning of matching placebo? Is this a matched pair randomization design? If so specify the blocking variables.

11) Specify units of measurement of body mass index

12) I further suggest authors to check and state whether the study is in agreement with the CONSORT guidelines for enhancing the quality and transparency of health research.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**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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