

A meta-analysis of clinical data published today in *Diabetologia*, the medical journal for the European Association for the Study of Diabetes (EASD), demonstrated that the Novo Nordisk long-acting insulin Levemir® (insulin detemir [rDNA origin] injection) was not associated with any increase in the incidence of cancer when compared to human insulin(1,2).

The analysis conducted by Novo Nordisk assessed the relative risk of a cancer diagnosis during clinical treatment with Levemir®. It included approximately 9,000 patients (approximately 5,200 taking Levemir®) in 21 randomized controlled trials and compared the incidence of cancer in patients treated with Levemir® with that of patients treated with either human insulin (NPH insulin) or insulin glargine.

The data revealed that treatment with Levemir® was associated with a statistically significantly lower incidence of cancer than with NPH insulin treatment (0.36 events per 100 patient years in the Levemir® group vs. 0.92 events in the NPH insulin group;  $p < 0.05$ ).

The incidence of cancer during Levemir® treatment was also lower than that seen during treatment with insulin glargine, but this difference was not statistically significant (0.87 events per 100 patient years in the Levemir® group vs. 1.27 events in the insulin glargine group;  $p > 0.05$ )(3).

"We have designed Levemir® with all aspects of safety for the patient in mind and these data are in line with what we would expect," said Dr. Alan Moses, Novo Nordisk Vice President and Chief Medical Officer. "Physicians, health care providers and patients can continue to feel confident in using Levemir® to effectively treat type 1 and type 2 diabetes."

The analysis was performed in response to the *Diabetologia* June publication of four registry studies(4). Those studies, while inconclusive due to methodological limitations, suggested a potential link between another long-acting insulin analog, insulin glargine, and cancer. As a basis for such a possible link, an accompanying editorial explained that certain insulin analogs have a structure making them more likely to bind to the IGF-1 receptor which is known to be involved in promoting tumor growth(5).

The full text of the manuscript can be found online at <http://www.diabetologia-journal.org>.

(1) DIABETOLOGIA ONLINE: Dejgaard A et al. No evidence of increased risk of malignancies in patients treated with insulin detemir: a meta-analysis. [www.diabetologia-journal.org](http://www.diabetologia-journal.org)

(2) Novo Nordisk data on file, presented at the EASD on 1 October 2009, to be published

(3) A meta-analysis is a systematic method that uses statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. Source: National Information Center on Health Services Research and Health Care Technology (NICHSR). <http://www.nlm.nih.gov/nichsr/hta101/ta101014.html>

(4) [www.diabetologia-journal.org](http://www.diabetologia-journal.org)

(5) Kurtzhals P, Schaffer L, Sorensen A, Kristensen C, Jonassen I, Schmid C, Trub T (2000): Correlations of receptor binding and metabolic and mitogenic potencies of insulin analogs designed for clinical use. *Diabetes* 49: 999-10055

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