Author's response to reviews

Title: Lower Risk of Hypoglycaemia and Greater Odds for Weight Loss with Initiation of Insulin Detemir Compared with Insulin Glargine in Turkish Patients with Type 2 Diabetes: local results of a multinational observational study

Authors:

Taner Damci (tdamci@gmail.com)
Rifat Emral (rifatemral@gmail.com)
Anne Louise Svendsen (aesv@novonordisk.com)
Tanzer Balkir (tanb@novonordisk.com)
Jiten Vora (jitenvora@btinternet.com)

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Author's response to reviews:

For the attention of the editor

Thank you for your consideration of this manuscript.

Please find a point by point description of the changes made to the manuscript following your initial assessment:

1. Please add ethics statement. Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/en/30publications/10policies/b3/index.html). A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

Response: The following statements have been added to the methodology section:

'The study was conducted in accordance with the Declaration of Helsinki and the Guidelines for Good Pharmacoepidemiology Practice.[7,8] Ethical approval was obtained from local institutional review boards (IRBs) or independent ethics committees (IECs) prior to commencement of the study in each of the participating countries.[9]'

References

7. Declaration of Helsinki. Ethical Principles for Medical Research Involving
Human Patients. 52nd WMA General Assembly, Edinburgh, Scotland, October 2000


I will provide further details regarding the name of the ethics committee and case reference, in due course.

2. Please clarify whether any of this data has been published in previous manuscripts arising from this study.

Response: Data from the global cohort has been published previously. A statement to this effect has been added to the Methods section:

'Results from the global cohort have been published previously.[10,11]'

References


These manuscripts present baseline and final safety and efficacy results for the total cohort of insulin detemir users.

Due to local regulatory requirements in Turkey, patients initiating any basal insulin analogue (either insulin detemir or insulin glargine) were offered to participate in the study. Data from the cohort of patients using insulin glargine has not been published previously.

Yours sincerely

Prof Taner Damci