

Summary: A Phase 3, open label, crossover study to evaluate the efficacy and safety of human insulin inhalation powder (HIIP) compared with once-daily insulin glargine in insulin-naïve patients with type 2 diabetes on oral meds. (56 weeks, 16 visits, 12 phone visits, 8 PFT's)

Inclusion Criteria:

- over age 18
- diagnosis with type 2 DM > 6 months, on stable dose one or more OAMs for at least 6 wks,(12 wks for TZDs) AND on insulin < 30 days throughout life and not within the past 6 months AND candidates for insulin therapy
- HgbA1C \geq 8.0 and \leq 10.5 % at screening
- Negative pregnancy test, using reliable birth control
- No smoking in past 6 months, no smokeless tobacco, serum cotinine level < 20 ng/ml
- Able to perform PFT' , meet all qualifying criteria for grading and quality
- Negative chest x-ray in pas 6 months, based on opinion of PI

Exclusion Criteria:

- employee or relative of personnel directly affiliated with the study
- treated in past 30 days with investigational drug (non approved drug)
- previously received 1 or more doses of inhaled insulin or participated in this study
- taking a TZD dose greater than what is indicated in combination with insulin according to the TZD label
- 2 or more episodes of severe hypoglycemia 6 months prior to study entry
- 1 or more hospitalization or ER visit due to poor diabetic control
- pneumonia in 3 months prior to study entry
- systemic glucocorticoid therapy within 3 months prior to study entry (topical, nasal, intra-articular , physiologic replacement ok)
- liver disease, acute or chronic hepatitis, ALT/SGPT > 3 times ULN
- renal transplant, dialysis or serum creatinin > 2.0mg/dl if NOT on metformin; males \geq 1.5mg/dl, females \geq 1.4 mg/dl if ON metformin
- history of angina, MI, Class III/IV cardia disease within 6 months prior to study entry
- active or untreated malignancy or in remission < 5 years
- lung cancer, past or present, lung transplant
- current or past history of asthma, COPD, cystic fibrosis, bronchiectasis, alpha-1 antitrypsin deficiency or clinically relevant pulmonary disease
- Byetta or incretin mimetics not approved with use of insulin, past 6 months
- Drug/alcohol abuse

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