ANG003-25-201: A Phase 2, Multicenter, Randomized, Active-controlled Study, to Assess the Safety and Efficacy of ANG003 at Two Different Dose Levels in Subjects with Exocrine Pancreatic Insufficiency due to Cystic Fibrosis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- age 12 or older - diagnosed with cystic fibrosis and severe exocrine pancreatic insufficiency (EPI) - taking a stable dose of pancreatic enzyme replacement therapy for at least 90 days - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- have had fibrosing colonopathy or repeated intestinal blockage within the past 6 months - have had a lung or liver transplant, are listed for an organ transplant, or have had major bowel surgery within the past 6 months - have a known severe allergy or reaction to Creon or ingredients in the study treatment - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: ANG003 Dose A, Drug: ANG003 Dose B, Drug: Creon
Conditions:
Digestive & Liver Health, Rare Diseases, Rare Diseases, Respiratory System
Keywords:
CF, cystic fibrosis, enzyme replacement

More Information

Description: The purpose of this study is to learn whether ANG003, a pancreatic enzyme replacement treatment, is safe and works as well as Creon in people with cystic fibrosis who have exocrine pancreatic insufficiency (EPI). What we learn may help us better understand treatment options for people with cystic fibrosis and EPI.
Study Contact: Dean Krueger - krue0100@umn.edu
Principal Investigator: Elissa Downs
Phase: PHASE2
IRB Number: STUDY00028143