

Is inhaled insulin delivery still a possibility? Why has it been a commercial failure?

September 23 2009

The commercial failure of Exubera (Pfizer, New York, NY), the first inhaled insulin product to come to market, led other companies such as Eli Lilly-Alkermes to halt studies of similar drug delivery in development intended to compete for a share of the lucrative diabetes market. Does this signal defeat for efforts to deliver insulin via the lungs? The science and circumstances behind the Lilly-Alkermes decision to discontinue trials of the AIR inhaled insulin product are explored in a special supplement to *Diabetes Technology & Therapeutics*.

The supplement presents the data on AIR inhaled insulin that has been made available by Eli Lilly (Indianapolis, IN) and Alkermes (Cambridge, MA), co-developers of the drug. Eight articles describe various protocols in which the effectiveness and safety of AIR were compared to traditional insulin injections in patients with type 1 or type 2 diabetes. These studies represent noninferiority trials, in which AIR was evaluated for its potential to be at least as safe and effective as subcutaneous (SC) insulin across a range of parameters.

Satish K. Garg, MD, Professor of Medicine and Pediatrics at the University of Colorado Denver, and Editor-in-Chief of *Diabetes Technology & Therapeutics*, and colleagues report the results of a 2-year Phase 3 trial conducted in 385 patients, in an article entitled, "Two-Year Efficacy and Safety of AIR Inhaled Insulin in Patients with Type 1 Diabetes: An Open-Label Randomized Controlled Trial." The study found AIR to be inferior to SC insulin (in a noninferiority clinical trial design) in its ability to maintain optimal blood glucose levels over time,

based on measurements of glycosylated hemoglobin (HbA1c).

Similarly, Angel L. Comulada, MD, FACE, Instituto de Endocrinología, Diabetes & Metabolismo, Toa Baja, Puerto Rico, and coworkers demonstrated inferiority of AIR in their study of 500 patients with type 1 diabetes over 6 months. They report their findings in the article "Efficacy and Safety of AIR Inhaled Insulin Compared to Insulin Lispro in Patients with Type 1 Diabetes Mellitus in a 6-Month, Randomized, Noninferiority Trial."

"The question now remains whether this route of delivering insulin has been exhausted or if it still remains to be explored," write Satish Garg, MD and William Kelly, BS from the University of Colorado Denver in the Editorial "Insulin Delivery via Lungs—Is It Still Possible?" MannKind Corporation recently filed a New Drug Application with the FDA for Technosphere [Insulin](#). It offers faster onset of action with lower postprandial blood glucose excursions especially in the first two hours and is weight neutral, according to the Editorial.

More information: The supplement is available free online at www.liebertpub.com/dia.

Source: Mary Ann Liebert, Inc.

Citation: Is inhaled insulin delivery still a possibility? Why has it been a commercial failure? (2009, September 23) retrieved 9 April 2024 from <https://medicalxpress.com/news/2009-09-inhaled-insulin-delivery-possibility-commercial.html>

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