

Study Shows Promising Results for Inhaled Insulin as Treatment for Type 1 Diabetes

Findings Reveal Efficacy of Novel Inhaler to Improve Glycemic Control for Patients with Type 1 Diabetes

ORLANDO, FL. (JUNE 22, 2024) – Today, findings from INHALE-3, a pivotal trial examining the use of inhaled insulin in adults with type 1 diabetes (T1D), were announced, highlighting the potential of an alternative insulin solution to enhance diabetes management. The results were presented as a symposium at the 84th Scientific Sessions of the American Diabetes Association® (ADA) in Orlando, FL.

Type 1 diabetes affects <u>11.6% of the American population and millions of individuals globally</u>, requiring ongoing insulin therapy to manage blood glucose levels. Traditional insulin delivery methods include multiple daily injections or automated insulin delivery systems. However, for some patients, there is a need for new solutions to improve convenience, ease of use, and effective glycemic management.

INHALE-3, a randomized trial, compared the efficacy of an inhaled insulin regimen (Afrezza) plus degludec insulin (Tresiba®) against usual care over 17 weeks at 19 centers in the U.S. The trial included 123 adults with type 1 diabetes divided into two groups: one receiving inhaled insulin (Afrezza) plus degludec insulin, and the other continuing their usual care, which included automated insulin delivery systems in about half or multiple daily injections. The study's primary endpoint was a change in HbA1c levels, a critical marker of long-term blood glucose control. Secondary endpoints included changes in time-in-range and hypoglycemia measured with continuous glucose monitoring and patient-reported outcomes on insulin delivery satisfaction.

More participants using the inhaled insulin regimen experienced significant improvements in HbA1c levels compared to those on usual care. Notably, 21% of those on inhaled insulin had an HbA1c improvement of greater than 0.5%, while this was seen in only 5% of those with standard care. Furthermore, among participants who had an HbA1c level greater than or equal to 7% at the start of the study, 21% of those on inhaled insulin achieved the HbA1c goal of less than 7% while no participants receiving standard care achieved this HbA1c goal. Nineteen percent of participants who switched from using an automated insulin delivery system to using inhaled insulin plus degludec achieved an HbA1c improvement greater than 0.5%. In contrast to these positive findings, the study found that the insulin regimen with inhaled insulin and degludec was not for everyone: 26% of the patients in the inhaled insulin group had a worsening of HbA1c greater than 0.5% compared with 3% with standard care. Importantly, over half of the study participants wished to continue the inhaled insulin after the study completion.

"The INHALE-3 study's findings will impact diabetes management by providing healthcare providers and patients with an alternative insulin delivery method," said Irl B. Hirsch, MD, University of Washington, and lead author of the study. "These results will assist in better informing clinical decisions and tailoring treatment plans to individual patient needs, potentially improving adherence, patient satisfaction, and overall outcomes."

Building on the promising results of INHALE-3, further research will focus on the impact of inhaled insulin on a broader patient population, including pediatrics and pregnancy. These studies aim to reinforce the role of inhaled insulin in comprehensive diabetes care.

Research presentation details:

Dr. Hirsch will present the findings at the following symposium:

- Symposium: The Efficacy and Safety of Inhaled Insulin Used with Insulin Degludec Compared with Automated Insulin Delivery or Multiple Daily Insulin Injections in Adults with Type 1 Diabetes— Results of the INHALE-3 Randomized Trial (Mannkind)
- Presented on Saturday, June 22, 2024 at 8:00 AM EDT.

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About the ADA's Scientific Sessions

The ADA's 84th Scientific Sessions, the world's largest scientific meeting focused on diabetes research, prevention, and care, will be held in Orlando, FL on June 21-24. More than 11,000 leading physicians, scientists, and health care professionals from around the world are expected to convene both in person and virtually to unveil cutting-edge research, treatment recommendations, and advances toward a cure for diabetes. Attendees will receive exclusive access to thousands of original research presentations and take part in provocative and engaging exchanges with leading diabetes experts. Join the Scientific Sessions conversation on social media using #ADAScientificSessions.

About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 83 years, the ADA has driven discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. Through advocacy, program development, and education we aim to improve the quality of life for the over 136 million Americans living with diabetes or prediabetes. Diabetes has brought us together. What we do next will make us Connected for Life®. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook (American Diabetes Association), Spanish Facebook (Asociación Americana de la Diabetes), LinkedIn (American Diabetes Association), Twitter (@AmDiabetesAssn), and Instagram (@AmDiabetesAssn).