Regional Monitoring of CF Lung Disease

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 years to 21 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- 1 Written informed consent (and assent when applicable) obtained from subject or subject's legal representative.

2 Use of highly effective modulators for more than 30 days (ie. Trikafta) 3 Willingness and ability to adhere to the study visit schedule and other protocol requirements.

4 Documentation of a CF diagnosis with prescription of Mechanical ACT 5 Ages 12-21 inclusive, at the time of consent. 6 Clinically stable with no respiratory tract infection or recent exacerbations. 7 Treating CF physician agreeable to study procedures. Only applicable to Aim 3.

8 No change in chronic maintenance therapies in the 28 days prior to enrollment.

9 Ability to cooperate with MRI procedures.

Exclusion Criteria:

1. Standard MRI exclusions (metal implants, claustrophobia).
2. For females of childbearing potential: Positive urine pregnancy test or Lactating.
3. Acute respiratory symptoms (e.g., wheezing) at the time of the MRI
4. Chronic lung or liver or pancreatic disease not related to CF.
5. Any other condition that, in the opinion of the Investigator, would preclude informed consent or assent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

Conditions & Interventions

Interventions:
PROCEDURE: Airway-clearance vest, DRUG: Hyperpolarized Xe129
Conditions:
Cystic Fibrosis

More Information

Description:
The main reason for this research study is to learn more about some new tests that are being developing for patients with Cystic Fibrosis (CF) to measure changes in the lungs. In this study, the focus will be to learn how stopping Airway Clearance (ACT) and re-starting ACT can affect these tests. These new tests include using a breathable gas called Xenon (Xe) with MRI (magnetic resonance imaging) to improve the pictures of changes in the lungs. The Xenon (Xe) gas that has been treated to have a larger MRI signal (also called hyperpolarized). The other new test is called LCI (Lung Clearance Index) that can measure how well the lungs are working. The MRI machine used in this study has been approved by the U.S. Food and Drug Administration (FDA) and is commercially available for sale in the USA. Hyperpolarized Xe gas is an FDA-approved, inhaled contrast agent for lung ventilation MRI. The new Xe MRI techniques that are being developed and used for this research study are investigational, meaning these new Xe MRI techniques are not FDA approved, but they are similar to FDA-approved techniques that are used clinically at Cincinnati Children's Hospital Medical Center (CCHMC). Xe gas and the new MRI techniques used in this research study have been used for many years in research, including in many research studies conducted at CCHMC like this one.

Contact(s): Carrie Stevens, BS - carrie.stevens@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: EARLY_PHASE1
IRB Number:
System ID: NCT06339593