

Insulin analogue glargine possibly increases cancer risk

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The risk of cancer possibly increases if patients with diabetes use the long-acting insulin analogue glargine instead of human insulin. The Institute for Quality and Efficiency in Health Care (IQWiG), in collaboration with the "Wissenschaftliches Institut der AOK" (WIdO), the research institute of the German Local Health Care Fund, analysed the data of almost 130,000 patients with diabetes in Germany who had been treated with either human insulin or the insulin analogues lispro (trade name: Humalog), aspart (Novorapid) or glargine (Lantus) between January 2001 and June 2005.

The analysis has now been published together with further studies in the scientific journal *Diabetologia*, the official organ of the European Association for the Study of Diabetes (EASD).

The disturbing result is that malignancies were found more frequently in patients treated with glargine than in those prescribed a comparable dose of human insulin. "Our analysis does not provide absolute proof that glargine promotes cancer," says Peter T. Sawicki, IQWiG's Director and co-author of the study. "Our study does, however, arouse an urgent suspicion which should have consequences for the treatment of patients."

No difference was found between the short-acting insulin analogues, lispro and aspart, and human insulin. Insulin analogues are [synthetic molecules](#) that do not occur naturally, whereas human insulin matches the insulin that the human body manufactures itself.

Is glargine the cause?

IQWiG emphasises that the link found between prescribing glargine and an increased cancer risk is a statistical association. Thus, it is possible that other factors as yet unknown are the cause of the increased risk, rather than glargine. However, it is disturbing that of three further studies published in the same edition of *Diabetologia*, two also describe an increase in cancer risk associated with glargine.

Glargine has been approved in Germany since 2000. Since then, several laboratory trials have been published which indicate that, under certain conditions, insulin analogues can stimulate the growth of cancer cell lines more strongly than human insulin. "These indications are discussed in the scientific world but have never been dispelled by proper studies," says Sawicki. According to IQWiG, the overall indications of a risk from glargine have now intensified to such an extent that the burden of proof has been reversed for precautionary reasons: as long as reliable studies do not prove the safety of glargine compared to human insulin, the drug should only be used if there are particularly important reasons for doing so.

Risk of disease increases with dose

The researchers also found that the risk of cancer rose further with increasing glargine dose when compared to human insulin. This dose-dependent relationship with glargine also confirms the suspicion that the drug plays a causal role.

The increase in cancer risk was relatively small and was only detected when other, important factors such as age, sex and daily insulin dose were taken into consideration. The patients were on average between 65 and 70 years of age, thus in principle were already exposed to a certain

degree of cancer risk. Out of 1000 patients treated with human insulin, about 41 developed malignancies within an average of 20 months. If "similar" patients were to be treated with glargine, the increases in cancer diagnoses would be as follows: in patients prescribed on average 10 glargine units daily, about 4 more patients per 1000 patients would develop cancer. In patients prescribed 50 glargine units daily, about 13 more patients per 1000 patients would develop cancer.

However, according to the German Local [Health Care](#) Fund data, most patients used glargine in relatively low doses. Of 100 patients using glargine, about 50 patients used less than 20 units daily, and only 5 of 100 patients used more than 50 units daily.

Don't change treatment hastily

However, the latest investigation is no reason for patients with diabetes to change their treatment hastily, especially if the glargine dose used is low. Diabetes is a complex disease and many aspects need to be considered in its treatment. "However, if a patient can be treated equally well with human insulin as with glargine, then, after consultation with his or her doctor, the patient should consider changing to human insulin," states Sawicki. "If at all possible, patients with an increased risk of cancer should use human insulin instead of glargine."

The researchers have no evidence that glargine or other insulin agents transform normal cells to cancer cells. However, it may be possible that glargine stimulates the growth of existing [cancer](#) cells more strongly than other types of insulin.

In their study, IQWiG and WIdO had access to pseudonymous data on disease and invoices for 17.9 million insurants of the AOK, of which over 320,000 patients had diabetes (particularly type 2). The data were evaluated of approximately 130,000 patients with diabetes who had used

either human insulin or an [insulin](#) analogue exclusively, and who had not developed malignancies up to 2001.

More information: www.diabetologia-journal.org/

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