

MULTI-STUDY EVALUATION OF CHANGES IN BODY WEIGHT WITH USE OF INHALED INSULIN VERSUS RAPID-ACTING ANALOG (RAA) INSULIN

BACKGROUND

- Inhaled insulin (Technosphere Insulin, TI) is a rapid acting inhaled human insulin indicated to improve glycemic control in adult and pediatric patients 6 years of age and older with diabetes mellitus¹
- Inhaled insulin lowers blood sugar levels by stimulating peripheral glucose uptake by skeletal muscle and fat, and by inhibiting hepatic glucose production¹
- Inhaled insulin absorption into the blood starts in less than one minute²

CONCLUSIONS

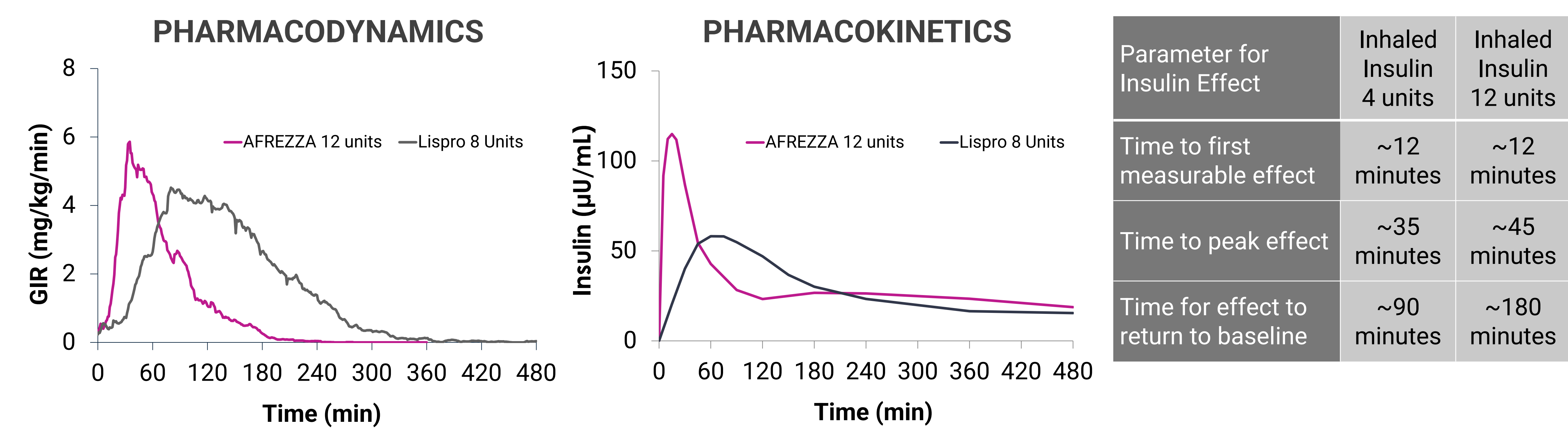
- Across three adult type 1 diabetes trials, inhaled insulin was associated with a neutral weight profile while participants on rapid-acting analog insulin experienced weight gain.



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METHODS & RESULTS

Figure 1. Inhaled Insulin Pharmacokinetics and Pharmacodynamics Profile¹



Body weight was measured at the start and end of adult type 1 diabetes clinical trials using inhaled insulin and injectable RAA insulins.

Across the Affinity-1³, STAT⁴, and INHALE-3^{5,6} trials, treatment difference between groups was lower in the inhaled insulin arm. In two of the trials no weight gain was observed and in the one trial weight increase by 0.1 kg. INHALE-3 demonstrated potentially directional differences based on a participant’s insulin modality before starting inhaled insulin treatment.

AFFINITY-1

24-week phase 3 trial which evaluated the efficacy and safety of inhaled insulin versus insulin aspart

Table 1. AFFINITY-1 Weight Change

	Inhaled Insulin (N=132)	Control (N=153)
Weight Change (24 weeks) Mean ± SD	-0.4 ± 5.0 kg	0.9 ± 5.5 kg
Treatment Difference	-1.3 kg (p=0.01)	

STAT

4-week phase 4 trial which evaluated glycemic management of inhaled insulin versus insulin aspart

Table 2. STAT Weight Change

	Inhaled Insulin (N=26)	Control (N=34)
Weight Change (4 weeks) Mean ± SD	-0.2 ± 1.3 kg	0.8 ± 1.3 kg
Weight Change Difference	-1.0 kg (p=0.006)	

INHALE-3

17-week phase 4 randomized controlled trial which evaluated the efficacy and safety of inhaled insulin compared to usual care [multiple daily injections (MDI), automated insulin delivery (AID) and sensor augmented pumps (SAP)]

Table 3. INHALE-3 Weight Change, All Participants

All	Inhaled Insulin (N=56)	Control (N=57)
Weight Change (17 weeks) Mean ± SD	0.1 ± 2.8 kg	1.4 ± 3.1 kg
Treatment Difference	-1.3 kg (p=0.03)	

Table 4. INHALE-3 Weight Change, AID Participants

AID at Start of Study	Inhaled Insulin (N=28)	Control (N=19)
Weight Change (17 weeks) Mean ± SD	-0.2 ± 1.3 kg	0.8 ± 1.3 kg

Table 5. INHALE-3 Weight Change, MDI/SAP Participants

MDI/SAP at Start of Study	Inhaled Insulin (N=28)	Control (N=20)
Weight Change (17 weeks) Mean ± SD	-0.2 ± 1.3 kg	0.8 ± 1.3 kg

References
1. Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation. 2. Data on File (PDC-INS-0002). MannKind Corporation. 3. Bode BW, et al. Diabetes Care. 2015;38(12):2266-73. 4. Akturk HK, et al. Diabetes Technol Ther. 2018;20(10):639-647. 5. Hirsch IB, Beck RW, Marak MC, et al. Diabetes Care. vol 48,00 (2025): 1-8. 6. Hirsch IB, Beck RW, Marak MC, et al. December 2024.