Author's response to reviews

Title: Effect of eplerenone on parathyroid hormone levels in patients with primary hyperparathyroidism: A randomized, double-blind, placebo-controlled trial

Authors:

Andreas Tomaschitz (andreas.tomaschitz@gmx.at)
Astrid Fahrleitner-Pammer (astrid.fahrleitner@medunigraz.at)
Karin Amrein (karin.amrein@yahoo.de)
Eberhard Ritz (prof.e.ritz@t-online.de)
Burkert M Pieske (burkert.pieske@meduni-graz.at)
Katharina Kienreich (katharina.kienreich@gmx.at)
Jörg H Horina (joerg.horina@medunigraz.at)
Albrecht Schmidt (Albrecht.Schmidt@klinikum-graz.at)
Elisabeth Kraigher Krainer (elisabeth_kraigherkainer@hotmail.com)
Thomas R Pieber (thomas.pieber@healthgate.at)
Andreas Meinitzer (andreas.meinitzer@medunigraz.at)
Stefan Pilz (Stefan.pilz@chello.at)

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Graz, 8th March, 2012

Re-submission of the Study protocol article entitled "Effect of eplerenone on parathyroid hormone levels in patients with primary hyperparathyroidism" by Tomaschitz et al.
MS Number: MS: 1720153578678991

Dear Ms. Gerobin,

enclosed please find our revised manuscript entitled “Effect of eplerenone on parathyroid hormone levels in patients with primary hyperparathyroidism”.

We have obtained the full ethical approval for the EPATH study on 14th Dec. 2011. The company of Pfizer is willing to exclusively provide the study medication. However, no personal or laboratory costs will be provided by Pfizer. The EPATH study is supported by a national scientific grant (OENB Jubilaeumsfond Nr. 14621; Grant amount: 70.000.- Euro), which was approved on 15th Dec. 2011. The OENB grant will be used to cover the personal and laboratory costs related to the EPATH study. Finally the trial has been successfully registered at the ISRCTN (Number: 33941607) on 20th Feb. 2012.

In the past, required changes of the study protocols of previous RCTs (due to peer reviewing processes), which were performed at our department, had been performed without difficulties. Thus, in case of changes which will be necessary due to the BMC peer review process, we usually forward the changes to the ethics...
committee, the company of Pfizer and the OENB and can conduct these changes without difficulties.

We have provided the ISRCTN number at the end of the manuscript abstract. Furthermore, the support of Pfizer (study medication) has been stated within the conflict of interest section. The ethical approval of the EPATH study has been attached during the re-submission process. All corresponding changes within the manuscript have been marked in red.

We herewith confirm that no further manuscripts are under submission with other journals based on this study protocol. We further confirm that, 1) none of the paper's contents have been published previously, 2) all authors have contributed to, read and approved the manuscript, and 3) none of the authors has a conflict of interest regarding the content of this manuscript.

We hope that you will find the manuscript suitable for publication.

With best regards,

Andreas Tomaschitz, MD
Medical University of Graz
Department of Internal Medicine
Division of Cardiology
Auenbruggerplatz 15
8036 Graz, Austria
Tel: +43 316 385 12544 or +43 664 1443993
FAX: +43 316 385 13733
andreas.tomaschitz@gmx.at
andreas.tomaschitz@medunigraz.at