A Phase 2, Double-Blind, Randomized, Active-Control, Parallel Group Study to Assess the Pharmacokinetics, Pharmacodynamics, Immunogenicity, and Safety of INBRX-101 Compared to Plasma Derived Alpha1-Proteinase Inhibitor (A1PI) Augmentation Therapy in Adults with Alpha-1 Antitrypsin Deficiency (AATD) Emphysema

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- age 18 to 80 - diagnosis of Alpha 1-Antitrypsin Deficiency (AATD) - symptoms of emphysema related to AATD - currently not smoking

Exclusion Criteria:

- diagnosis of type 1 diabetes or diagnosed with uncontrolled type 2 diabetes - on waiting list for lung or liver transplant - active cancers or has a history of cancer within past 5 years - significant congestive heart failure - additional exclusion criteria (study staff will review)

Conditions & Interventions

Interventions:
Drug: INBRX-101, Drug: Zemaira
Conditions:
Breathing, Lung & Sleep Health
Keywords:
Clinics and Surgery Center (CSC), Alpha 1-Antitrypsin Deficiency, Emphysema

More Information

Description: This study is for people who have emphysema (a disorder where too much air collects deep in the lungs) that is caused by the lack of a protein called alpha-1 antitrypsin (AAT) in the body. A deficiency of AAT (AATD) can damage lung and liver if not treated. The goal of this study is to evaluate the safety and study the therapeutic effects of INBRX-101 in subjects with AATD emphysema when compared with current approved AATD therapy with A1PI, known as Zemaira®.
Study Contact: Kayla Hoffman - hoff1364@umn.edu
Principal Investigator: Ronald Reilkoff
IRB Number: SITE00001985