INHALE-1: A 26-week Primary Treatment Phase, with 26-week Extension, Open-label, Randomized Clinical Trial Evaluating the Efficacy and Safety of Afrezza? Versus Rapid-acting Insulin Analog Injections, Both in Combination with a Basal Insulin, in Pediatric Subjects with Type 1 or Type 2 Diabetes Mellitus

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 4 years to under 18 years old - diagnosis of type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM) - using insulin for at least 6 months for T1DM, or at least 3 months for T2DM - treated with basal-bolus insulin therapy delivered by multiple daily injections for at least 2 weeks - bolus insulins are restricted to the RAAs insulin lispro, insulin aspart or insulin glulisine, including biosimilar products - basal insulins are restricted to insulin glargine, insulin degludec or insulin detemir, including biosimilar products - HbA1c between 7.0% and 11% - average prandial dose of insulin 2 or more units per meal - used CGM for at least 70% of the time over a consecutive 14-day period before starting the study - access to stable WiFi connection

Exclusion Criteria:

- history of recent blood transfusions (within previous 3 months) - recent history of asthma (defined as using any medications to treat within the last year) or any other clinically important lung disease - history of serious complications of diabetes - any other illness that isn't stable (study staff will review) - uncontrolled eating disorder (e.g., anorexia or bulimia nervosa) - current drug or alcohol abuse or a history of drug or alcohol abuse - smoking (includes cigarettes, cigars, pipes, marijuana, and vaping devices) for the preceding 6 months

Conditions & Interventions

Interventions:
Biological: Afrezza, Biological: Basal Insulin, Biological: Rapid-acting Insulin Analog
Conditions:
Diabetes & Endocrine
Keywords:
diabetes, insulin, type 1 diabetes, type 2 diabetes

More Information

Description: To assess the safety of Afrezza in a pediatric population when compared to the usual standard of care insulin.
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Phase: Phase 3
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