

BEGIN-OB-19: A Prospective Study to Evaluate Biological and Clinical Effects of Significantly Corrected CFTR Function in Infants and Young Children (BEGIN)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 18 years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- For Part A: less than 5 years of age at the first study visit - For Part B: participated in Part A OR less than 6 years of age at the first study visit, CFTR mutations consistent with FDA labeled indication of highly effective modulator therapy and physician intends to prescribe ivacaftor or elexacaftor/tezacaftor/ ivacaftor - Documented diagnosis of Cystic Fibrosis (CF)

Exclusion Criteria:

- use of ivacaftor or elexacaftor/tezacaftor/ ivacaftor within the 180 days - use of an investigational drug within 28 days prior to first study visit - use of chronic oral corticosteroids within the 28 days prior to first study visit

Conditions & Interventions

Conditions:

Rare Diseases

Keywords:

Cystic Fibrosis

More Information

Description: This is a study of highly effective CFTR modulators and their impact in children with CF on endocrine growth factors, the gut microbiome, respiratory microbiome, liver and pancreatic function, lung function, sweat chloride, and inflammatory markers.

Study Contact: Alyssa Perry - ahperry@umn.edu

Principal Investigator: Elissa Downs

IRB

Number: SITE00000975

Thank you for choosing StudyFinder. Please visit <http://studyfinder.umn.edu> to find a Study which is right for you and contact sfinder@umn.edu if you have questions or need assistance.