Sinus Disease in Young Children With Cystic Fibrosis

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years to 8 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

HEMT Group:

- Children with documentation of a CF diagnosis
- Age 2-8 years old at first study visit
- CFTR mutation consistent with FDA labeled indication of highly effective modulator therapy (ivacaftor or elexacaftor/tezacaftor/ivacaftor)
- Clinician intent to prescribe ivacaftor or ETI so that enrollment is before start of HEMT

Non-HEMT/Control Group:

- Children with documentation of a CF diagnosis
- Age 2-8 years at first study visit
- Ineligible for highly effective modulator therapy (ivacaftor or elexacaftor/tezacaftor/ivacaftor) based on CFTR mutation or clinical decision not to initiate HEMT if eligible

Exclusion Criteria:

For Both Groups:

- Use of an investigational drug within 28 days prior to the first study visit
- Use of ivacaftor or elexacaftor/tezacaftor/ivacaftor within the 180 days prior to and including the first study visit
- Use of chronic oral corticosteroids within the 28 days prior to and including the first study visit.
- Sinus surgery within 180 days prior to the first study visit

Conditions & Interventions

Interventions:
DRUG: Ivacaftor or elexacaftor/tezacaftor/ivacaftor
Conditions:
Cystic Fibrosis in Children, Cystic Fibrosis, Chronic Rhinosinusitis (Diagnosis), Olfactory Disorder, Olfactory Impairment
Keywords:
Cystic Fibrosis, Chronic Rhinosinusitis, Olfactory Dysfunction

More Information

Description:
This is a prospective, observational study examining the impact of highly effective cystic fibrosis transmembrane conductance regulator (CFTR) modulators on chronic rhinosinusitis (CRS) and olfactory dysfunction (OD) in young children with cystic fibrosis (YCwCF). This study involves two groups: children 2-8 years old, inclusive at initial visit, receiving highly effective modulator therapy (HEMT), and a control group of children 2-8 years old, inclusive at initial visit, not receiving HEMT. Outcomes will include sinus magnetic resonance imaging (MRI) scans, olfactory tests, and quality of life surveys obtained over a two-year period.

Contact(s): Megan Schmitt - megan.schmitt@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase:
IRB Number:
System ID: NCT06191640