

ABSTRACT

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Long-term Sustained Safety and Efficacy of Continued Use of Technosphere® Insulin in Subjects with Type 2 Diabetes

Nikhil Amin, Anders H. Boss, Peter C. Richardson

MannKind Corporation, Valencia, CA, United States

Background and aims: Technosphere® Insulin (TI) is a rapid-acting inhaled insulin with an action profile that mimics early meal-related insulin release. Safety and efficacy of TI has been previously demonstrated in controlled clinical trials of up to 2 years' duration. The goal of this study was to examine the changes in lung functions and glycemic control in subjects with type 2 diabetes over 4 years of continued treatment with TI.

Materials and methods: Subjects with diabetes who had completed any of the two 3-month, controlled, randomized phase 2 clinical trials were offered continued open-label TI as their exclusive prandial insulin regimen. Spirometry and lung carbon monoxide diffusing capacity (DL_{CO}) were measured every 6 and 12 months, respectively. HbA1c was measured every 3 months. Hypoglycemia for this study was defined as blood glucose levels less than 3.5 mmol/L or symptoms of hypoglycemia that resolved after appropriate caloric intake.

Results: A total of 229 subjects (59% male, 41% female) were enrolled in the trial. In all, 199 subjects were exposed to treatment for > 1 year, 175 for > 2 years, 60 for > 3 years, and 31 for > 42 months. Annualized change in forced expiratory volume in 1 second was -0.048 ± 0.0006 L/year and in DL_{CO} was -0.332 ± 0.085 mL/min/mm Hg after 4 years of continued treatment with TI. Mean HbA1c was 7.97% at baseline, 7.88% at month 3, 7.79% at month 6, 7.97% at month 12, 7.87% at month 18, 8.04% at month 24, 8.06% at month 30, 7.81% at month 36, 7.40% at month 42, and 6.45% at month 48. Overall, hypoglycemia rates remained stable at 0.31 events/subject-month during the first 6 months and 0.42 events/subject-month after 3 years, as measured over the final 12 months of TI therapy.

Conclusion: Changes in the lung functions after 4 years of TI therapy were small and similar to the changes expected in adults with type 2 diabetes. TI therapy maintained sustainable glycemic control for at least 4 years.